Magellan Rx Management Clinical Criteria

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TABLE OF CONTENTS

MEDICAL EXCEPTIONS 17
PRECISION/PLUS AND CORE FORMULARY EXCLUSION EXCEPTION PROCESS 18
ABECMA® (IDECABTAGENE VICLEUCEL) 20
ABRAXANE® (PACLITAXEL PROTEIN-BOUND PARTICLES) IV 24
ACROMEGALY AGENTS 29
H. P. ACTHAR® (CORTICOTROPIN, ACTH) 36
ACTIMMUNE® (INTERFERON GAMMA1-B) 37
ADAGEN® (PEGADEMASE BOVINE) 39
ADAKVEO® (CRIZANLIZUMAB-TMCA) 40
ADCETRIS® (BRENTUXIMAB VEDOTIN) 41
ADDYI® (FLIBANSERIN) 46
ADUHELM™ (ADUCANUMAB-AVWA) 47
AFINITOR® (EVEROLIMUS) 49
ALDURAZYME® (LARONIDASE) 54
ALECENSA® (ALECTINIB) 55
ALIMTA®, PEMFEXY™ (PEMETREXED DISODIUM) 56
ALIQOPA™ (COPANLISIB) 61
ALKINDI SPRINKLE (HYDROCORTISONE) 62
ALKYLATING AGENTS: VALCHLOR 63
ALPHA-1 PROTEINASE INHIBITORS 64
ALTERNATIVE MEDICATION 65
ALUNBRIG® (BRIGATINIB) 66
ALZHEIMER'S AGENTS 68
AMONDYS-45™ (CASIMERSEN) 69
ANALGESICS: BUPRENORPHINE PRODUCTS FOR OPIATE ADDICTION 70
ANALGESICS: NARCOTICS: LONG-ACTING 71
ANALGESICS: NARCOTICS: SHORT-ACTING 75
ANALGESICS: NSAIDS – ORAL 77
ANALGESICS: NSAIDS – RECTAL 81
ANALGESICS: NSAIDS – TOPICAL 82

Magellan Rx MANAGEMENT℠

ANALGESICS: SUBLOCADE (BUPRENORPHINE EXTENDED-RELEASE) 84
ANAPHYLAXIS AGENTS 86
ANDROGENS 87
ANGIOTENSIN RECEPTOR BLOCKERS 91
ANTI-ALCOHOLIC PREPARATIONS 92
ANTI-ALLERGEN EXTRACTS 93
ANTI-ARRHYTHMICS 95
ANTI-PLATELET AGENTS 96
ANTIBIOTICS: GYNECOLOGICAL 97
ANTIBIOTICS: CEPHALOSPORINS (TEFLARO®) 98
ANTIBIOTICS: GASTROINTESTINAL 99
ANTIBIOTICS: OXAZOLIDINONES 100
ANTIBIOTICS: QUINOLONES 103
ANTIBIOTICS: TETRACYCLINES 104
ANTIBIOTICS: XENLETA (LEFAMULIN) 109
ANTICOAGULANTS 110
ANTICONVULSANTS 111
ANTIDEPRESSANTS 119
ANTIEMETICS 121
ANTIEMETICS: DELTA-9THC DERIVATIVES 125
ANTIFUNGALS: ORAL 126
ANTIFUNGALS: TOPICAL 128
ANTIHISTAMINE PRODUCTS 130
ANTIHYPERKINESIS MEDICATIONS (STIMULANTS AND RELATED MEDICATIONS) 131
ANTIMALARIALS 133
ANTIMIGRAINE MEDICATIONS: TRIPTANS 134
ANTIPARASITICS 136
ANTIPSYCHOTICS 137
APOKYN® (APOMORPHINE) 142
ARCALYST® (RILONACEPT) 143
ARIKAYCE® (AMIKACIN LIPOSOMAL INHALATION) 146
ARRANON® (NELARABINE) 147
ARZERRA® (OFATUMUMAB) 148
ASPARLAS® (CALASPARGASE PEGOL-MKNL) 150
AVASTIN® (BEVACIZUMAB), MVASI™ (BEVACIZUMAB-AWWB), ZIRABEV™ (BEVACIZUMAB-BVZR) 151
AVEED® (TESTOSTERONE UNDECANOATE) 159
AYVAKIT® (AVAPRITINIB) 161
AZEDRA® (IOBENGUANE I-131) IV 163

BALVERSA® (ERDAFITINIB) 164
BAVENCIO® (AVELUMAB) 168
BELEODAQ® (BELINOSTAT) 170
BENDAMUSTINE (TREANDA®, BENDEKA™, BELRAPZO™) 172
BESPONSA® (INOTUZUMAB OZOGAMICIN) 176
BETA BLOCKER 177
BILE ACID AGENTS 178
BIOLOGICAL AGENTS – OTHER ALLERGENIC EXTRACT AGENTS – BENEFIT BUILDER 181
BISPHOSPHONATES 186
BLENREP® (BELANTAMAB MAFODOTIN-BLMF) 187
BLINCYTO® (BLINATUMOMAB) 188
BLOOD FORMATION MODIFIERS – COLONY STIMULATORY FACTORS (CSF) 189
BLOOD PRESSURE SUPPLIES – BENEFIT BUILDER 197
BLOOD PRODUCTS 198
BONIVA® (IBANDRONATE) IV 212
BOSULIF® (BOSUTINIB) 214
BOTOX® (ONABOTULINUMTOXINA) 220
BPH MEDICATIONS 232
BRAFTOVI™ (ENCORAFENIB) 233
BRAND/GENERIC STEP THERAPY INITIATIVE 235
BREYANZI® (LISOCABTAGENE MARALEUCEL) 236
BRINEURA™ (CERLIPONASE ALFA) 237
BRONCHITOL® (MANNITOL) 238
BRUKINSA (ZANUBRUTINIB) 239
BYLVAY™ (ODEVIXIBAT) 241
CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS 242
CALCIUM CHANNEL BLOCKERS 247
CALQUENCE® (ACALABRUTINIB) 248
CAMPATH® (ALEMTUZUMAB) 250
CAMPTOSAR® (IRINOTECAN) 251
CAPRELSA® (VANDETANIB) 252
CARDIOVASCULAR AGENTS: MISCELLANEOUS 253
CAYSTON® (AZTREONAM) 254
CERDELGA® (ELIGLUSTAT) 255
CEREZYME® (IMIGLUCERASE) 257
CINQAIR® (RESLIZUMAB) 258
COMETRIQ®; CABOMETYX® (CABOZANTINIB) 260
COMPOUNDS 265

CONSENSI (AMLODIPINE/CELECOXIB) 270
COPD AGENTS 271
COPIKTRA® (DUVELISIB) 272
CORLANOR (IVABRADINE) 274
COSELA™ (TRLACICLIB) 275
COSMETIC AGENTS – BENEFIT BUILDER 276
COTELLIC® (COBIMETINIB) 277
CRYSVITA® (BUROSUMAB-TWZA) 280
CYCLOSET® (BROMOCRIPTINE) 282
CYRAMZA® (RAMUCIRUMAB) 283
CYSTEAMINE (CYSTAGON, PROCYSBI, CYSTARAN, CYSTADROPS) 285
CYTOXAN® (CYCLOPHOSPHAMIDE) 286
DACOGEN® (DECITABINE) IV 287
DANYELZA® (NAXITAMAB-GQGK) 288
DARAPRIM® (PYRIMETHAMINE) 289
DARZALEX FASPRO® (DARATUMUMAB AND HYALURONIDASE-FIHJ) 290
DARZALEX® (DARATUMUMAB) 292
DAURISMO® (GLASDEGIB) 294
DEPO-SUBQ PROVERA 104 295
DERMATOLOGICS: ISOTRETINOIN 296
DERMATOLOGICS: STEROIDS 297
DERMATOLOGICS: TOPICAL (MISCELLANEOUS) 299
DERMATOLOGICS: TOPICAL ANTIBIOTIC AGENTS FOR ACNE/ROSACEA 300
DERMATOLOGICS: TOPICAL ANTIBIOTICS 302
DERMATOLOGICS: TOPICAL ANTINEOPLASTICS 303
DERMATOLOGICS: TOPICAL ANTIVIRALS 305
DERMATOLOGICS: TOPICAL IMMUNOMODULATORS 306
DERMATOLOGICS: TOPICAL PHOSPHODIESTERASE-4 INHIBITORS (PDE-4) 307
DERMATOLOGICS: TOPICAL RETINOIDS 308
DERMATOLOGICS: VITAMIN D ANALOGS 310
DERMATOLOGICS: VITAMIN D ANALOG/ANTI-INFLAMMATORY STEROIDS 311
DIABETIC SUPPLIES 312
DIURETICS 316
DMARDS 317
DOJOLVI® (TRIHEPTANOIN) 319
DOPTELET® (AVATROMBOPAG) 320
DOXIL®, LIPODOX (DOXORUBICIN) 322
DUPIXENT® (DUPILUMAB) 324

DYSPORT® (ABOTULINUM TOXIN A) 328
EGRIFTA® (TESAMORELIN) 336
ELAPRASE® (IDURSULFASE) 337
ELELYSO® (TALIGLUCERASE ALFA) 338
ELITEK® (RASBURICASE) 339
ELMIRON® (PENTOSAN POLYSULFATE SODIUM) 340
ELOXATIN® (OXALIPLATIN) 341
ELZONRIS® (TAGRAXOFUSP-ERZS) 344
EMFLAZA® (DEFLAZACORT) 345
EMPAVELI™ (PEGCETACOPLAN) 346
EMPLICITI® (ELOTUZUMAB) 348
EMVERM® (MEBENDAZOLE) 349
ENDARI® (L-GLUTAMINE) 350
ENHERTU® (FAM-TRASTUZUMAB DERUXTECAN-NXKI) 351
ENSPRYNG (SATRALIZUMAB-MWGE) 353
ENTEREG (ALVIMOPAN) 355
ENTYVIO® (VEDOLIZUMAB) 356
ENVARSUS XR® (TACROLIMUS) 359
ERBITUX® (CETUXIMAB) 360
ERECTILE DYSFUNCTION AGENTS 364
ERIVEDGE® (VISMODEGIB) 366
ERLEADA® (APALUTAMIDE) 367
ERWINAZE (ASPARAGINASE ERWINIA CHRYSANTHEMI) 368
ESTROGEN AGENTS 369
EVENITY® (ROMOSOZUMAB-AQQA) 370
EVKEEZA™ (EVINACUMAB-DGNB) 372
EVOMELA® (MELPHALAN) 374
EVRYSDI® (RISDIPLAM) 375
EXONDYS51® (ETEPLIRSEN) 377
EYSUVIS (LOTEPREDNOL ETABONATE) 378
FABRAZYME® (AGALSIDASE BETA) 379
FARYDAK® (PANOBINOSTAT) 380
FASENRA® (BENRALIZUMAB) 381
FASLODEX® (FULVESTRANT) 384
FEMARA® (LETROZOLE) 386
FERAHEME® (FERUMOXYTOL) 387
FERTILITY AGENTS 389
FIRDAPSE® (AMIFAMPRIDINE) 392

FIRMAGON® (DEGARELIX) 393
FOLOTYN® (PRALATREXATE) 394
FOTIVDA® (TIVOZANIB) 396
GALAFOLD® (MIGALASTAT) 397
GAMIFANT® (EMAPALUMAB-LZSG) 398
GAMMACORE 400
GASTROINTESTINALS: PANCRELIPASE 401
GASTROINTESTINALS: PPIS 402
GASTROINTESTINAL: IBS, CONSTIPATION, DIARRHEA 403
GATTEX® (TEDUGLUTIDE) 407
GAVRETO™ (PRALSETINIB) 408
GAZYVA® (OBINUTUZUMAB) 410
GEMZAR® (GEMCITABINE) 413
GILOTRIF® (AFATINIB) 415
GIMOTI (METOCLOPRAMIDE) 416
GIVLAARI™ (GIVOSIRAN) 418
GLAUCOMA 419
GLEEVEC® (IMATINIB) 420
GOUT AGENTS 435
GROWTH HORMONE 437
HALAVEN® (ERIBULIN) 444
HEALTHCARE REFORM COVERAGE OF CONTRACEPTIVES 445
HEMATOPOEITIC AGENTS 446
HEPATITIS B THERAPY: INJECTABLE 455
HEPATITIS B THERAPY: ORAL 456
HEPATITIS B THERAPY: VEMLIDY® 459
HEPATITIS C – EPCLUSA® AND SOFOSBUVIR/VELPATASVIR 460
HEPATITIS C – HARVONI® (LEDIPASVIR; SOFOSBUVIR) 463
HEPATITIS C – MAVYRET® (GLECAPREVIR; PIBRENTASVIR) 467
HEPATITIS C – PEGINTERFERON 470
HEPATITIS C – RIBAVIRIN (REBETOL®, RIBASPHERE®, RIBAPAK®) 479
HEPATITIS C – SOVALDI® 480
HEPATITIS C – VIEKIRA® 483
HEPATITIS C – VOSEVI® (SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR) 488
HEPATITIS C – ZEPATIER® (ELBASVIR; GRAZOPREVIR) 491
HERCEPTIN HYLECTA™ (TRASTUZUMAB AND HYALURONIDASE-OYSK) 495
HERCEPTIN® (TRASTUZUMAB), HERZUMA® (TRASTUZUMAB-PKRB), KANJINTI® (TRASTUZUMAB-ANNS), OGIVRI™ (TRASTUZUMAB-DKST), ONTRUZANT® (TRASTUZUMAB-DTTB), AND TRAZIMERA™ (TRASTUZUMAB-QYYP) 497

HEREDITARY ANGIOEDEMA 501
HEREDITARY TYROSINEMIA 513
HICON® (SODIUM IODIDE I-131) 514
HIV AGENTS 515
HORMONE AGENTS 523
HUNTINGTONS DISEASE CHOREA 524
HYCAMTIN® (TOPOTECAN) 527
HYPOGLYCEMICS: AMYLIN ANALOG 529
HYPOGLYCEMICS: BIGUANIDE 530
HYPOGLYCEMICS: DIPEPTIDYL PEPTIDASE IV (DPP4) INHIBITORS 531
HYPOGLYCEMICS: INCRETIN MIMETICS 532
HYPOGLYCEMICS: INCRETIN MIMETICS/INSULIN 534
HYPOGLYCEMICS: INSULINS 535
HYPOGLYCEMICS: SODIUM GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITOR 537
HYPOGLYCEMICS: THIAZOLIDINEDIONES (TZDS) 539
IBRANCE® (PALBOCICLIB) 540
ICLUSIG® (PONATINIB) 541
IDHIFA® (ENASIDENIB) 551
ILARIS® (CANAKINUMAB) 552
ILUVIEN® (FLUOCINONIDE ACETONIDE IMPLANT) 555
IMBRUVICA® (IBRUTINIB) 556
IMCIVREE™ (SETMELANOTIDE) 560
IMFINZI® (DURVALUMAB) 561
IMLYGIC® (TALIMOGENE LAHERPAREPVEC) 562
IMMUNE GLOBULINS 563
IMMUNOMODULATORS 574
ACTEMRA (TOCILIZUMAB) (EFFECTIVE DATE 06/01/2021) 574
CIMZIA (CERTOLIZUMAB PEGOL) (EFFECTIVE DATE 06/01/2021) 579
COSENTYX (SECUKINUMAB) (EFFECTIVE DATE 09/24/2021) 583
ENBREL (ETANERCEPT) (EFFECTIVE DATE 06/01/2021) 591
HUMIRA (ADALIMUMAB) (EFFECTIVE DATE 06/01/2021) 596
ILUMYA (TILDRAKIZUMAB-ASMN) (EFFECTIVE DATE 09/01/2021) 603
INFLIXIMAB (EFFECTIVE DATE 09/01/2021) 604
KEVZARA (SARILUMAB) (EFFECTIVE DATE 05/01/2021) 619
KINERET (ANAKINRA) (EFFECTIVE DATE 04/01/2021) 620
OLUMIANT (BARICITINIB) (EFFECTIVE DATE 09/24/2021) 623
OLUMIANT (BARICITINIB) (CONTINUED) 624
OLUMIANT (BARICITINIB) (CONTINUED) 625
OLUMIANT (BARICITINIB) (CONTINUED) 626

OTEZLA® (APREMILAST) (EFFECTIVE DATE 12/01/2021) *629*
RINVOQ (UPADACITINIB) (EFFECTIVE DATE 10/01/2021) *631*
RITUXAN (RITUXIMAB) (EFFECTIVE DATE 09/24/2021) *632*
SILIQ (BRODALUMAB) (EFFECTIVE DATE 07/01/2021) *638*
SIMPONI, SIMPONI ARIA (GOLIMUMAB) (EFFECTIVE DATE 02/01/2021) *639*
SKYRIZI (RISANKIZUMAB-RZAA) (EFFECTIVE DATE 08/01/2021) *643*
DOSAGE AND ADMINISTRATION *643*
STELARA (USTEKINUMAB) (EFFECTIVE DATE 11/1/2021) *644*
DOSAGE AND ADMINISTRATION FOR ALL FORMULARIES *649*
TALTZ (IXEKIZUMAB) (EFFECTIVE DATE 9/01/2021) *650*
DOSAGE AND ADMINISTRATION FOR ALL FORMULARIES *655*
TREMFYA (GUSELKUMAB) (EFFECTIVE DATE 05/01/2021) *656*
XELJANZ (TOFACITINIB), XELJANZ XR (TOFACITINIB EXTENDED-RELEASE) (EFFECTIVE DATE 11/01/2021) *657*
IMMUNOSUPPRESSANTS 662
IMPAVIDO (MILTEFOSINE) 666
INBRIJA® (LEVODOPA INHALATION POWDER) 668
INCRELEX® (MECASERMIN) 669
INFUGEM™ (GEMCITABINE) 670
INGREZZA® (VALBENAZINE) 672
INHALED ANTICHOLINERGICS 673
INHALED BETA AGONISTS 676
INHALED BETA AGONISTS COMBINATIONS 678
INHALED GLUCOCORTICOIDS 680
INJECTABLE DRUGS – BENEFIT BUILDER 682
INJECTAFER® (FERRIC CARBOXYMYALTOSE INJECTION) 683
INLYTA® (AXITINIB) 685
INQOVI® (DECITABINE AND CEDAZURIDINE) 687
INREBIC® (FEDRATINIB) 688
INTERFERONS 690
INTRON-A (INTERFERON ALFA 2B) 691
IRESSA® (GEFITINIB) 695
IRON CHELATORS 696
ISTODAX®, ROMIDEPSIN (LIQUID) 698
ISTURISA® (OSILODROSTAT) 699
IXEMPRA® (IXABEPILONE) 700
JAKAFI® (RUXOLITINIB) 701
JELMYTO® (MITOMYCIN) 706
JEMPERLI® (DOSTARLIMAB-GXLY) 707
JEVTANA® (CABAZITAXEL) 708

JUXTAPID® (LOMITAPIDE) 709
JYNARQUE™ (TOLVAPTAN) 711
KADCYLA® (ADO-TRASTUZUMAB EMTANSINE) 712
KALYDECO® (IVACAFTOR) 715
KANUMA® (SEBELIPASE ALFA) 717
KEPIVANCE® (PALIFERMIN) 718
KERENDIA® (FINERENONE) 719
KEVEYIS™ (DICHLORPHENAMIDE) 720
KEYTRUDA® (PEMBROLIZUMAB) 722
KISQALI® (RIBOCICLIB) 739
KORLYM® (MIFEPRISTONE) 742
KOSELUGO® (SELUMETINIB) 743
KRYSTEXXA® (PEGLOTICASE) 745
KUVAN® (SAPROPTERIN) 746
KYMRIAH® (TISAGENLECLEUCEL) 747
KYNAMRO® (MIPOMERSEN) 749
KYNMOBI™ (APOMORPHINE) 751
KYPROLIS® (CARFILZOMIB) 752
LAMPIT (NIFURTIMOX) 754
LARTRUVO (OLARATUMAB) 755
LENVIMA® (LENVATINIB) 756
LEUKOTRIENE ANTAGONISTS 759
LEUPROLIDE PRODUCTS 760
LEVOLEUCOVORIN (FUSILEV®AND KHAPZORY™) 763
LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEMS (MIRENA®, SKYLA®, LILETTA®, KYLEENA®) 768
LIBTAYO® (CEMIPLIMAB-RWLC) 770
LIPOTROPICS 772
LONSURF® (TRIFLURIDINE AND TIPIRACIL) 774
LORBRENA® (LORLATINIB) 775
LUCEMYRA™ (LOFEXIDINE) 776
LUMAKRAS™ (SOTORASIB) 779
LUMIZYME® (ALGLUCOSIDASE ALFA) 780
LUMOXITI® (MOXETUMOMAB PASUDOTOX-TDFK) 781
LUPKYNIS™(VOCLOSPORIN) 782
LUTATHERA® (LUTETIUM LU 177 DOTATATE) IV 783
LUXTURNA® (VORETIGENE NEPARVOVEC-RZYL) 785
LYNPARZA® (OLAPARIB) 786
MAKENA® (HYDROXYPROGESTERONE CAPROATE) 789

MARGENZA® (MARGETUXIMAB-CMKB) 790
MARQIBO® (VINCRISTINE SULFATE LIPOSOMAL) 791
MEKINIST® (TRAMETINIB) 792
MEKTOVI® (BINIMETINIB) 796
MEPSEVII™ (VESTRONIDASE ALFA-VJBK) 797
METASTRON™ (STRONTIUM-89 CHLORIDE) 798
MIFEPREX® (MIFEPRISTONE) 799
MONJUVI® (TAFASITAMAB-CXIX) 800
MONOFERRIC™ (FERRIC DERISOMALTOSE) 801
MULPLETA® (LUSUTROMBOPAG) 802
MULTIPLE SCLEROSIS THERAPY 803
MULTIPLE SCLEROSIS THERAPY: AMPYRA®(DALFAMPRIDINE) 820
MYALEPT® (METRELEPTIN) 822
MYFEMBREE® (RELUGOLIX/ESTRADIOL/NORETHINDRONE ACETATE) ORIAHNN® (ELAGOLIX/ESTRADIOL/NORETHINDRONE ACETATE; ELAGOLIX) 823
MYLOTARG™ (GEMTUZUMAB OZOGAMICIN) 824
MYOBLOC® (RIMABOTULINUMTOXINB) 826
NAGLAZYME® (GALSULFASE) 832
NALTREXONE/NALOXONE 833
NATPARA® (PARATHYROID HORMONE) 834
NAVELBINE® (VINORELBINE) 835
NERLYNX® (NERATINIB) 837
NEUPRO® (ROTIGOTINE PATCH) 839
NEUROPATHIC PAIN AGENTS 840
NEW FDA-APPROVED INDICATIONS 841
NEXAVAR® (SORAFENIB) 842
NEXLETOL® (BEMPEDOIC ACID) AND NEXLIZET® (BEMPEDOIC ACID/EZETIMIBE) 848
NEXVIAZYME™ (AVALGLUCOSIDASE ALFA-NGPT) 849
NINLARO® (IXAZOMIB) 850
NITROGLYCERIN 852
NO CRITERIA PA REQUIRED DRUGS 853
NOCTIVA® AND NOCDURNA® (DESMOPRESSIN ACETATE) 854
NORTHERA® (DROXIDOPA) 855
NUBEQA® (DAROLUTAMIDE) 856
NUCALA® (MEPOLIZUMAB) 857
NUEDEXTA® (DEXTROMETHORPHAN / QUININE SULFATE) 861
NULIBRY™ (FOSDENOPTERIN) 862
NULOJIX® (BELATACEPT) 863

NUTRITIONAL DIET SUPPLEMENTS 864
ODOMZO® (SONIDEGIB) 865
OFF-LABEL USE 866
ONCASPAR® (PEGASPARGASE) 869
ONIVYDE® (IRONOTECAN LIPOSOME) 871
ONPATTRO™ (PATISIRAN LIPID COMPLEX) IV 872
ONUREG® (AZACITIDINE) 873
OPDIVO® (NIVOLUMAB) IV 874
OPHTHALMICS: ALLERGIC CONJUNCTIVITIS 885
OPHTHALMICS: ANTI-INFLAMMATORY 886
OPHTHALMICS: DRY EYE AGENTS 887
OPHTHALMICS: OTHERS 891
OPHTHALMICS: SPECIALTY 892
OPIOID ANALGESICS: TIRF (TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL) 896
ORAL CONTRACEPTIVES 899
ORGOVYX® (RELUGOLIX) 900
ORILISSA® (ELAGOLIX SODIUM) 901
ORKAMBI® (LUMACAFTOR/IVACAFTOR) 902
ORTIKOS™ (BUDESONIDE ER) 903
OSTEOARTHRITIS AGENTS 904
OTIC ANTIBIOTICS 906
OXBRYTA® (VOXELOTOR) 907
OXLUMO™ (LUMASIRAN) 908
OZOBAX® (BACLOFEN SOLUTION) 909
PADCEV™ (ENFORTUMAB VEDOTIN-EJFV) 910
PALYNZIQ™ (PEGVALIASE-PQPZ) 911
PARAPLATIN® (CARBOPLATIN) 912
PARKINSON'S 914
PEMAZYRE® (PEMIGATINIB) 917
PENICILLAMINE AGENTS 918
PEPAXTO® (MELPHALAN FLUFENAMIDE) 921
PERJETA® (PERTUZUMAB) 922
PHESGO® (PERTUZUMAB, TRASTUZUMAB, AND HYALURONIDASE-ZZXF) 924
PHOTOFRIN® (PORFIMER SODIUM) 926
PIQRAY® (ALPELISIB) 929
POLIVY™ (POLATUZUMAB VEDOTIN-PIIG) 930
POMALYST® (POMALIDOMIDE) 932
PORTRAZZA® (NECITUMUMAB) 935

POTELIGEO® (MOGAMULIZUMAB-KPKC) 936
PRETOMANID 937
PREVYMIS® (LETERMOVIR) 938
PRIALT® (ZICONOTIDE) 939
PROLEUKIN® (ALDESLEUKIN, IL-2) 940
PROLIA® (DENOSUMAB) 942
PROMACTA® (ELTROMBOPAG) 944
PROPROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE 9 INHIBITOR (PCSK9) 947
PROVENGE® (SIPULEUCEL-T/ LACTATED RINGERS) 951
PULMONARY ARTERIAL HYPERTENSION AGENTS 952
PULMONARY FIBROSIS 958
PULMOZYME® (DORNASE ALFA) 961
QBREXZA® (GLYCOPYRRONIUM TOSYLATE) 962
QINLOCK™ (RIPRETINIB) 963
QUADRAMET® (SAMARIUM SM 153 LEXIDRONAM) 964
QUANTITY LIMITS 966
QUTENZA® (CAPSAICIN) 969
RADICAVA® (EDARAVONE) 970
RAVICTI® (GLYCEROL PHENYLBUTYRATE) 971
RAYOS® (PREDNISONE, DELAYED-RELEASE) 972
REBLOZYL (LUSPATERCEPT-AAMT) 974
RELISTOR® (METHYLNALTREXONE BROMIDE) INJECTION 977
RETEVMO® (SELPERCATINIB) 978
REVCOVI™ (ELAPEGADEMASE-LVLR) 981
REVLIMID® (LENALIDOMIDE) 982
REYVOW® (LASMIDITAN) 987
REZUROCK™ (BELUMOSUDIL) 988
RITUXAN HYCELA® (RITUXIMAB AND HYALURONIDASE HUMAN) 989
ROZLYTREK® (ENTRECTINIB) 992
RSV PROPHYLAXIS – SYNAGIS® 996
RUBRACA® (RUCAPARIB) 999
RUXIENCE (RITUXIMAB-PVVR) 1000
RUZURGI® (AMIFAMPRIDINE) 1004
RYBREVANT™ (AMIVANTAMAB-VMJW) 1005
RYDAPT® (MIDOSTAURIN) 1006
RYLAZE™ (ASPARAGINASE ERWINIA CHRYSANTHEMI [RECOMBINANT]-RYWN) 1008
RYPLAZIM® (PLASMINOGEN, HUMAN-TVMH) 1009
SAMSCA® (TOLVAPTAN) 1010

SAPHNELO™ (ANIFROLUMAB-FNIA) 1011
SARCLISA® (ISATUXIMAB-IRFC) 1013
SCENESSE (AFAMELANOTIDE) 1014
SCULPTRA® (INJECTABLE POLY-L-LACTIC ACID) 1015
SEDATIVE HYPNOTIC AGENTS 1016
SENSIPAR® (CINACALCET) 1019
SIGNIFOR®/SIGNIFOR® LAR (PASIREOTIDE) 1021
SIRTURO® (BEDAQUILINE) 1023
SKELETAL MUSCLE RELAXANTS 1024
SMOKING CESSATION 1025
SOGROYA® (SOMAPACITAN-BECO) 1026
SOLIRIS® (ECULIZUMAB) 1028
SPINRAZA® (NUSINERSEN) 1032
SPRAVATO® (ESKETAMINE) 1034
SPRYCEL® (DASATINIB) 1036
STEP THERAPY 1049
STIVARGA® (REGORAFENIB) 1050
STRENSIQ® (ASFOTASE ALFA) 1052
SUCRAID® (SACROSIDASE) 1053
SUTENT® (SUNITINIB) 1054
SYLATRON® (PEGINTERFERON ALFA-2B) 1058
SYLVANT® (SILTUXIMAB) 1059
SYMDEKO® (TEZACAFTOR/IVACAFTOR AND IVACAFTOR) 1060
SYNAREL® (NAFARELIN ACETATE) 1062
SYNRIBO® (OMACETAXINE MEPESUCCINATE) 1063
TABRECTA® (CAPMATINIB) 1064
TAFINLAR® (DABRAFENIB) 1065
TAGRISSO® (OSIMERTINIB) 1070
TALZENNA® (TALAZOPARIB) 1072
TARCEVA® (ERLOTINIB) 1073
TARGRETIN® (BEXAROTENE) ORAL FORMULATION 1076
TASIGNA® (NILOTINIB) 1077
TAVALISSE™ (FOSTAMATINIB) 1091
TAXOL® (PACLITAXEL) 1092
TAXOTERE® (DOCETAXEL) 1093
TAZVERIK™ (TAZEMETOSTAT) 1094
TECARTUS® (BREXUCABTAGENE AUTOLEUCEL) 1095
TECENTRIQ® (ATEZOLIZUMAB) 1097

TEGSEDI® (INOTERSEN) 1101
TEMODAR® (TEMOZOLOMIDE): IV FORMULATION 1102
TEMODAR® (TEMOZOLOMIDE): ORAL FORMULATION 1106
TEPEZZA® (TEPROTUMUMAB-TRBW) 1107
TEPMETKO™ (TEPOTINIB) 1108
TERIPARATIDE (FORTEO®, BONSITY™) 1109
TESTOPEL® (TESTOSTERONE PELLETS) (SUBCUTANEOUS IMPLANT) 1113
THALOMID® 1115
THIOLA (TIOPRONIN) 1117
THYROGEN® (THYROTROPIN ALFA) 1119
TIBSOVO® (IVOSIDENIB) 1120
EXSERVAN™ (RILUZOLE FILM) AND TIGLUTIK® (RILUZOLE SUSPENSION) 1122
TOBRAMYCIN NEBULIZER 1123
TORISEL® (TEMSIROLIMUS) 1124
TRIKAFTA® (ELEXACAFTOR/TEZACAFTOR/IVACAFTOR) 1125
TRODELVY® (SACITUZUMAB GOVITECAN-HZIY) 1127
TRUSELTIQ™ (INFIGRATINIB) 1129
TRUXIMA® (RITUXIMAB-ABBS) 1130
TUKYSA® (TUCATINIB) 1135
TURALIO™ (PEXIDARTINIB) 1137
TYKERB® (LAPATINIB) 1139
TYMLOS® (ABALOPARATIDE) 1141
UKONIQ® (UMBRALISIB) 1143
ULCERATIVE COLITIS THERAPY 1144
ULTOMIRIS® (RAVULIZUMAB-CWVZ) 1146
UNITUXIN® (DINUTUXIMAB) 1148
UPLIZNA™ (INEBILIZUMAB-CDON) 1149
UPNEEQ® (OXYMETAZOLINE) 1151
URINARY TRACT ANTISPASMODICS 1152
VACCINES 1153
VECTIBIX® (PANITUMUMAB) 1160
VELCADE® (BORTEZOMIB) AND BORTEZOMIB IV 1161
VENCLEXTA® (VENETOCLAX) 1165
VERQUVO (VERICIGUAT) 1167
VERZENIO® (ABEMACICLIB) 1168
VIBERZI® (ELUXADOLINE) 1171
VIDAZA® (AZACITIDINE) 1172
VILTEPSO® (VILTOLARSEN) 1173

VIMIZIM® (ELOSULFASE ALFA) 1174
VISUDYNE® (VERTEPORFIN) 1175
VITRAKVI® (LAROTRECTINIB) 1176
VIZIMPRO® (DACOMITINIB) 1180
VOTRIENT® (PAZOPANIB) 1181
VPRIV® (VELAGLUCERASE ALFA) 1187
VYEPTI™ (EPTINEZUMAB-JJMR) 1188
VYLEESI® (BREMELANOTIDE) 1191
VYNDAMAX™ (TAFAMIDIS)/VYNDAQEL® (TAFAMIDIS MEGLUMINE) 1192
VYONDYS-53™ (GOLODIRSEN) 1193
VYXEOS® (DAUNORUBICIN AND CYTARABINE) LIPSOME 1194
WAKIX® (PITOLISANT) 1195
WEIGHT LOSS AGENTS 1197
WELIREG™ (BELZUTIFAN) 1200
WINLEVI (CLASCOTERONE) 1201
XALKORI® (CRIZOTINIB) 1202
XELODA® (CAPECITABINE) 1204
XEOMIN® (INCOBUTULINUM TOXIN A) 1205
XERMELO® (TELOTRISTAT ETHYL) 1213
XGEVA® (DENOSUMAB) 1214
XIAFLEX® (COLLAGENASE CLOSTRIDIUM HISTOLYTICUM) 1216
XOFIGO® (RADIUM RA 223 DICHLORIDE) 1218
XOLAIR® (OMALIZUMAB) 1219
XOSPATA® (GILTERITINIB) 1228
XPOVIO® (SELINEXOR) 1229
XTANDI® (ENZALUTAMIDE) 1230
XYREM® (SODIUM OXYBATE), XYWAV™ (CALCIUM, MAGNESIUM, POTASSIUM, AND SODIUM OXYBATES) 1231
YERVOY® (IPILIMUMAB) 1234
YESCARTA® (AXICABTAGENE CILOLEUCEL) 1239
YONDELIS® (TRABECTEDIN) 1240
YUTIQ™ (FLUOCINOLONE ACETONIDE IMPLANT) 1242
ZALTRAP® (ZIV-AFLIBERCEPT) 1243
ZAVESCA® (MIGLUSTAT) 1244
ZEJULA® (NIRAPARIB) 1245
ZELBORAF® (VEMURAFENIB) 1246
ZEMPLAR® (PARICALCITOL) 1250
ZEPZELCA™ (LURBINECTEDIN) 1251
ZEVALIN® (IBRITUMOMAB TIUXETAN) 1252

ZILRETTA® (TRIAMCINOLONE ACETONIDE ER) 1253
ZINECARD® (DEXRAZOXANE) 1254
ZOKINVY™ (LONAFARNIB) 1255
ZOLEDRONIC ACID (ZOMETA®, RECLAST®) (INTRAVENOUS) 1258
ZOLGENSMA® (ONASEMNOGENE ABEPARVOVEC-XIOI) 1261
ZOLINZA® (VORINOSTAT) 1262
ZONTIVITY® (VORAPAXAR) 1263
ZYDELIG® (IDELALISBIB) 1264
ZYKADIA® (CERITINIB) 1266
ZYNLONTA® (LONCASTUXIMAB TESIRINE-LPYL) 1268
REVISION HISTORY 1269

MEDICAL EXCEPTIONS

Length of Authorization:	Up to 1 year
Initiative:	MNC: Drug Exclusion (2211) MNC: Non-Formulary Product (Reject 50076)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

Note: The medical exception criteria below is only for items that are excluded on the formulary. Any medication that is excluded by the plan itself in CRM will have to be authorized for approval by the individual plan, requests for exception review by patients and prescribers will be admin denied by RPH if CRM has PA model as "yes." If PA model is "no," close as informational and let the prescriber know it's a plan exclusion. For plan admin denials, the prescriber has to be aware it's a plan exclusion; initial requests will be closed as informational and the canned fax back for plan benefit exclusion will be sent to the prescriber (unless notes indicate that the prescriber is aware they are asking for an exclusion review, then it may be admin denied initially).

Note: Non-formulary products that are not FDA-approved (examples: Levicyn, Ceramax, etc.) are not covered and an admin denial is to be placed by the pharmacists. RPH team: please reach out to an SR pharmacist if you have any questions on these medications.

Note: Minimal Value Generic (MVG), Minimal Value Brand (MVB), Exclusions with an OTC alternative (EWO), High Cost Generics (HCG) and Select Brand Alternatives (SBA) are considered formulary exclusions and may be reviewed using the medical exceptions process. ***Exceptions***: any plan that has an attached list of exclusions that include medications that fall into these categories will be a ***plan*** exclusion and will be an admin denial by RPH (follow process above under first note).

- Is it a Precision/plus or core Exclusionary Class?
  - If "Yes": Please follow "precision/plus and core formulary exclusion exception process" section below.
  - If "No": follow any drug-specific criteria; **AND**
- For drugs with 2 or more alternatives in class:
  - Verbal or written attestation, including paid claims, of failure or contraindication to at least 2 preferred formulary alternatives.
- For drugs with < 2 alternatives in class:
  - Verbal or written attestation, including paid claims, of failure, contraindication, or intolerance to at least 1 preferred formulary alternative, if available.
- For off-label use:
  - Prescriber must submit credible peer clinical evidence (Class 1 or 2 peer review studies) that provides medical evidence pertaining to the drug being requested instead of what is available on the health plan's formulary.

For drugs that are considered medical (typically administered by a healthcare provider); default to plan coverage of medical drugs.

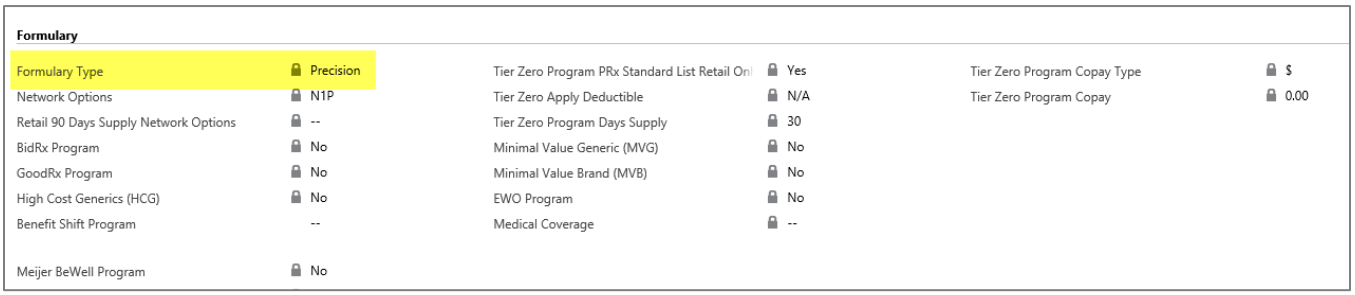
Approval time: 1 year, unless drug therapy duration warrants a shorter time frame, as per clinical pharmacist review.

PRECISION/PLUS AND CORE FORMULARY EXCLUSION EXCEPTION PROCESS

Length of Authorization:	Up to 1 year (follow approval length in individual drug class)
Initiative:	MNC: Non-Formulary Product (Reject 50698)

Note: Rejections will be 50698 Product not formulary. Review of these rejections are only for the **PRECISION/PLUS and CORE FORMULARY excluded items**. If the CRM has an exclusion in the includes/excludes, the product will have to be admin denied by RPH if an exclusion review is requested (see medical exception process above).

Verify via CRM if the patient has the Precision/Plus or Core Formulary.



For standard formulary exception requests, follow procedures above using the Medical exceptions.

FOR PRECISION/PLUS AND CORE FORMULARY

Written attestation (e.g., fax form, chart notes, cover sheet, paid claims) of failure, contraindication, or intolerance to two preferred alternatives (if listed) on the Precision Formulary Exclusions List under that therapeutic class (please use most up to date listing on the Magellan Rx precision formulary page or CORE formulary look up tool). If *combination* products are listed as preferred alternatives, account for the use, contraindication, or intolerance to only one agent containing the preferred formulary product.

Follow any clinical criteria and any drug-specific criteria for clinical information in drug specific criteria sections. The precision exception process is for trial requirements (unless noted in drug-specific sections like some immunomodulators).

PA review will follow the standard practice of initial review, internal appeal, and external review based on plan allowance.

TURNAROUND TIMES AND MONITORING

- Turnaround Time:

Expedited Concurrent	Expedited Preservice	Standard Preservice/Standard Concurrent	Standard Postservice
24 calendar hours	72 calendar hours	15 calendar days	30 calendar days

  - Every effort is made to complete a request as soon as possible upon receipt of all required clinical documentation in support of the request. The Pharmacist uses his or her clinical judgment when a case requires handling in a more expedited manner.

PROCEDURE

1. Either the member or the prescriber may request a drug exception.
   - The prescriber does not require the member's permission to request a drug exception.
2. Requests for a drug exception review will be addressed within the timeframes noted in the table above.
   - The clinical pharmacist will ensure requests are handled in a timely manner.
   - Escalate to the pharmacist queue to ensure evaluation of the request to determine if the clinical situation warrants expedited handling within 72 hours (i.e., 3 calendar days).
3. Requests for a drug exception may be submitted telephonically (i.e., member or prescriber), via the Member Web Portal (i.e., member), or by fax.
4. When a member calls to request a drug exception, the member must provide the following information:
   - Member name and cardholder identification (ID)
   - Prescriber name and phone number
   - Drug name
   - Reasons they are requesting a drug exception
5. When a prescriber calls to request a drug exception, the prescriber must provide the following information at the beginning of the call:
   - Member name and cardholder identification (ID)
   - Prescriber name and national provider identifier (NPI)
   - Drug name, route, and dosing
   - Reasons they are requesting a drug exception
   - Appropriate clinical documentation
6. Regardless of the method by which the request is received, the agent will set up the case in FirstTrax℠ including the detail elements noted above.
7. The CTI will be set as the following:
   - Category (C): MAP Exception Inquiry
   - Type (T): MAP Exclusion Exception
   - Item (I): In Progress Exception
8. When a member calls, the CPhT informs the member the request may take up to 15 business days (72 hours/3 calendar days if the request is an expedited review), excluding holidays and weekends. The member will receive a written notification of the decision.
   - Set up the CTI as the following:
     - Category (C): MAP Exception Inquiry
     - Type (T): MAP Exclusion Exception
     - Item (I): In Progress Exception
   - The PA should be built with initiative MNC: Non-Formulary Product
   - The case is placed in the Clinical Pharmacist queue for an exception review.

PROCEDURE *(CONTINUED)*

9. When a prescriber calls the CPhT sets up, the PA and the call is forwarded to a clinical pharmacist when a pharmacist is available to take a call. A pharmacist will discuss the exception request with the prescriber. In the event that a pharmacist is unavailable, submit the contact detail to the MAP Pharmacist queue for review.
   - Set up the CTI as the following:
     - Category (C): MAP Exception Inquiry
     - Type (T): MAP Exclusion Exception
     - Item (I): In Progress Exception
   - The PA should be built with initiative MNC: Non-Formulary Product
10. The pharmacist will discuss the prescriber's clinical rationale and render a decision if appropriate.
11. If the pharmacist can **approve** the exception based on medical necessity, the following steps occur:
    - Inform the caller that the exception request is approved and the prescriber will receive a PA fax back.
    - Complete the necessary documentation in FirstTrax℠ and steps to generate the prescriber's PA fax back, including updating of all clinical notes to include the details of the discussion between the prescriber and the pharmacist.
    - Set the Response Code to the appropriate Item for a PA approval.
    - Mark the request as *Resolved*.
12. If the Pharmacist is **not able to approve** the request based on medical necessity:
    - Inform the caller that the exception request is denied and the prescriber will receive a PA fax back.
    - Complete the necessary documentation in FirstTrax℠ and steps to generate the prescriber's PA fax back, including updating of all clinical notes to include the details of the discussion between the prescriber and the pharmacist.
    - Set the Response Code to appropriate denial response.
    - Mark the request as *Resolved*.

ABECMA® (IDECABTAGENE VICLEUCEL)

Length of Authorization:	Coverage will be provided for one treatment course (1 dose of Abecma) and may not be renewed.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Submission of medical records related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation via direct upload through the PA web portal or by fax.

Diagnosis of **Multiple Myeloma**

- Patient is at least 18 years of age; **AND**
- Healthcare facility has enrolled in the ABECMA REMS Program, and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
- Patient has not received prior CAR-T or B-cell maturation antigen (BCMA) targeted therapy; **AND**
- Patient has not received prior allogeneic hematopoietic stem cell transplant; **AND**
- Patient does not have an active infection or inflammatory disorder; **AND**

- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and patient will not receive live vaccines during idecabtagene vicleucel treatment and until immune recovery following treatment; **AND**
- Patient has been screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**
- Used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); **AND**
- Patient does not have known central nervous system (CNS) involvement with myeloma or a history or presence of clinically relevant CNS pathology; **AND**
- Patient does not have active or a history of plasma cell leukemia; **AND**
- Patient has an ECOG performance status of 0-1; **AND**
- Patient has relapsed or refractory disease; **AND**
- Patient has received at least four prior therapies, including a proteasome inhibitor (e.g., bortezomib, etc.), an immunomodulatory agent (e.g., lenalidomide, thalidomide, etc.), and an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc.)

CLINICAL CRITERIA FOR RENEWAL

May not be renewed

ABIRATERONE ACETATE (ZYTIGA®, YONSA®)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 – 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Prostate Cancer**

- Patient is 18 years of age or older; **AND**
- Patient will receive concurrent treatment with a GnRH-analog or has had a bilateral orchiectomy; **AND**
- Used in combination with prednisone, methylprednisolone, or dexamethasone; **AND**
- Patient will avoid concomitant use with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has not progressed following previous receipt of either formulation of abiraterone; **AND**
  - Used as initial therapy for patients in the regional risk group (i.e., any T, N1, M0) with a life expectancy of > 5 years or is symptomatic (*Zytiga® only*); **OR**
  - Patient has metastatic castration-resistant prostate cancer (mCRPC) (*Zytiga or Yonsa*) ; **AND**
    - Patient has not received prior docetaxel or prior novel hormone therapy (e.g., enzalutamide, darolutamide, apalutamide, etc.); **OR**
    - Patient has received prior docetaxel and no prior novel hormone therapy; **OR**
    - Patient has received prior novel hormone therapy and no prior docetaxel; **OR**
    - Patient has received prior docetaxel and prior novel hormone therapy; **AND**
      - Patient does not have visceral metastases; **OR**
  - Patient has metastatic castration-sensitive/castration-naïve disease (*Zytiga® only*); **AND**
    - Patient has high-risk disease with at least 2 of the following at baseline:
      - Total Gleason score of ≥ 8;
      - Presence of ≥ 3 lesions on bone scan;
      - Evidence of measurable visceral metastases; **OR**
- Patient has progressed following previous receipt of either abiraterone formulation ; **AND**
  - Patient has metastatic castration-resistant prostate cancer (mCRPC) *(Zytiga or Yonsa);* **AND**
  - Patient has received prior novel hormone therapy and no prior docetaxel
- ***Please continue below for additional formulary specific criteria.***

BRAND ZYTIGA (NO GRANDFATHERING)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

- In addition to the above clinical criteria:
  - Patient has a documented failure (minimum three-month trial), contraindication or intolerance to abiraterone

YONSA® (NO GRANDFATHERING)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

- In addition to the above clinical criteria:
  - Patient has a documented failure (minimum three-month trial), contraindication or intolerance to abiraterone

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: uncontrolled hypertension, hypokalemia, fluid retention, hepatotoxicity, adrenocortical insufficiency, severe hypoglycemia, etc.

ABRAXANE® (PACLITAXEL PROTEIN-BOUND PARTICLES) IV

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of Breast Cancer

- Patient is at least 18 years of age; AND
- Patient failed on combination chemotherapy for metastatic disease or relapsed within 6 months of adjuvant therapy; **AND**
  - Previous chemotherapy included an anthracycline; **OR**
- Patient has recurrent unresectable (local or regional) or metastatic (stage IV [M1]) disease; **AND**
  - Used as a single agent OR in combination with carboplatin in patients with high tumor burden, rapidly progressing disease, and visceral crisis; **AND**
    - Disease is HER2-negative; **AND**
      - Disease is hormone receptor negative; **OR**
      - Disease is hormone receptor positive and patient is refractory to endocrine therapy or has a visceral crisis; **OR**
  - Used as third line or greater therapy in combination with trastuzumab for disease that is HER2-positive; **OR**
  - Used in combination with atezolizumab or pembrolizumab for PD-L1 positive triple-negative disease
- May be substituted for paclitaxel or docetaxel if patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication

Diagnosis of **Non-Small Cell Lung Cancer**

- Patient is at least 18 years of age; AND
- Used as first-line therapy for locally advanced or metastatic disease in combination with carboplatin in patients who are not candidates for curative surgery or radiation therapy; **OR**
- May be substituted for paclitaxel or docetaxel if patient has experienced hypersensitivity reactions despite premedication or if the patient has contraindications to standard hypersensitivity premedication; **OR**
- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **AND**
    - Used in combination with carboplatin AND pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology); **AND**
      - Used in patients with tumors that have negative actionable molecular markers ***; **AND**
        - PD-L1 < 1% with performance status (PS) score of ≤ 1; **OR**
        - PD-L1 expression positive (≥ 1%) tumors with PS ≤ 2; **OR**
      - Used in patients with BRAF V600E-mutation, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation AND PS score of ≤ 1; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Used in combination with carboplatin in patients with contraindications **¥** to PD-1 or PD-L1 inhibitors (PS score of ≤ 2) or as a single agent (PS 2); **AND**
  - Used in patients with tumors that have negative actionable molecular markers ***** and PD-L1 < 1%; **OR**
  - Used in patients with BRAF V600E-mutation, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation, or RET rearrangement positive tumors; **OR**

– Used as subsequent therapy; **AND**
- Used in combination with carboplatin AND pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology) in patients with PS score of ≤ 1; **AND**
  - Used in patients with BRAF V600E-mutation, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation positive tumors; **OR**
  - Used in patients with ROS1 rearrangement positive tumors who received prior targeted therapy for those aberrations; **OR**
- Used in combination with carboplatin in patients with contraindications to PD-1 or PD-L1 inhibitors (PS score of ≤ 2) or as a single agent (PS 2); **AND**
  - Used in patients with BRAF V600E-mutation, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation, or RET rearrangement positive tumors; **OR**
  - Used in patients with EGFR, ALK, or ROS1 rearrangement positive tumors who received prior targeted therapy for those aberrations; **OR**
  - Used in patients with PD-L1 expression-positive (≥ 1%) tumors that have negative actionable molecular markers ***** with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-doublet chemotherapy

** Note: Actionable molecular genomic biomarkers include EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, and RET rearrangement. If there is insufficient tissue to allow testing for all of the EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET, and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*
¥ Note: Contraindications for treatment with PD-1/PD-L1 inhibitors may include active or previously documented auto-immune disease and/or current use of immunosuppressive agents, or presence of an oncogene (e.g., EGFR [exon 19 deletions, p.L858R point mutation in exon 21], ALK rearrangements, RET rearrangements), which would predict lack of benefit.

Diagnosis of **Ovarian Cancer (Epithelial Ovarian/Fallopian Tube/Primary Peritoneal)**

- Patient is 18 years of age or older; **AND**
- Patient has recurrent or persistent disease; **AND**
- Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **AND**

  – Used as a single agent; **AND**
  - Patient has platinum-resistant disease; **AND**
    - Used for progression on primary, maintenance, or recurrence therapy; **OR**
    - Used for stable or persistent disease if not currently on maintenance therapy; **OR**
    - Used for relapsed disease <6 months following complete remission from prior chemotherapy; **OR**
  - Patient has platinum-sensitive disease; **AND**
    - Used for radiographic and/or clinical relapse ≥6 months after complete remission from prior chemotherapy; **OR**

  – Used in combination with carboplatin for platinum-sensitive disease with confirmed taxane hypersensitivity; **AND**
  - Used for relapse ≥ 6 months after complete remission from prior chemotherapy

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Pancreatic Adenocarcinoma**

- Patient is at least 18 years of age; **AND**
- Used in combination with gemcitabine; **AND**
  - Patient has locally advanced or metastatic disease; **AND**
    - Used as first-line therapy; **OR**
    - Used as induction therapy followed by chemoradiation *(locally advanced disease only)*; **OR**
    - Used as subsequent therapy after progression with a fluoropyrimidine-based therapy; **OR**
  - Patient has recurrent disease in the pancreatic operative bed or metastatic disease, post-resection; AND
    - Used ≥ 6 months after completion of primary therapy; **OR**
    - Used < 6 months from completion of primary therapy with a fluoropyrimidine-based regimen; **OR**
  - Used as neoadjuvant therapy; **AND**
    - Patient has resectable disease with high-risk features (i.e., very highly elevated CA 19-9, large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain); **OR**
    - Patient has biopsy positive borderline resectable disease

Diagnosis of **Melanoma**

- Patient is at least 18 years of age; **AND**
  - Patient has cutaneous melanoma; **AND**
    - Used as a single agent or in combination with carboplatin for metastatic or unresectable disease; **AND**
      - Used as subsequent therapy for disease progression; **OR**
      - Used after maximum clinical benefit from BRAF targeted therapy; **OR**
  - Patient has uveal melanoma; **AND**
    - Used as a single agent for distant metastatic disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Uterine Cancer**

- Patient is at least 18 years of age; **AND**
- Used as single agent therapy; **AND**
- Patient has tried paclitaxel and treatment with paclitaxel was not tolerated due to a documented hypersensitivity reaction, despite use of recommended premedication or there is a documented medical contraindication to recommended premedication; **AND**
  - Patient has endometroid adenocarcinoma; **AND**
    - Used as primary treatment of disease NOT suitable for primary surgery; **AND**
      - Patient has suspected or gross cervical involvement *(**excluding** patients using as chemotherapy alone)*; **OR**
      - Patient has locoregional extrauterine disease; **OR**
      - Patient has distant metastases; **OR**
    - Used as primary treatment of disease suitable for primary surgery; **AND**
      - Used preoperatively for abdominal/pelvic confined disease; **OR**
      - Patient has distant metastases; **OR**
    - Used as adjuvant treatment for stage III-IV disease; **OR**
    - Used for locoregional recurrence or disseminated metastases; **OR**
  - Patient has carcinosarcoma, clear cell carcinoma, serous carcinoma, or un-/de-differentiated carcinoma; **AND**
    - Used for locoregional recurrence or disseminated metastases; **OR**
    - Used as additional treatment of disease suitable for primary surgery; **OR**
    - Used as primary treatment of disease NOT suitable for primary surgery

Diagnosis of **Hepatobiliary Adenocarcinoma (intrahepatic/extrahepatic cholangiocarcinoma, Gallbladder)**

- Patient is at least 18 years of age; **AND**
- Used in combination with gemcitabine for unresectable or metastatic disease; **AND**
  - Used as primary treatment; **OR**
  - Use as subsequent treatment for progression on or after systemic therapy

Diagnosis of **Small Bowel Adenocarcinoma/Advanced Ampullary Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has advanced or metastatic disease; **AND**
- Used as single agent or in combination with gemcitabine; **AND**
  - Used as subsequent therapy; **OR**
  - Patient has had prior adjuvant oxaliplatin exposure, or a contraindication to oxaliplatin; **AND**
    - Used as initial therapy; **OR**
    - Used as subsequent therapy in patients who previously received initial therapy with nivolumab with or without ipilimumab, or pembrolizumab

Diagnosis of **Kaposi Sarcoma**

- Patient is at least 18 years of age; **AND**
- Used as subsequent therapy; **AND**
  - Used as a single agent for patients that do not have HIV; **OR**
  - Used in combination with antiretroviral therapy (ART) for patients with HIV; **AND**
- Patient has relapsed/refractory advanced, cutaneous, oral, visceral, or nodal disease; **AND**
- Disease has progressed on or not responded to first-line therapy; **AND**
- Disease has progressed on alternate first-line therapy.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include bone marrow suppression (e.g., severe neutropenia [absolute neutrophil count < 1,500 cell/mm^3] or thrombocytopenia), sensory neuropathy, sepsis, pneumonitis, severe hypersensitivity reactions including anaphylactic reactions, etc.

ACROMEGALY AGENTS

Length of Authorization:	Noted below
Initiative:	SPC: Acromegaly Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

SANDOSTATIN® LAR—APPROVAL IS 6 MONTHS AND MAY BE RENEWED

Diagnosis of **Acromegaly**

- Patient is 18 years of age or older; **AND**
- Patient is being treated with octreotide acetate subcutaneously for at least 2 weeks and has shown a response and no adverse effects prior to starting therapy with the long-acting release (LAR) formulation; **AND**
- Patient diagnosis confirmed by elevated (age-adjusted) or equivocal serum IGF-1 as well as inadequate suppression of GH after a glucose load; **AND**
- Patient has documented inadequate response to surgery and/or radiotherapy, or it is not an option for the patient; **AND**
- Used as long-term maintenance therapy; **AND**
- Patient's tumor has been visualized on imaging studies (i.e., MRI or CT-scan); **AND**
- Baseline growth hormone (GH) and IGF-1 blood levels (renewal will require reporting of current levels)

Diagnosis of **Diarrhea associated with Vasoactive Intestinal Peptide tumors (VIPomas)**

- Patient is 18 years of age or older; **AND**
- Patient is being treated with octreotide acetate subcutaneously for at least 2 weeks and has shown a response and no adverse effects prior to starting therapy with the LAR formulation; **AND**
- Patient has profuse watery diarrhea

Diagnosis of **Carcinoid Tumors/Neuroendocrine Tumors (e.g., Gastrointestinal tract, lung, thymus, pancreas, adrenal)**

- Patient is 18 years of age or older; **AND**
- Patient is being treated with octreotide acetate subcutaneously for at least 2 weeks and has shown a response and no adverse effects prior to starting therapy with the LAR formulation; **AND**
- Patient has severe diarrhea/flushing episodes (carcinoid syndrome); **OR**
- Used to treat symptoms related to hormone hypersecretion in neuroendocrine tumors of the pancreas; **AND**
  - Patient has a gastrinoma, glucagonoma, or VIPoma; **OR**
- Use as primary treatment of unresected primary gastrinoma; **OR**
- Used for locoregional unresectable bronchopulmonary or thymic disease as primary therapy or as subsequent therapy if progression on first-line therapy (including disease progression on prior treatment with octreotide LAR in patients with functional tumors); **AND**
  - Used for management of hormone symptoms and/or somatostatin receptor positive disease determined by imaging (i.e., 68Ga-dotatate imaging PET/CT or PET/MRI or somatostatin receptor scintigraphy [octreotide scan])

SANDOSTATIN® LAR—APPROVAL IS 6 MONTHS AND MAY BE RENEWED *(CONTINUED)*

Diagnosis of **Carcinoid Tumors/Neuroendocrine Tumors (e.g., GI tract, lung, thymus, pancreas, adrenal)** ***(continued)***

- Patient has distant metastatic bronchopulmonary or thymic disease; **AND**
  - Used for somatostatin receptor positive disease and/or symptomatic hormonal disease if clinically significant tumor burden and low grade (typical) histology OR evidence of progression OR intermediate grade (atypical histology); **AND**
    - Used as primary therapy or as subsequent therapy if progression on first-line therapy (including disease progression on prior treatment with octreotide LAR in patients with functional tumors); **OR**
  - Used for somatostatin receptor positive disease and/or hormonal symptoms if asymptomatic with low tumor burden and low grade (typical histology); **OR**
  - Used for somatostatin receptor positive disease and/or chronic cough/dyspnea that is not responsive to inhalers with multiple lung nodules or tumorlets and evidence of diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH); **OR**
- Used for the management of locoregional advanced or distant metastatic disease of the gastrointestinal tract; **AND**
  - Patient is asymptomatic with a low tumor burden; **OR**
  - Patient with a clinically significant tumor burden; **OR**
  - Patient has disease progression and is not already receiving octreotide LAR; **OR**
  - Patient has disease progression with functional tumors and will be continuing treatment with octreotide LAR; **OR**
- Used for tumor control of locoregional advanced and/or distant metastatic neuroendocrine tumors of the pancreas (***Note:** for insulinoma **only**, patient must have somatostatin-receptor positive disease); **AND**
  - Patient is asymptomatic with a low tumor burden and stable disease; **OR**
  - Patient is symptomatic; **OR**
  - Patient has a clinically significant tumor burden; **OR**
  - Patient has clinically significant progression and is not already receiving octreotide LAR; **OR**
- Patient has pheochromocytoma or paraganglioma; **AND**
  - Patient has symptomatic locally unresectable somatostatin receptor-positive disease; **OR**
  - Patient has distant metastatic disease

Diagnosis of **Thymic Carcinomas/Thymomas**

- Patient is 18 years of age or older; **AND**
- Patient is being treated with octreotide acetate subcutaneously for at least 2 weeks and has shown a response and no adverse effects prior to starting therapy with the LAR formulation; **AND**
- Used with or without prednisone therapy; **AND**
  - Used as first line therapy or postoperative treatment, in patients who are unable to tolerate first-line combination regimens; **OR**
  - Used as second-line therapy for unresectable or metastatic disease

SOMATULINE® – INITIAL APPROVAL IS 3 MONTHS, ELIGIBLE FOR RENEWAL FOR 6 MONTHS

Diagnosis of **Acromegaly**

- Patient is 18 years of age or older; **AND**
- Patient has not received a long-acting somatostatin analogue (e.g., Octreotide LAR depot, Lanreotide SR, Lanreotide autogel, pasireotide LAR depot, etc.) within the last 4 weeks; **AND**
- Patient's diagnosis is confirmed by elevated (age-adjusted) or equivocal serum IGF-1 as well as inadequate suppression of growth hormone (GH) after a glucose load; **AND**
- Patient has documented inadequate response to surgery and/or radiotherapy **OR** it is not an option for the patient; **AND**
- Patient's tumor has been visualized on imaging studies (i.e., MRI or CT-scan); **AND**
- Baseline GH and IGF-1 blood levels (renewal will require reporting of current levels); **AND**
- Will not be used in combination with oral octreotide

Diagnosis of **Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)**

- Patient is 18 years of age or older; **AND**
- Patient has not received a long-acting somatostatin analogue (e.g., Octreotide LAR depot, Lanreotide SR, Lanreotide autogel, pasireotide LAR depot, etc.) within the last 4 weeks; **AND**
- Patient has unresectable, locally advanced or metastatic disease; **AND**
- Patient has non-functioning tumors without hormone-related symptoms; **AND**
- Patient has well or moderately differentiated disease.

Diagnosis of **Carcinoid Syndrome**

- Patient is 18 years of age or older; **AND**
- Patient has not received a long-acting somatostatin analogue (e.g., Octreotide LAR depot, Lanreotide SR, Lanreotide autogel, pasireotide LAR depot, etc.) within the last 4 weeks; **AND**
- Patient has documented neuroendocrine tumors with a history of carcinoid syndrome (flushing and/or diarrhea); **AND**
  - Used to reduce the frequency of short-acting somatostatin analog rescue therapy; **OR**
  - Used for treatment and/or control of symptoms.

SOMATULINE® – INITIAL APPROVAL IS 3 MONTHS, ELIGIBLE FOR RENEWAL FOR 6 MONTHS *(CONTINUED)*

Diagnosis of **Neuroendocrine and Adrenal Tumors (e.g., GI Tract, Lung, Thymus, Pancreas, and Pheochromocytoma/Paraganglioma)**

- Patient is 18 years of age or older; **AND**
- Patient has not received a long-acting somatostatin analogue (e.g., Octreotide LAR depot, Lanreotide SR, Lanreotide autogel, pasireotide LAR depot, etc.) within the last 4 weeks; **AND**
- Used as primary treatment for unresected primary gastrinoma; **OR**
- Used for locoregional unresectable bronchopulmonary or thymic disease as primary therapy or as subsequent therapy if progression on first-line therapy (including disease progression on prior treatment with lanreotide in patients with functional tumors); **AND**
  - Used for management of hormone symptoms and/or somatostatin receptor positive disease determined by imaging (i.e., 68Ga-dotatate imaging PET/CT or PET/MRI or somatostatin receptor scintigraphy); **OR**
- Patient has distant metastatic bronchopulmonary or thymic disease; **AND**
  - Used for somatostatin receptor positive disease and/or symptomatic hormonal disease if clinically significant tumor burden and low grade (typical) histology OR evidence of progression OR intermediate grade (atypical histology); **AND**
    - Used as primary therapy or as subsequent therapy if progression on first-line therapy (including disease progression on prior treatment with lanreotide in patients with functional tumors); **OR**
  - Used for somatostatin receptor positive disease and/or hormonal symptoms if asymptomatic with low tumor burden and low grade (typical) histology; **OR**
  - Used for somatostatin receptor positive disease and/or chronic cough/dyspnea that is not responsive to inhalers with multiple lung nodules or tumorlets and evidence of diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH); **OR**
- Used for the management of locoregional advanced or distant metastatic disease of the gastrointestinal tract; **AND**
  - Patient is asymptomatic with a low tumor burden; **OR**
  - Patient with a clinically significant tumor burden; **OR**
  - Patient has disease progression and is not already receiving lanreotide; **OR**
  - Patient has disease progression with functional tumors and will be continuing treatment with lanreotide; **OR**
- Used to manage symptoms related to hormone hypersecretion of locoregional neuroendocrine tumors of the pancreas (well differentiated grade 1/2); **AND**
  - Patient has gastrinoma, glucagonoma, or VIPoma; **OR**
- Used for tumor control of locoregional advanced and/or distant metastatic neuroendocrine tumors of the pancreas (well differentiated grade 1/2) [*****NOTE:** for insulinoma ONLY, patient must have somatostatin-receptor positive disease]; **AND**
  - Patient is asymptomatic with a low tumor burden and stable disease; **OR**
  - Patient is symptomatic; **OR**
  - Patient has a clinically significant tumor burden; **OR**
  - Patient has clinically significant progression and is not already receiving lanreotide; **OR**
- Patient has unresectable locally advanced or metastatic neuroendocrine tumors (well differentiated grade 3); **AND**
  - Patient has favorable biology (e.g., relatively low Ki-67 [<55%], somatostatin receptor-positive disease); **OR**
- Patient has pheochromocytoma or paraganglioma; **AND**
  - Patient has symptomatic locally unresectable somatostatin receptor-positive disease; **OR**
  - Patient has distant metastatic disease

SANDOSTATIN®/BYNFEZIA™/OCTREOTIDE – APPROVAL IS 6 MONTHS AND MAY BE RENEWED

Note: This criteria does not apply to Sandostatin® LAR. Please refer to that criteria above.

Diagnosis of **Acromegaly**:

- Patient is at least 18 years of age

Diagnosis of **Vasoactive Intestinal Peptide Tumors (VIPomas):**

- Patient is at least 18 years of age

Diagnosis of **Diarrheal States Related to One of the Following:**

- Patient is at least 18 years of age; **AND**
  - AIDS-related diarrhea; **OR**
  - Short bowel (ileostomy) syndrome; **OR**
  - Diarrhea caused by radiation treatment in cancer patients; **OR**
  - Chemotherapy-associated diarrhea

Diagnosis of **Dumping Syndrome:**

- Patient is at least 18 years of age

Diagnosis of **Symptoms of Cushing's Syndrome Secondary to Neuroendocrine Tumors - Adrenal Gland Tumors**

- Patient is at least 18 years of age

Diagnosis of **Neuroendocrine Tumors (Pancreas, GI Tract, Lung, and Thymus)**

- Patient is at least 18 years of age; **AND**
- Includes gastrinomas, glucagonomas, insulinomas and VIPomas, etc.

Diagnosis of **Carcinoid Tumors**

- Patient is at least 18 years of age

Diagnosis of **Pheochromocytoma/Paraganglioma**

- Patient is at least 18 years of age

Diagnosis of **Thymomas and Thymic Carcinomas**

- Patient is at least 18 years of age

Diagnosis of **Variceal bleeding**

- Patient is at least 18 years of age

MYCAPSSA® — APPROVAL IS 6 MONTHS AND MAY BE RENEWED

Diagnosis of **Acromegaly**

- Patient is at least 18 years of age; **AND**
- Patient is being treated with somatostatin analogs (e.g., octreotide or lanreotide) for at least 6 months with stable doses for at least the last 3 months and has shown a response and no adverse effects prior to starting therapy with oral octreotide; **AND**
- Will be used as single-agent therapy; **AND**
- Patient will avoid concomitant therapy with acid-reducing agents (e.g., proton pump inhibitors, H2-receptor antagonists, or antacids) which may reduce bioavailability. If therapy is unavoidable, stagger the administration and the patient will be monitored closely for signs and symptoms of acromegaly; **AND**
- Patient has not received a long-acting somatostatin analogue (e.g., octreotide LAR depot, lanreotide SR/auto gel, pasireotide LAR depot, etc.) within the last 4 weeks; **AND**
- Will not be used in combination with other short-acting somatostatin analogs (e.g., octreotide, lanreotide, pasireotide, etc.); **AND**
- Will not be used as maintenance switch-therapy for, or in combination with, pasireotide LAR depot; **AND**
- Patient diagnosis confirmed by elevated (age-adjusted) or equivocal serum IGF-1 as well as inadequate suppression of growth hormone (GH) after a glucose load; **AND**
- Patient has documented inadequate response to surgery and/or radiotherapy or is not a candidate; **AND**
- Used as long-term maintenance therapy; **AND**
- Patient's tumor has been visualized on imaging studies (e.g., MRI or CT-scan); **AND**
- Baseline growth hormone (GH) and IGF-I blood levels have been obtained (necessary for renewal)

CLINICAL CRITERIA FOR RENEWAL

SANDOSTATIN® LAR

- Coverage can be renewed based on the following criteria:
  - Absence of unacceptable toxicity from the drug (e.g., cholelithiasis and complications of cholelithiasis [i.e., cholecystitis, cholangitis, pancreatitis], hyperglycemia, hypoglycemia, hypothyroidism, sinus bradycardia, cardiac arrhythmias, cardiac conduction abnormalities, depressed vitamin B_{12} levels); **AND**
    - Disease response with improvement in patient's symptoms including reduction in symptomatic episodes (such as diarrhea, rapid gastric dumping, flushing, bleeding, etc.) and/or stabilization of glucose levels or decrease in size of tumor or tumor spread; **OR**
    - **Acromegaly only:** Disease response as indicated by an improvement in signs and symptoms compared to baseline; **AND**
      - Reduction of growth hormone (GH) from pre-treatment baseline; **OR**
      - Age-adjusted normalization of serum IGF-1
  - **Neuroendocrine tumors (gastrointestinal tract, bronchopulmonary, thymus, or pancreas only):** Patient has had disease progression and therapy will be continued in patients with functional tumors.

SANDOSTATIN®/OCTREOTIDE/BYYNFEZIA®

- Absence of unacceptable toxicity from the drug (e.g., biliary tract abnormalities, hypothyroidism, goiter, sinus bradycardia, cardiac arrhythmias, cardiac conduction abnormalities pancreatitis)
- Disease response with improvement in patient's signs and/or symptoms

CLINICAL CRITERIA FOR RENEWAL (CONTINUED)

SOMATULINE®—RENEWAL IS 6 MONTHS

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: formation of gallstones, cardiovascular abnormalities (bradycardia, sinus bradycardia, and hypertension), uncontrolled blood glucose abnormalities (hyperglycemia or hypoglycemia), thyroid disorders (hypothyroidism), etc.; **AND**

Acromegaly:

Disease response as indicated by an improvement in signs and symptoms compared to baseline; **AND**

- Reduction of growth hormone (GH) by random testing to < 1.0 mcg/L; **OR**
- Age-adjusted normalization of serum IGF-1

Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs):

- Disease response with treatment as indicated by an improvement in symptoms including reduction in symptomatic episodes (such as diarrhea, rapid gastric dumping, flushing, bleeding, etc.) and/or stabilization of glucose levels and/or decrease in size of tumor or tumor spread

Carcinoid Syndrome:

- Disease response with treatment as indicated by reduction in use of short-acting somatostatin analog rescue medication (e.g., octreotide) and a decrease in the frequency of diarrhea ad flushing events, when compared to baseline

Neuroendocrine and Adrenal Tumors (e.g., GI Tract, Lung, Thymus, Pancreas, and Pheochromocytoma/Paraganglioma)

- Disease response with treatment as indicated by an improvement in symptoms including reduction in symptomatic episodes (e.g., diarrhea, rapid gastric dumping, flushing, bleeding) and/or stabilization of glucose levels and/or decrease in size of tumor or tumor spread; **OR**
- Patient has had disease progression and therapy will be continued in patients with functional tumors

MYCAPSSA® — RENEWAL IS 6 MONTHS

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: cholelithiasis and complications of cholelithiasis (e.g., cholecystitis, cholangitis, pancreatitis), hyperglycemia, hypoglycemia, hypothyroidism, sinus bradycardia, cardiac arrhythmias, cardiac conduction abnormalities, severe depressed vitamin B_{12} levels, etc.; **AND**
- Disease response as indicated by an improvement in signs and symptoms compared to baseline; **AND**
  - Reduction of growth hormone (GH) by random testing to < 1.0 mcg/L; **OR**
  - Age-adjusted normalization of serum IGF-1

H. P. ACTHAR® (CORTICOTROPIN, ACTH)

Length of Authorization:	1 month; may be renewed
Initiative:	SPC: Hormonal Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Infantile Spasms (West Syndrome)**

- Patient is less than 2 years old; **AND**
- Clinical documentation indicating patient suffers from infantile spasms (West Syndrome); **AND**
- Must be used as monotherapy; **AND**
- Documentation that patient does not have a suspected congenital infection

Note: All other diagnoses are considered **not approvable**. Escalate to a pharmacist for a **deny** decision.

Use of repository corticotropin injection for indications including, but not limited to, those additionally listed in the product labeling are not supported by substantial clinical evidence.
Repository corticotropin injection was originally approved by the U.S. Food and Drug Administration (FDA) in 1952 for a variety of disorders and diseases that at the time were thought to benefit from steroid mediated immunosuppression. The initial approval of H.P. ACTH gel occurred prior to the Kefauver-Harris amendment to the Federal Food, Drug and Cosmetic Act of 1962, which introduced the requirement of "substantial evidence" of two adequate and well controlled trials. At the time of the original approval drug manufacturers only had to show the drug was safe for use in humans. The original data included case reports from a few physicians describing patients with conditions originally treated with Acthar powder that were transferred to treatment with Acthar Gel and gave dosing guidance for treatment of these individual conditions. These data would be grossly inadequate to support approval of a new drug or new indications by the Agency under current standards requiring evidence from adequate and well-controlled clinical trials. A Drug Efficacy Study Implementation (DESI) review of corticotrophin injection was initiated in 1971 and finalized in 1977.[3]

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Disease response with treatment as indicated by resolution of symptoms and/or normalization of laboratory tests; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe infections, severe electrolyte imbalances, gastric bleeding or ulcer, hypertension, hypokalemia, severe depression, frank psychotic manifestations, posterior subcapsular cataracts, glaucoma)

ACTIMMUNE® (INTERFERON GAMMA1-B)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Granulomatous Disease (CGD)**

- Patient is 1 year of age or older; **AND**
- Patient diagnosis is confirmed by the following biochemical and genetic tests:
  - Patient has a mutation in one or more of the phagocyte oxidase (PHOX) genes (e.g., gp91, p47, p22, p67, and p40 phox-genes) and/or a mutation in the CYBC1 gene; **AND**
  - Patient has abnormal dihydrorhodamine (DHR) neutrophil function as measured on a quantitative assay (i.e., DHR-123 oxidation test); **AND**
- Used to decrease the frequency and severity of serious infections, defined as a clinical event requiring hospitalization and the use of parenteral antibiotics; **AND**
- Patient is receiving antibiotic prophylaxis therapy

Diagnosis of **Severe Malignant Osteopetrosis (SMO)**

- Patient is ≥ 1 month old and ≤ 8 years of age; **AND**
- Patient diagnosis is confirmed by all of the following radiographic and genetic tests:
  - Classical radiographic presentation (e.g., bone-within-bone, club shaped long bones, generalized osteosclerosis, transverse bands, etc.) on a skeletal survey; **AND**
  - Identification of a pathogenic sub-type mutation in the CLCN7 gene or other gene variants; **AND**
- Patient has severe, malignant disease; **AND**
- Intent of treatment is to delay the progression of disease; **AND**
- Patient is receiving concurrent calcium and Vitamin D supplementation; **AND**
- Patient is receiving concurrent calcitriol

Diagnosis of **Mycosis Fungoides (MF)/Sézary Syndrome (SS)**

- Patient is 18 years of age or older; **AND**
- Patient has stage IA-IV disease (excluding stage IA-IIA MF with B1 blood involvement)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: cardiovascular disorder exacerbation, mental status changes, gait disturbances, dizziness, severe neutropenia and/or thrombocytopenia, severe elevations in liver enzymes (AST and/or ALT), severe hypersensitivity reactions, renal toxicity, etc.; **AND**

Mycosis Fungoides/Sézary Syndrome

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

Chronic Granulomatous Disease

- Disease response as evidenced by all of the following:
  - Decrease in the frequency and severity of infection; **AND**
  - Decrease in the rate of hospitalizations and requirement for parenteral antibiotics

Severe Malignant Osteopetrosis (SMO)

- Disease response as evidenced by stabilization or delayed progression of disease (disease progression is defined as any of the following: significant reduction in hemoglobin or platelet counts, a serious bacterial infection requiring antibiotics, or a 50 dB decrease in hearing or progressive optic atrophy); **AND**
- Patient is ≤ 8 years of age

ADAGEN® (PEGADEMASE BOVINE)

Length of Authorization:	1 year, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Adenosine Deaminase (ADA) deficiency**

- Patient has severe combined immunodeficiency disease (SCID) with a definitive diagnosis of adenosine deaminase deficiency as determined by one of the following:
  - Deficient ADA catalytic activity (< 1% of normal) in hemolysates (in un-transfused individuals) or in extracts of other cells (e.g., blood mononuclear cells, fibroblasts); **OR**
  - Detection of pathogenic mutations in the *ADA* gene by molecular genetic testing; **AND**
- Patient has a marked elevation of the metabolite dATP or total dAdo nucleotides (the sum of dAMP, dADP, and dATP) in erythrocytes; **AND**
- Patient is not a candidate for or has failed bone marrow transplantation (BMT); **AND**
- Patient does not have severe thrombocytopenia (< 50,000/microL); **AND**
- Baseline values for plasma ADA activity and red blood cell deoxyadenosine triphosphate (dATP) levels have been obtained

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe injection site reactions, hemolytic anemia, severe thrombocytopenia, lymphoma); **AND**
- Adequate documentation of disease stability and/or improvement as indicated by one or more of the following:
  - Increase in plasma ADA activity (target trough level 15-35 µmol/hr/mL)
  - Red blood cell dATP level decreased (target ≤ 0.005 to 0.015 µmol/mL)
  - Improvement in immune function with diminished frequency/complications of infection

ADAKVEO® (CRIZANLIZUMAB-TMCA)

Length of Authorization:	Initial: 6 months, Renewal: 12 months
Initiative:	SPC: miscellaneous pa required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR APPROVAL

Diagnosis of **Sickle Cell Disease**

- Patient is at least 16 years of age; **AND**
- Therapy will not be used in conjunction with voxelotor (Oxbryta) or L-glutamine (Endari); **AND**
- Patient has a confirmed diagnosis of sickle cell disease of any genotype (e.g., HbSS, HbSC, HbS/beta^0-thalassemia, HbS/beta$^+$-thalassemia, and others) as determined by one of the following:
  - Identification of significant quantities of HbS with or without an additional abnormal β-globin chain variant by hemoglobin assay; **OR**
  - Identification of biallelic *HBB* pathogenic variants where at least one allele is the p.Glu6Val pathogenic variant on molecular genetic testing; **AND**
- Patient had an insufficient response to a minimum 3-month trial of hydroxyurea (unless contraindicated or intolerant); **AND**
- Patient experienced one or more vaso-occlusive crises (VOC)***** in the previous year, despite adherence to hydroxyurea therapy
  - *****VOC is defined as an event prompting either a visit or outreach to the provider, resulting in a diagnosis of VOC being made, necessitating subsequent interventions such as narcotic pain management, non-steroidal anti-inflammatory therapy, hydration, etc.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infusion related reactions (e.g., ever, chills, nausea, vomiting, fatigue, dizziness, pruritus, urticaria, sweating, shortness of breath or wheezing), etc.; **AND**
- Disease response compared to pretreatment baseline as evidenced by a decrease in the frequency of vaso-occlusive crises (VOC) necessitating treatment, reduction in number or duration of hospitalizations, and/or reduction in severity of VOC

ADCETRIS® (BRENTUXIMAB VEDOTIN)

Length of Authorization:	6 months, may be renewed **Note:** Treatment for Adult cHL post-auto HSCT, Pediatric cHL, mycosis fungoides (MF)/Sézary syndrome (SS), and primary cutaneous CD30+ T-cell lymphoproliferative disorders has a maximum of 16 cycles. • Treatment of previously untreated adult stage III or IV classical Hodgkin lymphoma (cHL) has a maximum of 12 doses. • Treatment of previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL) has a maximum of 8 doses • Treatment of breast-implant associated anaplastic large cell lymphoma (ALCL) has a maximum of 6 cycles as adjuvant therapy
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Adult Classic Hodgkin Lymphoma (cHL)**

- Patient is at least 18 years of age; **AND**
- Patient has CD30-positive disease; **AND**
- Patient must not be receiving concomitant bleomycin; **AND**
- Patient does not have severe renal impairment (i.e., CrCl < 30 mL/min); **AND**
- Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); **AND**
- Used as a single agent; **AND**
  - Used as consolidation/maintenance therapy post-autologous hematopoietic stem cell transplant (auto-HSCT) in patients at high risk* for relapse or progression; **OR**
  - Patient has relapsed disease, after failure of auto-HSCT or after failure of at least 2 prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates; **OR**
  - Used as subsequent systemic therapy (if not previously used) for relapsed or refractory disease; **OR**
  - Used as palliative therapy for relapsed or refractory disease in patients > 60 years of age; **OR**
- Used in combination with bendamustine; **AND**
  - Used as subsequent systemic therapy (if not previously used) for relapsed or refractory disease; **OR**
- Used in combination with nivolumab; **AND**
  - Used as subsequent systemic therapy (if not previously used) for relapsed or refractory disease; **OR**
- Used in combination with dacarbazine; **AND**
  - Used as primary treatment in patients > 60 years of age with stage I-II unfavorable or stage III-IV disease**; OR**
- Used in combination with doxorubicin, vinblastine, and dacarbazine (AVD); **AND**
  - Used as initial therapy for previously untreated stage III or IV disease; **OR**
  - Used as initial therapy for previously untreated stage I or II unfavorable disease in patients > 60 years of age

**High risk for relapse or progression may be defined as:*

- *Refractory disease, relapse within 12 months, or extranodal disease following frontline therapy **OR** 2 or more of the following: PET+ response at time of transplant, B symptoms, and/or > 1 salvage/subsequent therapy regimen*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Pediatric Classic Hodgkin Lymphoma (cHL)**

- Patient is ≤ 18 years of age; **AND**
- Patient has CD30-positive disease; **AND**
- Patient must not be receiving concomitant bleomycin; **AND**
- Patient does not have severe renal impairment (i.e., CrCl < 30 mL/min); **AND**
- Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); **AND**
- Patient has relapsed or refractory disease; **AND**
  - Used as re-induction or subsequent therapy; **AND**
    - Used in combination with bendamustine, nivolumab, or gemcitabine; **AND**
      - Used in heavily pretreated patients with platinum or anthracycline-based chemotherapy; **OR**
      - Used if a decrease in cardiac function is observed; **OR**
  - Used as maintenance therapy following high-dose therapy and autologous stem cell rescue (HDT/ASCR); **AND**
    - Used as a single agent in high-risk patients (i.e., progressive disease, refractory disease, or relapse within 1 year of original diagnosis)

Diagnosis of **T-Cell Lymphoma**

- Peripheral T-Cell Lymphoma (PTCL)
  - Patient is at least 18 years of age; **AND**
  - Patient has CD30-positive disease; **AND**
  - Patient must not be receiving concomitant bleomycin; **AND**
  - Patient does not have severe renal impairment (i.e., CrCl < 30 mL/min); **AND**
  - Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); **AND**
  - Used as a single agent after failure of at least one prior chemotherapy regimen for one of the following:
    - Systemic anaplastic large cell lymphoma (sALCL)
    - Peripheral T-cell lymphoma (PTCL) not otherwise specified
    - Angioimmunoblastic T-cell lymphoma (AITL); **OR**
  - Used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP) as initial therapy for previously untreated:
    - Systemic anaplastic large cell lymphoma (sALCL)
    - Peripheral T-cell lymphoma (PTCL) not otherwise specified
    - Angioimmunoblastic T-cell lymphoma (AITL)
    - Enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma with TFH phenotype, or follicular T-cell lymphoma

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Breast-implant associated anaplastic large cell lymphoma (ALCL)
  - Patient is at least 18 years of age; **AND**
  - Patient has CD30-positive disease; **AND**
  - Patient must not be receiving concomitant bleomycin; **AND**
  - Patient does not have severe renal impairment (i.e., CrCl < 30 mL/min); **AND**
  - Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); **AND**
  - Used as adjuvant therapy as a single agent or in combination with cyclophosphamide, doxorubicin, and prednisone (CHP); **AND**
    - Patient has localized disease to the capsule, implant, or breast with either lymph node involvement or radiation therapy is not feasible; **OR**
    - Patient has extended disease (stage II-IV); **OR**
  - Used as subsequent therapy for relapsed or refractory as a single agent
- Adult T-cell leukemia/lymphoma
  - Patient is at least 18 years of age; **AND**
  - Patient has CD30-positive disease; **AND**
  - Patient must not be receiving concomitant bleomycin; **AND**
  - Patient does not have severe renal impairment (i.e., CrCl < 30 mL/min); **AND**
  - Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); **AND**
  - Used as a single agent for acute subtypes or lymphoma subtypes; **AND**
    - Used as subsequent therapy for non-responders to first-line therapy; **OR**
  - Used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP); **AND**
    - Used as first-line therapy or continued treatment in responders to first-line therapy for acute subtypes or lymphoma subtypes; **OR**
    - Used as subsequent therapy for non-responders to first-line therapy for chronic or smoldering disease
- Extranodal NK/T-cell lymphoma
  - Patient is at least 18 years of age; **AND**
  - Patient has CD30-positive disease; **AND**
  - Patient must not be receiving concomitant bleomycin; **AND**
  - Patient does not have severe renal impairment (i.e., CrCl < 30 mL/min); **AND**
  - Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); **AND**
  - Used as a single agent for relapsed or refractory disease; **AND**
  - Used following additional therapy with alternate combination chemotherapy regimen (asparaginase-based) not previously used

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Hepatosplenic gamma-delta T-cell lymphoma
  - Patient is at least 18 years of age; **AND**
  - Patient has CD30-positive disease; **AND**
  - Patient must not be receiving concomitant bleomycin; **AND**
  - Patient does not have severe renal impairment (i.e., CrCl < 30 mL/min); **AND**
  - Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); **AND**
  - Used as single-agent therapy; **AND**
    - Used for refractory disease as subsequent therapy after progression on two primary treatment regimens; **OR**
  - Used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP); **AND**
    - Used as preferred first-line treatment; **OR**
    - Used as additional therapy if no response or progression after first-line therapy, if not previously used

Diagnosis of **Primary Cutaneous Lymphomas**

- Mycosis fungoides (MF)/Sézary syndrome (SS)
  - Patient is at least 18 years of age; **AND**
  - Patient has CD30-positive disease; **AND**
  - Patient must not be receiving concomitant bleomycin; **AND**
  - Patient does not have severe renal impairment (i.e., CrCl < 30 mL/min); **AND**
  - Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); **AND**
  - Used as a single agent; **AND**
    - Used as primary therapy *(excluding patients with stage IA-IIA MF with B1 blood involvement)*; **OR**
    - Used as subsequent therapy *(excluding patients with relapsed or persistent stage IA-IIA MF with B1 blood involvement)*
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders
  - Patient is at least 18 years of age; **AND**
  - Patient has CD30-positive disease; **AND**
  - Patient must not be receiving concomitant bleomycin; **AND**
  - Patient does not have severe renal impairment (i.e., CrCl < 30 mL/min); **AND**
  - Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); **AND**
  - Used as a single agent; **AND**
    - Patient has primary cutaneous anaplastic large cell lymphoma (pcALCL); **OR**
    - Patient has cutaneous ALCL with regional nodes (excludes systemic ALCL); **OR**
    - Patient has lymphomatoid papulosis (LyP) with extensive lesions that is relapsed or refractory to treatment options (e.g., clinical trial, observation, retreatment with primary treatment, or treatment with alternative regimen); **OR**
  - Used in combination with cyclophosphamide, doxorubicin, and prednisone (CHP); **AND**
    - Patient has cutaneous ALCL with regional node (N1) (excludes systemic ALCL)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **B-cell lymphomas**

- Patient is at least 18 years of age; **AND**
- Patient has CD30-positive disease; **AND**
- Patient must not be receiving concomitant bleomycin; **AND**
- Patient does not have severe renal impairment (i.e., CrCl < 30 mL/min); **AND**
- Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); **AND**
- Diffuse large B-cell lymphoma (DLBCL) or high-grade B-cell lymphoma
  - Used as subsequent therapy for partial response, no response, relapsed, progressive, or refractory disease in non-candidates for transplant; **OR**
- AIDS-related DLBCL, primary effusion lymphoma, or HHV8-positive DLBCL, not otherwise specified
  - Used as subsequent therapy for relapsed disease in non-candidates for transplant; **OR**
- Monomorphic Post-Transplant Lymphoproliferative Disorders (PTLD)
  - Used as subsequent therapy for patients with partial response, persistent disease, or progressive disease after receiving chemoimmunotherapy (e.g., RCHOP, etc.) as first-line treatment for B-cell type disease; **OR**
  - Used in combination with CHP (cyclophosphamide, doxorubicin, prednisone) for T-cell type disease; **OR**
- Histologic transformation of follicular lymphoma or nodal marginal zone lymphoma to diffuse large B-cell lymphoma (DLBCL) in patients who have received multiple lines of therapy for transformed or indolent disease
  - Patient has received multiple lines of chemoimmunotherapy (e.g., BR, RCHOP, etc.) for transformed or indolent disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include progressive multifocal leukoencephalopathy, peripheral neuropathy, anaphylaxis and infusion reactions, hematologic toxicities (thrombocytopenia, neutropenia, and anemia), serious infections, opportunistic infections, tumor lysis syndrome, hepatotoxicity, pulmonary toxicity, serious dermatologic reactions, gastrointestinal complications, uncontrolled hyperglycemia, etc.

ADDYI® (FLIBANSERIN)

Length of Authorization:	8 weeks
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) **OR** Diagnosis of Female sexual interest/ arousal disorder and the symptoms of HSDD or female sexual interest/arousal disorder have persisted for at least 6 months; **AND**
- Patient must be premenopausal (between ages of 18 and 60 years of age); **AND**
- The patient does not have hepatic impairment (i.e., Child-Pugh score of 6 points or greater); **AND**
- Patient must not be taking a moderate to strong CYP3A4 inhibitor (i.e., ciprofloxacin, clarithromycin, diltiazem, fluconazole, itraconazole, ketoconazole, ritonavir, verapamil).

CLINICAL CRITERIA FOR RENEWAL

Coverage can be renewed based on the following criteria:

- Patient must have positive clinical response with Addyi therapy; **AND**
- Patient must continue to be premenopausal; **AND**
- The patient does not have hepatic impairment (i.e., Child-Pugh score of 6 points or greater); **AND**
- Patient must not be taking a moderate to strong CYP3A4 inhibitor (i.e., ciprofloxacin, clarithromycin, diltiazem, fluconazole, itraconazole, ketoconazole, ritonavir, verapamil)

ADUHELM™ (ADUCANUMAB-AVWA)

Length of Authorization:	6 months and may be renewed
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Alzheimer's Disease (AD)**

- Patient is at least 18 years of age; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., Mini-Mental Status Exam [MMSE], Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB], etc.); **AND**
- Patient does not have any of the following within 1 year of treatment initiation: pre-treatment localized superficial siderosis, 10 or more brain microhemorrhages, or brain hemorrhage > 1 cm; **AND**
- Must be prescribed by, or in consultation with, a specialist in neurology or gerontology; **AND**
- Patient has received a baseline brain magnetic resonance imaging (MRI) prior to initiating treatment (within one year prior) and periodically throughout therapy *(see prescribing information for schedule of MRI scans)*; **AND**
- Patient has not had a stroke or transient ischemic attack (TIA) or unexplained loss of consciousness in the past 12 months; **AND**
- Patient does not have any relevant brain hemorrhage, bleeding disorder, cerebrovascular abnormalities, or recent (within the prior year) cardiovascular condition (e.g., unstable angina, myocardial infarction, advanced CHF, or clinically significant conduction abnormalities); **AND**
- Patient does not have a clinically significant and unstable psychiatric illness in the past six months; **AND**
- Patient is not currently receiving anti-platelet agents (with the exception of prophylactic aspirin), anticoagulants (e.g., Factor Xa inhibitors), or anti-thrombins (e.g., heparin); **AND**
- Patient does not have a history of alcohol or substance abuse in the preceding year; **AND**
- Other conditions mimicking, but of non-Alzheimer's dementia etiology, have been ruled out (e.g., vascular dementia, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD], normal pressure hydrocephalus, etc.); **AND**
- Patient has mild cognitive impairment (MCI) due to AD or has mild Alzheimer's dementia (there is insufficient evidence in moderate or severe AD) as evidenced by all of the following:
  - Clinical Dementia Rating (CDR)-Global Score of 0.5
  - Objective evidence of cognitive impairment at screening
  - MMSE score between 24 and 30 (inclusive)
  - Positron Emission Tomography (PET) scan is positive for amyloid beta plaque

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: amyloid related imaging abnormalities-edema (ARIA-E), severe hypersensitivity reactions, etc.; **AND**
- Patient has responded to therapy compared to pretreatment baseline as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment in one or more of the following (not all-inclusive): ADAS-Cog 13; ADCS-ADL-MCI; MMSE; CDR-SB, etc.; **AND**
- Patient has not progressed to moderate or severe AD; **AND**
- Patient has received a pre-7th AND -12th infusion MRI for monitoring of Amyloid Related Imaging Abnormalities-hemosiderin (ARIA-H) microhemorrhages; **AND**
  - Patient has < 10 new incident microhemorrhages or ≤ 2 focal areas of superficial siderosis (radiographic mild to moderate ARIA-H) are observed; **OR**
  - Patient has ≥ 10 new incident microhemorrhages or > 2 focal areas of superficial siderosis (radiographic severe ARIA-H*) are observed; **AND**
    - Treatment is continued with caution only after a clinical evaluation; **AND**
    - Subsequent follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H*); **AND**
- Patient must continue maintenance therapy at the recommended dosage of 10 mg/kg every four weeks *(Note: clinical efficacy was demonstrated only at the highest dose, therefore doses below 10 mg/kg are not supported and will not be approved)*

*ARIA Type [1]	Radiographic Severity		
	Mild	Moderate	Severe
ARIA-E	FLAIR hyperintensity confined to sulcus and/or cortex/subcortical white matter in one location < 5 cm	FLAIR hyperintensity 5 to 10 cm, or more than 1 site of involvement, each measuring < 10 cm	FLAIR hyperintensity measuring > 10 cm, often with significant subcortical white matter and/or sulcal involvement. One or more separate sites of involvement may be noted
ARIA-H microhemorrhage	≤ 4 new incident microhemorrhages	5 to 9 new incident microhemorrhages	10 or more new incident microhemorrhages
ARIA-H superficial siderosis	1 focal area of superficial siderosis	2 focal areas of superficial siderosis	> 2 focal areas of superficial siderosis

AFINITOR® (EVEROLIMUS)

Length of Authorization:	6 months, eligible for renewal
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **renal cell carcinoma**

- Patient is at least 18 years of age; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Must not be administered for at least 2 weeks following major surgery and until adequate wound healing; **AND**
- Patient will avoid coadministration with combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole, etc.); **AND**
- Patient has advanced disease; **AND**
  - Patient has failed previous treatment with sunitinib or sorafenib; **OR**
- Patient has relapsed or metastatic disease; **AND**
  - Used in combination with bevacizumab in patients with non-clear cell histology; **OR**
  - Used as a single agent or in combination with lenvatinib; **AND**
    - Patient has non-clear cell histology**; OR**
    - Used as subsequent therapy for clear cell histology

Diagnosis of **tuberous sclerosis complex (TSC)**

- Patient has subependymal giant cell astrocytoma (SEGA); **AND**
  - Patient does not have an active infection, including clinically important localized infections; **AND**
  - Must not be administered concurrently with live vaccines; **AND**
  - Must not be administered for at least 2 weeks following major surgery and until adequate wound healing; **AND**
  - Patient will avoid coadministration with combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole, etc.); **AND**
  - Patient is 1 year of age or older; **AND**
  - Patient is not a candidate for curative surgical resection; **OR**
- Patient has renal angiomyolipoma which does not require immediate surgery; **AND**
  - Patient is 18 years of age or older; **AND**
  - Patient does not have an active infection, including clinically important localized infections; **AND**
  - Must not be administered concurrently with live vaccines;
  - Must not be administered for at least 2 weeks following major surgery and until adequate wound healing; **AND**
  - Patient will avoid coadministration with combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole, etc.); **OR**
- Patient has partial-onset seizures; **AND**
  - Patient does not have an active infection, including clinically important localized infections; **AND**
  - Must not be administered concurrently with live vaccines; **AND**
  - Must not be administered for at least 2 weeks following major surgery and until adequate wound healing; **AND**
  - Patient will avoid coadministration with combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole, etc.); **AND**
  - Patient is 2 years or older; **AND**
  - Used in combination with other anti-epileptic drugs

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma**

- Patient is at least 18 years of age; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Must not be administered for at least 2 weeks following major surgery and until adequate wound healing; **AND**
- Patient will avoid coadministration with combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole, etc.); **AND**
- Used as a single agent therapy; **AND**
- Patient has failed with primary therapy; **OR**
- Patient has progressive or relapsed disease

Diagnosis of **pancreatic endocrine tumors (Islet cell tumors, PNET)**

- Patient is at least 18 years of age; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Must not be administered for at least 2 weeks following major surgery and until adequate wound healing; **AND**
- Patient will avoid coadministration with combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole, etc.); **AND**
- Disease is progressive, symptomatic, or tumor burden is clinically significant; **AND**
  - Used as a single agent; **AND**
  - Patient has unresectable disease, locally advanced disease, or metastatic disease; **OR**
- Used to stabilize glucose levels; **AND**
  - Used as a single agent for symptomatic therapy of metastatic insulinoma; **OR**
- Used as preoperative therapy of locoregional insulinoma with or without diazoxide

Diagnosis of **breast cancer**

- Patient is at least 18 years of age; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Must not be administered for at least 2 weeks following major surgery and until adequate wound healing; **AND**
- Patient will avoid coadministration with combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole, etc.); **AND**
- Patient is postmenopausal, premenopausal with ovarian ablation/suppression, or male with suppression of testicular steroidogenesis; **AND**
- Patient has recurrent or locally advanced or metastatic disease with no visceral crisis; **AND**
- Patient has hormone receptor positive disease; **AND**
- Patient has human epidermal growth factor receptor (HER2)-negative disease; **AND**
  - Used in combination with exemestane after failure with letrozole or anastrozole; **OR**
  - Used in combination with fulvestrant or tamoxifen

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **neuroendocrine tumors (NET) of the lung, GI tract, or thymus**

- Patient is at least 18 years of age; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Must not be administered for at least 2 weeks following major surgery and until adequate wound healing; **AND**
- Patient will avoid coadministration with combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole, etc.); **AND**
- Patient has progressive well-differentiated, non-functional disease of the lung or GI tract that is unresectable, locally advanced, or metastatic; **OR**
- Patient has advanced or metastatic disease of the GI tract with clinically significant tumor burden or progression on octretotide or lanreotide ‡; **OR**
- Patient has bronchopulmonary/thymic disease **‡: AND**
  - Disease is unresectable; **OR**
  - Used for metastatic disease with one of the following:
    - Low grade histology and clinically significant tumor burden
    - Evidence of disease progression
    - Intermediate grade histology
    - Symptomatic disease

Diagnosis of **soft tissue sarcoma**

- Patient is at least 18 years of age; **AND**
- Must be used as a single agent; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Must not be administered for at least 2 weeks following major surgery and until adequate wound healing; **AND**
- Patient will avoid coadministration with combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole, etc.); **AND**
- Used in combination with either imatinib, sunitinib or regorafenib after disease progression on single-agent tyrosine kinase inhibitor (imatinib, sunitinib, or regorafenib) therapy; **AND**
  - Used for unresectable, recurrent, or metastatic gastrointestinal stromal tumors (GIST); **OR**
- Used as a single agent therapy for one of the following sub-indications:
  - PEComa
  - Angiomyolipoma
  - Lymphangioleiomyomatosis

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **classical Hodgkin lymphoma (HL)**

- Patient is at least 18 years of age; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Must not be administered for at least 2 weeks following major surgery and until adequate wound healing; **AND**
- Patient will avoid coadministration with combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole, etc.); **AND**
- Used for refractory or relapsed disease as third-line or subsequent therapy; **AND**
- Must be used as a single agent

Diagnosis of **thymomas or thymic carcinomas**

- Patient is at least 18 years of age; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Must not be administered for at least 2 weeks following major surgery and until adequate wound healing; **AND**
- Patient will avoid coadministration with combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole, etc.); **AND**
- Used as a single agent; **AND**
  - Used, as first line therapy or postoperative treatment, in patients who are unable to tolerate first-line combination regimens; **OR**
  - Used as second-line therapy for unresectable or metastatic disease

Diagnosis of **thyroid carcinoma (follicular, Hürthle cell, or papillary carcinoma)**

- Patient is at least 18 years of age; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Must not be administered for at least 2 weeks following major surgery and until adequate wound healing; **AND**
- Patient will avoid coadministration with combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole, etc.); **AND**
- Patient has unresectable, recurrent, persistent, or metastatic disease; **AND**
- Disease is progressive and/or symptomatic iodine-refractory; **AND**
- Clinical trials or other therapies are not available or not available and/or appropriate for the patient

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **uterine cancer**

- Patient is at least 18 years of age; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Must not be administered for at least 2 weeks following major surgery and until adequate wound healing; **AND**
- Patient will avoid coadministration with combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole, etc.); **AND**
- Used in combination with letrozole for endometrioid type disease; **AND**
- Used as one of the following**:**
  - Primary treatment *(excluding patients with cervical involvement who are not surgical candidates when treatment is chemotherapy alone)*
  - Adjuvant treatment for surgically staged patients *(excluding patients with stage II disease)*
  - Used as treatment of locoregional recurrent or metastatic disease *(excluding isolated metastases)*

Diagnosis of **subependymal giant cell astrocytoma (SEGA)**

- Patient is at least 18 years of age; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Must not be administered for at least 2 weeks following major surgery and until adequate wound healing; **AND**
- Patient will avoid coadministration with combined P-gp and strong CYP3A inhibitors (e.g., ketoconazole, etc.); **AND**
- Used as single agent adjuvant therapy

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: Localized or systemic infection, severe hypersensitivity reactions, renal failure, myelosuppression, Grade 2 or Grade 3 stomatitis, Grade 3 or Grade 4 non-hematologic toxicities (excluding metabolic events), Grade 3 or Grade 4 metabolic events (e.g., hyperglycemia, dyslipidemia), angioedema, wound healing complications, etc.; **AND**

TSC-Associated Partial-Onset Seizures:

- Patient has responded to therapy compared to pretreatment baseline with disease stability or improvement as indicated by a reduction in seizure frequency

Oncology Indications:

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread

ALDURAZYME® (LARONIDASE)

Length of Authorization:	1 year, may be renewed
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Mucopolysaccharidosis I (MPS I)**

- Patient is 6 months of age or older; **AND**
- Patient has a definitive diagnosis of MPS I confirmed by one of the following:
  - Detection of biallelic pathogenic mutations in the *IDUA* gene by molecular genetic testing; **OR**
  - Detection of deficient activity of the lysosomal enzyme α-L-iduronidase (IDUA); **AND**
- Patient has one of the following diagnoses:
  - Hurler (severe) or Hurler-Scheie (attenuated) forms of disease; **OR**
  - Scheie (attenuated) form of disease with moderate to severe symptoms
- Patient has absence of severe cognitive impairment; **AND**
- Documented baseline value for urinary glycosaminoglycan (uGAG) has been obtained; **AND**
- Documented baseline values for one or more of the following have been obtained:
  - **Patients of age 6 years or older**: percent predicted forced vital capacity (FVC), 6-minute walk test, joint range of motion, left ventricular hypertrophy, growth, quality of life (CHAQ/HAQ/MPS HAQ); **OR**
  - **Patients of age 6 months to under 6 years**: cardiac status, upper airway obstruction during sleep, growth velocity, mental development, FVC, and/or 6-minute walk test.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., anaphylaxis and severe hypersensitivity reactions, acute respiratory complications, acute cardiorespiratory failure, severe infusion reactions); **AND**
- Patient does not have progressive/irreversible severe cognitive impairment; **AND**
- Patient has a documented reduction in uGAG levels compared to pretreatment baseline; **AND**
- Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following:
  - **Patients 6 years or older**: stability or improvement in percent predicted FVC and/or 6-minute walk test, increased joint range of motion, decreased left ventricular hypertrophy, improved growth, improved quality of life (clinically meaningful change in the CHAQ/HAQ/MPS HAQ disability index); **OR**
  - **Patients 6 months to less than 6 years**: stability or improvement in cardiac status, upper airway obstruction during sleep, growth velocity, mental development, FVC, and/or 6-minute walk test.

ALECENSA® (ALECTINIB)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-small Cell Lung Cancer**

- Patient is at least 18 years of age or older; **AND**
- Used as a single agent; **AND**
- Patient has anaplastic lymphoma kinase (ALK)-positive disease as detected by an FDA-approved or CLIA compliant test; **AND**
- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first line therapy; **OR**
  - Used in patients who are intolerant to crizotinib; **OR**
  - Used as subsequent therapy following disease progression on first-line therapy with crizotinib, except in cases of symptomatic systemic disease with limited metastases; **OR**
  - Used as continuation of therapy if used first-line, except in cases of symptomatic systemic disease with multiple lesions

Diagnosis of **Central Nervous System (CNS) Cancers (Limited or Extensive Brain Metastases)**

- Patient is at least 18 years of age or older; **AND**
- Used as a single agent; **AND**
- Patient has brain metastases from non-small cell lung cancer ; **AND**
  - Used as initial treatment in patients with small, asymptomatic brain metastases; **OR**
  - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
  - Used for recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe elevations in ALT/AST or bilirubin, severe myalgia, bradycardia, interstitial lung disease/pneumonitis, severe elevations in creatine phosphokinase (CPK), severe renal impairment, etc.

ALIMTA®, PEMFEXY™ (PEMETREXED DISODIUM)

Length of Authorization:	6 months, may be renewed Thymomas/Thymic Carcinoma: Coverage will be provided for six 21-day cycles and may not be renewed MPM: Coverage will be provided for six 21-day cycles and may not be renewed when used in combination with platinum therapy and bevacizumab
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Primary Central Nervous System (CNS) Lymphoma**

- Patient is at least 18 years of age; **AND**
- Used as a single agent as induction therapy in patients unsuitable for or intolerant to high-dose methotrexate (MTX); **OR**
- Used as single agent therapy for relapsed or refractory disease; **AND**
  - Patient received prior whole brain radiation therapy (RT); **OR**
  - Patient failed prior methotrexate (MTX)-based regimen without prior radiation therapy; **OR**
  - Used in combination with whole brain RT or involved field RT in patients who received a prior high-dose MTX-based regimen without prior RT with either no response or short response (< 12-month duration) to prior regimen; **OR**
  - Patient received prior high-dose chemotherapy with stem cell rescue

Diagnosis of **Malignant Pleural* Mesothelioma**

- Patient is at least 18 years of age; **AND**
- Used in combination with cisplatin or carboplatin; **AND**
  - Patient has stage IIIB or IV disease, sarcomatoid, or medically inoperable tumors and used as first-line therapy with or without bevacizumab; **OR**
  - Patient has stage I-IIIA disease with epithelioid or biphasic histology; **AND**
    - Used as induction therapy; **OR**
    - Used as first-line therapy with or without bevacizumab for unresectable disease; **OR**
    - Used as first-line for resected disease not previously treated with induction chemotherapy; **OR**
- Used as a single agent: **AND**
  - Patient has stage IIIB or IV disease, sarcomatoid, or medically inoperable tumors and used as first-line therapy; **OR**
  - Patient has stage I-IIIA disease with epithelioid or biphasic histology; **AND**
    - Used as first-line therapy for unresectable disease; **OR**
    - Used as first-line therapy for resected disease not previously treated with induction chemotherapy; **OR**
  - Used as subsequent therapy, if not administered first-line; **OR**
  - Used as a re-challenge, if pemetrexed was administered first-line with a good, sustained response at the time initial chemotherapy was interrupted

*****Peritoneal, pericardial, and tunica vaginalis testis mesothelioma will be evaluated on a case-by-case basis

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Non-Squamous Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years of age; **AND**
  - Used in combination with carboplatin or cisplatin; **AND**
    - Used as induction, neoadjuvant, or adjuvant chemotherapy; **OR**
    - Used as concurrent chemoradiation for locoregional recurrence or symptomatic local disease in the mediastinal lymph nodes or for superior vena cava obstruction; **OR**
    - Used as initial therapy as definitive concurrent chemoradiation for unresectable, advanced, or metastatic disease; **OR**
  - Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
    - Used as first-line therapy; **AND**
      - Used for PD-L1 ≥ 1% tumors that have negative actionable molecular markers *****; **AND**
        - Used in combination with pembrolizumab and either carboplatin or cisplatin in patients with PS 0-2; **OR**
        - Used in combination with nivolumab, ipilimumab, and either carboplatin or cisplatin in patients with PS 0-2; **OR**
      - Used for one of the following:
        - PD-L1 < 1% and tumors that have negative actionable molecular markers *****
        - BRAF V600E-mutation, NTRK1/2/3 gene fusion, or MET exon-14 skipping mutation positive tumors; **AND**
          - Used as a single agent in patients with PS 2; **OR**
          - Used in combination with pembrolizumab and either carboplatin or cisplatin in patients with PS 0-1 *(excluding use in patients who have received prior PD-1/PD-L1 inhibitor therapy or who have RET rearrangement positive tumors)*; **OR**
          - Used in combination with cisplatin in patients with PS 0-1; **OR**
          - Used in combination with carboplatin in patients with PS 0-2; **OR**
          - Used in combination with nivolumab, ipilimumab, and either carboplatin or cisplatin in patients with PS 0-1; **OR**
          - Used in combination with nivolumab, ipilimumab, and either carboplatin or cisplatin in patients with PS 0-1 **OR**
          - Used in combination with bevacizumab and either cisplatin or carboplatin in patients with PS 0-1; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Non-Squamous Non-Small Cell Lung Cancer (NSCLC)** ***(continued)***

- Used as subsequent therapy; **AND**
  - Used as a single agent (if not previously given) in patients with a PS 0-2; **OR**
  - Used for one of the following:
    - EGFR, ALK, or ROS1 positive tumors and prior targeted therapy for those aberrations
    - BRAF V600E-mutation, NTRK1/2/3 gene fusion, or MET exon-14 skipping mutation positive tumors
    - PD-L1 ≥ 1% tumors that have negative actionable molecular markers***** with prior PD-1/PD-L1 inhibitor therapy but no prior platinum doublet chemotherapy; **AND**
      - Used in combination with pembrolizumab and either carboplatin or cisplatin in patients with PS 0-1;
      - Used in combination with cisplatin in patients with PS 0-1; **OR**
      - Used in combination with carboplatin in patients with PS 0-2; **OR**
      - Used in combination with nivolumab, ipilimumab, and either carboplatin or cisplatin in patients with PS 0-1; **OR**
      - Used in combination with bevacizumab and either cisplatin or carboplatin in patients with PS 0-1; **OR**
- Used as maintenance therapy in patients who have achieved tumor response or stable disease following initial therapy; **AND**
  - Used as a single agent for continuation maintenance therapy; **OR**
  - Used as a single agent for switch maintenance therapy; **OR**
  - Used for continuation maintenance therapy in combination with bevacizumab following a first-line bevacizumab/pemetrexed/platinum chemotherapy regimen; **OR**
  - Used for continuation maintenance therapy in combination with pembrolizumab following a first-line pembrolizumab/pemetrexed and either carboplatin or cisplatin regimen

****** Note: Actionable molecular genomic biomarkers include EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, and RET rearrangement. If there is insufficient tissue to allow testing for all of the EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET, and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

Note: Contraindications for treatment with PD-1/PD-L1 inhibitors may include active or previously documented auto-immune disease and/or current use of immunosuppressive agents, or presence of an oncogene (e.g., EGFR [exon 19 deletions, p.L858R point mutation in exon 21], ALK rearrangements, RET rearrangements), which would predict lack of benefit.

Diagnosis of **Thymomas and Thymic Carcinoma**

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
  - Used as first line therapy or postoperative treatment in patients who are unable to tolerate first-line combination regimens; **OR**
  - Used as second-line therapy for unresectable or metastatic disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Ovarian Cancer (epithelial ovarian/fallopian tube/primary peritoneal cancer)**

- Patient is at least 18 years of age; **AND**
- Patient has recurrent or persistent disease; **AND**
- Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **AND**
- Used as a single agent; **AND**
  - Patient has platinum-resistant disease; **AND**
    - Used for progression on primary, maintenance, or recurrence therapy; **OR**
    - Used for stable or persistent disease if not currently on maintenance therapy; **OR**
    - Used for relapsed disease < 6 months following complete remission from prior chemotherapy; **OR**
  - Patient has platinum-sensitive disease; **AND**
    - Used for radiographic and/or clinical relapse ≥6 months after complete remission from prior chemotherapy

Genomic Aberration/Mutational Driver Targeted Therapies (Note: *not all inclusive, refer to guidelines for appropriate use*) §				
Sensitizing *EGFR* mutation-positive tumors	*ALK* rearrangement-positive tumors	*ROS1* rearrangement-positive tumors	*BRAF* V600E-mutation positive tumors	*NTRK* Gene Fusion positive tumors
Afatinib Erlotinib Dacomitinib Gefitinib – Osimertinib – Amivantamab – *(exon-20 insertion)*	– Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib	– Ceritinib – Crizotinib – Entrectinib	– Dabrafenib ± Trametinib – Vemurafenib	– Larotrectinib – Entrectinib
PD-1/PD-L1 expression-positive tumors (≥ 1%)	*MET* Exon-14 skipping mutations	*RET* rearrangement-positive tumors	KRAS G12C mutations	
– Pembrolizumab – Atezolizumab Nivolumab ± ipilimumab	– Capmatinib – Crizotinib – Tepotinib	– Selpercatinib – Cabozantinib – Vandetanib – Pralsetinib	– Sotorasib	

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: bone marrow suppression (e.g., neutropenia, febrile neutropenia, thrombocytopenia, anemia), renal impairment (CrCl < 45 mL/min), bullous and exfoliative skin toxicity (e.g., Stevens-Johnson Syndrome/Toxic epidermal necrolysis), interstitial pneumonitis, radiation recall, etc.; **AND**

ALIMTA® (PEMETREXED DISODIUM)

Continuation of Maintenance Therapy for Non-Squamous Non-Small Cell Lung Cancer (NSCLC)

- Refer to initial criteria

MPM

- May not be renewed when used in combination with platinum therapy and bevacizumab

Thymomas/Thymic Carcinoma

- May not be renewed

ALIQOPA™ (COPANLISIB)

Length of Authorization:	6 months, eligible for renewal
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **B-cell lymphoma**:

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Patient has relapsed, refractory, or progressive disease; **AND**
- Used as subsequent therapy after at least 2 prior therapies; **AND**
- Patient has **one** of the following diagnoses:
  - Follicular lymphoma (FL); **OR**
  - Non-gastric MALT lymphoma (noncutaneous); **OR**
  - Gastric MALT lymphoma; **OR**
  - Nodal marginal zone lymphoma; **OR**
  - Splenic marginal zone lymphoma

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious infections (e.g., pneumocystis jiroveci pneumonia [PJP] of any grade), uncontrolled hyperglycemia, uncontrolled hypertension, non-infectious pneumonitis, neutropenia (i.e., ANC < 0.5 x 10^3 cells/mm^3), severe cutaneous reactions (i.e., Grade 3 or 4), etc.; **AND**
- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread.

ALKINDI SPRINKLE (HYDROCORTISONE)

Length of Authorization:	12 months, may be renewed
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient must be < 18 years of age; **AND**
- Patient must have a diagnosis of adrenocortical insufficiency; **AND**
- Patient has had a trial of hydrocortisone tablets UNLESS the patient has difficulty swallowing solid dosage forms, or the dosage needed is not available in another formulation.

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet initial authorization criteria; **AND**
- Patient is experiencing symptom improvement or maintenance; **AND**
- The patient is not experiencing any treatment-limiting adverse reactions of the medication.

ALKYLATING AGENTS: VALCHLOR

Length of Authorization:	6 months, eligible for renewal
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Valchlor® will be approved if ALL of the following are met:

- Diagnosis of Stage IA or IB mycosis fungoides; **AND**
- Patient has received skin directed therapy

ALPHA-1 PROTEINASE INHIBITORS

Length of Authorization:	1 Year, eligible for renewal
Initiative:	SPC: Alpha-1 Proteinase Inhibitor (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

ARALAST NP, GLASSIA, PROLASTIN, PROLASTIN C, ZEMAIRA

Emphysema due to alpha-1-antitrypsin (AAT) deficiency:

- Patient is 18 years or older; **AND**
- Patient is not a tobacco smoker; **AND**
- Patient is receiving optimal medical therapy (e.g., comprehensive case management, pulmonary rehabilitation, vaccinations, smoking cessation, self-management skills); **AND**
- Patient does not have immunoglobulin-A (IgA) deficiency with antibodies against IgA; **AND**
- Patient has an FEV_1 in the range of 30-65% of predicted; **AND**
- Patient has alpha-1-antitrypsin (AAT) deficiency with PiZZ, PiZ (null), or Pi (null, null) phenotypes; **AND**
- Patient has AAT deficiency and clinical evidence of panacinar/panlobular emphysema; **AND**
- Patient has low serum concentration of AAT ≤ 50 mg/dL or ≤ 11 µM/L as measured by nephelometry

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

- Disease response with treatment as defined by elevation of AAT levels above baseline, substantial reduction in rate of deterioration of lung function as measured by percent predicted FEV1, or improvement in CT scan lung density; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity reactions)

ALTERNATIVE MEDICATION

Length of Authorization:	1 year
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

SPEEDGEL RX, TRANZGEL RX

Diagnosis of **Pain and inflammation**

- Patient is 18 or older; **AND**
- Patient is not pregnant; **AND**
- Patient has tried and failed at least **two** of the following unless contraindicated an oral NSAID, a topical NSAID, a non-prescription topical analgesic (i.e., capsaicin, menthol), or Tramadol.

COLCIGEL

Diagnosis of **gout**

- Patient is at least 18; **AND**
- Patient is not pregnant; **AND**
- Patient has had ≥ 2 acute gout attacks within the past year; **AND**
- Patient has tried a xanthine oxidase inhibitor monotherapy (i.e., Allopurinol, Uloric, etc.) at maximum tolerated does unless contraindicated; **AND**
- Patient has tried at least one NSAID or corticosteroid (unless contraindicated); **AND**
- Patient does not have an active prescription (filled within past 30 days) for oral colchicine

LIDORX

- Patient must have tried and failed FDA-approved lidocaine 2% or 4% gels; **OR**
- Prescriber must provide documentation why the patient cannot take the FDA approved lidocaine 2% or 4% topical gels

ALUNBRIG® (BRIGATINIB)

Length of Authorization:	6 months, eligible for renewal
Initiative:	SPC: oncology (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC):**

- Patient is at least 18 years old; **AND**
- Must be used as a single agent; **AND**
- Patient's disease is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved or CLIA-compliant test; **AND**
- Patient has advanced, metastatic or recurrent disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **OR**
  - Patient is intolerant to crizotinib; **OR**
  - Used as subsequent therapy; **AND**
    - Patient has previously failed on first-line treatment with crizotinib, except in cases of symptomatic systemic disease with limited metastases; **OR**
    - Used as continuation of therapy if used first-line, except in cases of symptomatic systemic disease with multiple lesions

Diagnosis of **Soft Tissue Sarcoma (Inflammatory Myofibroblastic Tumor [IMT])**

- Patient is at least 18 years old; **AND**
- Must be used as a single agent; **AND**
- Patient's disease is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved or CLIA-compliant test

Diagnosis of **Central Nervous System (CNS) Cancers (Limited or Extensive Brain Metastases)**

- Patient is at least 18 years old; **AND**
- Must be used as a single agent; **AND**
- Patient's disease is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved or CLIA-compliant test; **AND**
  - Used as initial treatment of with small, asymptomatic brain lesions; **OR**
  - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **OR**
  - Used as continuation of therapy if used first-line, except in cases of symptomatic systemic disease with multiple lesions ; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypertension, bradycardia, interstitial lung disease/pneumonitis, visual disturbances, creatine phosphokinase (CPK) elevation, pancreatic enzyme elevation, severe hyperglycemia, etc.

ALZHEIMER'S AGENTS

Length of Authorization:	6 months, eligible for renewal
Initiative:	MNC: Alzheimer's Agents (IE 2462 / NCPDP 75, 50081 and 2193)

STEP CRITERIA

NAMZARIC (NO GRANDFATHERING)

- Trial and failure of memantine **and** donepezil

AMONDYS-45™ (CASIMERSEN)

Length of Authorization:	6 months, eligible for renewal
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Duchenne muscular dystrophy (DMD)**:

- Patient is not on concomitant therapy with other DMD-directed antisense oligonucleotides (e.g., eteplirsen, golodirsen, viltolarsen, etc.); **AND**
- Patient serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio (UPCR) are measured prior to starting therapy and periodically during treatment; **AND**
- Patient must have a confirmed mutation of the *DMD* gene that is amenable to exon 45 skipping; **AND**
- Patient has been on a stable dose of corticosteroids, unless contraindicated or intolerance, for at least 6 months; **AND**
- Patient retains meaningful voluntary motor function (e.g., patient is able to speak, manipulate objects using upper extremities, ambulate, etc.); **AND**
- Patient should be receiving physical and/or occupational therapy; **AND**
- Baseline documentation of **one or more** of the following:
  - Dystrophin level
  - 6-minute walk test (6MWT) or other timed function tests (e.g., time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB])
  - Upper limb function (ULM) test
  - North Star Ambulatory Assessment (NSAA)
  - Forced Vital Capacity (FVC) percent predicted

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: renal toxicity/proteinuria, etc.; **AND**
- Patient has responded to therapy compared to pretreatment baseline in **one or more** of the following (not all-inclusive):
  - Increase in dystrophin level
  - Stability, improvement, or slowed rate of decline in 6MWT or other timed function tests (e.g., time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB])
  - Stability, improvement, or slowed rate of decline in ULM test
  - Stability, improvement, or slowed rate of decline in NSAA
  - Stability, improvement, or slowed rate of decline in FVC% predicted
  - Improvement in quality of life

ANALGESICS: BUPRENORPHINE PRODUCTS FOR OPIATE ADDICTION

Length of Authorization:	Initial 3 months; 6 months for 1st renewal; 12 months for subsequent renewals
Initiative:	MNC: Opiate Abuse Treatment (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Renewals must meet this criteria and clinical criteria for renewal.

Diagnosis of **Opioid Dependence**

Internal note: Is the patient a member of a **fully insured** plan **and** is the plan written in a state that does not allow a PA for buprenorphine products (i.e., MD, NY)? If yes, please approve indefinitely. ***This does not apply to self-insured plans.***

- Requesting physician must be registered to prescribe buprenorphine and provide the XDEA number; **AND**
- Provide verbal or written attestation of a comprehensive treatment plan between provider and patient; **AND**
- Provide verbal or written attestation that patient has a referral **or** active involvement in substance abuse counseling **or** reason patient is unable to have counseling; **AND**
- Provide verbal or written attestation that that patient is **not** prescribed concurrent opioid medication without explanation (verified by state opioid database, if available); **AND**
- Patient is **not** taking buprenorphine (Probuphine) implant or (Sublocade) injection; **AND**
- Patient is **not** pregnant (women of childbearing age have a negative pregnancy test within prior 30 days), **or** pregnant patient has already tried single-ingredient buprenorphine.

For Single Ingredient Buprenorphine only:

- Patient must meet all criteria noted above and meet **one** of the following:
  - Patient is pregnant; **OR**
  - 2-Day Induction to Suboxone Request; **OR**
  - The patient has an allergy to naloxone

Escalate to Pharmacists for Clinical Judgment if:

- Clinical Criteria not met
- Request exceeds QTY limit
- Concurrent use with opioids
- More than 1 strength or buprenorphine product is requested
- Buprenorphine single ingredient product required due to contraindication to naloxone

CLINICAL CRITERIA FOR RENEWAL

- Initial request criteria must be met; **AND**
- The patient has been compliant with no gaps in therapy since initial authorization, gaps in therapy will need to be explained; **AND**
- The patient has had continued participation in substance abuse counseling **or** reason patient is unable to have counseling **or** no longer needs counseling; **AND**
- Verbal or written attestation of regular urine drug screens including buprenorphine. (Recommendation): 1 being within the past 60 days of the renewal request, it should **not** be negative for buprenorphine or positive for opioids.

ANALGESICS: NARCOTICS: LONG-ACTING

STANDARD FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

Length of Authorization:	3- 6 months, eligible for renewal 6 months for active cancer pain, Palliative/End of Life Care or hospice patient,
Initiative:	MNC: Narcotic Analgesics: Long Acting (IE 2462 / NCPDP 75, 50081 and 2193) MNC: Quantity limit per day exceeded (IE 15110)

STANDARD FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

INITIAL CRITERIA FOR ALL LONG-ACTING NARCOTICS

Diagnosis of **Active Cancer Pain, Palliative/End-of-Life Care or Hospice Patient**

- Approve for 6 months for palliative/end-of-life care, or hospice care
- Approve for active cancer for up to 6 months

Diagnosis of **Any Other Pain:**

For brand Avinza®, Embeda®, Exalgo®, Hysingla® ER, Kadian®, Morphabond®, MS Contin®, Opana® ER, Oxycontin®, Targiniq® ER, Troxyca® ER, Zohydro® ER, the patient must have a trial of Xtampza® ER (no grandfathering)

- Patient must be 18 years of age or older; **AND**
- Patient is inadequately controlled on short acting (SA) opioid equivalent; **AND**
- Patient must require around the clock pain management; **AND**
- Patient must have chronic pain, greater than 3 months, **AND**
- Patient has a diagnosis of moderate to severe pain that can be defined by **ALL** of the following:
  - Non-responsive or inadequately responsive to non-pharmacologic treatment (i.e., physical therapy, pain psychology, alternative treatments);
  - Non-responsive or inadequately responsive to non-opioid analgesic treatment (i.e., NSAIDs, APAP, gabapentin, lidocaine patch, muscle relaxers)
  - Significantly impairs physical functioning (e.g., sleep, work, activities of daily living); **AND**
- The prescriber attests to monitoring the state prescription monitoring program (PMP) prior to prescribing any controlled medications (if available in the state); **AND**
- Patient does not have a documented history of opioid addiction or abuse; **AND**
- The patient is not currently undergoing active treatment for opioid addiction; **AND**
- The prescriber attests to having a treatment plan in place with the patient that addresses such things as benefits and harms of opioid use, expectations and goals of treatment, stipulations for continued treatment such as functional improvement, a single opioid prescriber, and/or regular dispensing pharmacy; **AND**
- The prescriber attests to completing a urine drug screen at least annually, with date of last drug screen provided.
- The prescriber provides the underlying condition causing the patient pain; **AND**
- The patient has consulted with a pain specialist; **AND**
- The patient has been offered counseling on the risks of overdose, addiction, and/or drug diversion; **AND**
- The patient is not on a benzodiazepine or sedative hypnotic; **AND**
- A naloxone kit is being prescribed; **AND**
- The prescriber provides a list of concurrent pain treatments being used (e.g., non-opioid medications, physical therapy)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Any Other Pain *(continued)*:**

- The patient is receiving or is scheduled to receive counseling for weaning opioids, undergoing active dose titration, or stabilized for a chronic condition that requires ongoing therapy:
  - If stable, can approve for 6 months; **OR**
  - If weaning or undergoing active dose titration, only approve for 3 months

Note: Clinical judgment can be used by pharmacists for approval if all the above criteria is not met.

DRUG SPECIFIC CRITERIA **IN ADDITION TO** ABOVE CRITERIA

- **Butrans®** will be approved based on **ALL** of the following criteria:
  - Not to be approved for acute or post-operative pain; AND
  - Patient does not actively abuse alcohol; AND
  - If patient is concomitantly using a short-acting opioid agonist for breakthrough pain or titration, provider attests that withdrawal symptoms are known to occur with mixed opiate agonist/antagonist use
- **Belbuca®** will be approved based on **ALL** of the following criteria:
  - If patient is concomitantly using a short-acting opioid agonist for breakthrough pain or titration, provider attests that withdrawal symptoms are known to occur with mixed opiate agonist/antagonist use; AND
  - Patient does not actively abuse alcohol
- **ConZip®** (tramadol)
  - Patient has no diagnosis of a seizure disorder
  - Do not approve for treatment of acute pain or if current cumulative tramadol dose is >300mg/day
- **Methadone**
  - Requires EKG with normal QTc within 30 days prior to initiation of medication
  - Requires EKG with QTc <450 at least once a year
  - QTc of 450-500 can be approved if the doctor has significant justification that the benefit of the therapy outweighs the risk.
- **Nucynta ER** (no grandfathering)
  - For pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate:
    - Patient has tried and failed or has a contraindication to Xtampza® ER **AND** one of the following: hydromorphone HCl ER, morphine sulfate ER, oxycodone HCl ER, oxymorphone HCl ER, tramadol ER
  - For severe neuropathic pain associated with diabetic peripheral neuropathy:
    - Has a diagnosis of diabetic peripheral neuropathy; **AND**
    - Patient has tried and failed or has a contraindication to any two of the following classes of medications
      - Anticonvulsants (pregabalin, gabapentin)
      - SNRIs (duloxetine, venlafaxine)
      - TCAs (amitriptyline, desipramine, nortriptyline); **AND**
    - Patient has tried and failed a tramadol-containing product

CLINICAL CRITERIA FOR RENEWAL

- Initial request criteria must be met; **AND**
- Patient is stabilized on current regimen

PRECISION/PLUS FORMULARY CRITERIA

CORE FORMULARY CRITERIA

Length of Authorization:	3–6 months, eligible for renewal 6 months for active cancer pain, Palliative/End of Life Care or hospice patient
Initiative:	MNC: Narcotic Analgesics: Long Acting (IE 2462 / NCPDP 75) MNC: Quantity limit per day exceeded (IE 15110)

PRECISION/PLUS FORMULARY CRITERIA

CORE FORMULARY CRITERIA

INITIAL CRITERIA FOR ALL LONG-ACTING NARCOTICS

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

Diagnosis of **Active Cancer Pain, Palliative/End of Life Care or Hospice Patient**

- Approve for 6 months for palliative/end-of-life care, or hospice care
- Approve for active cancer for up to 6 months

Diagnosis of **Any Other Pain**:

For brand Morphabond®, the patient must have a trial of Xtampza® ER (no grandfathering)

- Patient must be 18 years of age or older; **AND**
- Patient is inadequately controlled on short acting (SA) opioid equivalent; **AND**
- Patient must require around the clock pain management; **AND**
- Patient must have chronic pain, greater than 3 months; **AND**
- Patient has a diagnosis of moderate to severe pain that can be defined by **ALL** of the following:
  - Non-responsive or inadequately responsive to non-pharmacologic treatment (i.e., physical therapy, pain psychology, alternative treatments); **AND**
  - Non-responsive or inadequately responsive to non-opioid analgesic treatment (i.e., NSAIDs, APAP, gabapentin, lidocaine patch, muscle relaxers)
  - Significantly impairs physical functioning (i.e., sleep, work, activities of daily living); **AND**
- The prescriber attests to monitoring the state prescription monitoring program (PMP) prior to prescribing any controlled medications (if available in the state); **AND**
- Patient does not have a documented history of opioid addiction or abuse; **AND**
- The patient is not currently undergoing active treatment for opioid addiction; **AND**
- The prescriber attests to having a treatment plan in place with the patient that addresses such things as benefits and harms of opioid use, expectations and goals of treatment, stipulations for continued treatment such as functional improvement, a single opioid prescriber and/or regular dispensing pharmacy; **AND**
- The prescriber attests to completing a urine drug screen at least annually, with date of last drug screen provided.
- The prescriber provides the underlying condition causing the patient pain; **AND**
- The patient has consulted with a pain specialist; **AND**
- The patient has been offered counseling on the risks of overdose, addiction, and/or drug diversion; **AND**
- The patient is not on a benzodiazepine or sedative hypnotic; **AND**
- A naloxone kit is being prescribed; **AND**
- The prescriber provides a list of concurrent pain treatments being used (i.e., non-opioid medications, physical therapy)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Any Other Pain *(continued)*:**

- The patient is receiving or is scheduled to receive counseling for weaning opioids, undergoing active dose titration, or stabilized for a chronic condition that requires ongoing therapy:
  - If stable, can approve for 6 months; **OR**
  - If weaning or undergoing active dose titration, only approve for 3 months.

  Note: Clinical judgment can be used by pharmacists for approval if all the above criteria is not met.

DRUG SPECIFIC CRITERIA **IN ADDITION TO** ABOVE CRITERIA

- **Butrans®** will be approved based on **ALL** of the following criteria:
  - Not to be approved for acute or post-operative pain; AND
  - Patient does not actively abuse alcohol; AND
  - If patient is concomitantly using a short-acting opioid agonist for breakthrough pain or titration, provider attests that withdrawal symptoms are known to occur with mixed opiate agonist/antagonist use
- **Belbuca®** will be approved based on **ALL** of the following criteria:
  - If patient is concomitantly using a short-acting opioid agonist for breakthrough pain or titration, provider attests that withdrawal symptoms are known to occur with mixed opiate agonist/antagonist use; AND
  - Patient does not actively abuse alcohol
- **ConZip®** (tramadol)
  - Patient has no diagnosis of a seizure disorder
  - Do not approve for treatment of acute pain or if current cumulative tramadol dose is > 300 mg/day
- **Methadone**
  - Requires EKG with normal QTc within 30 days prior to initiation of medication
  - Requires EKG with QTc < 450 at least once a year
  - QTc of 450-500 can be approved if the doctor has significant justification that the benefit of the therapy outweighs the risk.
- **Nucynta® ER** (neuropathic pain indication **only**)
  - For severe neuropathic pain associated with diabetic peripheral neuropathy:
    - Has a diagnosis of diabetic peripheral neuropathy; **AND**
    - Patient has tried and failed or has a contraindication to any two of the following classes of medications
      - Anticonvulsants (pregabalin, gabapentin)
      - SNRIs (duloxetine, venlafaxine)
      - TCAs (amitriptyline, desipramine, nortriptyline); **AND**
    - Patient has tried and failed a tramadol-containing product

    Note: Nucynta® ER for precision and core formulary will reject for 50698 but is covered for neuropathic pain with the criteria above, all other diagnoses please follow the precision exclusion process for review.

CLINICAL CRITERIA FOR RENEWAL

- Initial request criteria must be met; **AND**
- Patient is stabilized on current regimen

ANALGESICS: NARCOTICS: SHORT-ACTING

Length of Authorization:	1 month to 6 months (see below), eligible for renewal
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75) MNC: Short Acting Opioid: Acute Use (IE 2708, 7008, 2641, 15110/NCPDP 75) MNC: Short Acting Opioid: Chronic Use (IE 2708, 7008, 2641, 15110/NCPDP 75)

MILLIGRAM MORPHINE EQUIVALENTS GREATER THAN 1 PER 29 DAYS

Note: The opioid program if the plan opts in has the MME set at > 90 MME. There could be plans that have noted other MME limitations that could be lower. This criteria applies to any MME over the selected limit.

Diagnosis of **Active Cancer pain, Palliative/End of Life Care or hospice patient**

- Approve for 6 months for Palliative/End of Life Care or hospice patient
- Approve for 6 months for active cancer pain

Diagnosis of **any other pain**:

- Patient must be 18 years of age or older; **AND**
- Patient has a diagnosis of moderate to severe pain that can be defined by **ALL** of the following:
  - Non-responsive or inadequately responsive to non-pharmacologic treatment (i.e., physical therapy, pain psychology, alternative treatments); **AND**
  - Non-responsive or inadequately responsive to non-opioid analgesic treatment (i.e., NSAIDs, APAP, gabapentin, lidocaine patch, muscle relaxers)
  - Significantly impairs physical functioning (i.e., sleep, work, activities of daily living); **AND**
- The prescriber attests to monitoring the state prescription monitoring program (PMP) prior to prescribing any controlled medications (if available in the state); **AND**
- Patient does not have a documented history of opioid addiction or abuse; **AND**
- The patient is not currently undergoing active treatment for opioid addiction; **AND**
- The prescriber provides the underlying condition causing the patient pain; **AND**
- The prescriber provides justification why the high dose of opioid is necessary and why a lower dose will be inadequate, **AND**
- The patient has consulted with a pain specialist; **AND**
- The patient has been offered counseling on the risks of overdose, addiction, and/or drug diversion, **AND**
- The patient is not on a benzodiazepine or sedative hypnotic, **AND**
- A naloxone kit is being prescribed; **AND**
- The prescriber provides a list of concurrent pain treatments being used (i.e., non-opioid medications, physical therapy, etc.)

GREATER THAN 50 MILLIGRAM MORPHINE EQUIVALENTS/ >1/29 DAYS *(CONTINUED)*

- For **acute** pain:
  - If less than 30 days requested, authorize for indicated treatment duration permitting the other conditions above are met
  - If greater than 30 days requested, authorize for 30 days only permitting the other conditions above are met. Requires reauthorization after 30 days.
- For **chronic** pain:
  - The prescriber attests to having a treatment plan in place with the patient that addresses such things as benefits and harms of opioid use, expectations and goals of treatment, stipulations for continued treatment such as functional improvement, a single opioid prescriber and/or regular dispensing pharmacy; **AND**
  - The prescriber attests to completing a urine drug screen at least annually, with date of last drug screen provided.
  - If the patient is stable on current regimen, approve for 6 months
  - If the patient is weaning or undergoing active dose titration, approve for 3 months

Note: Clinical judgment can be used by pharmacists for approval if all the above criteria are not met.

ANALGESICS: NSAIDS – ORAL

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Category A: PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

CAMBIA®

Patient has tried and failed **TWO** of the following: diclofenac, diclofenac CR, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmetin

DUEXIS® (IBUPROFEN/FAMOTIDINE)

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of rheumatoid arthritis or osteoarthritis; **AND**
- Documentation that the patient has of **one** of the following risk factors for NSAID-induced adverse GI events:
  - Patient is greater than or equal to 65 years of age; **OR**
  - Prior history of peptic, gastric, or duodenal ulcer; **OR**
  - History of NSAID-related ulcer; **OR**
  - History of clinically significant GI bleeding; **OR**
  - Untreated or active H. Pylori gastritis; **OR**
  - Concurrent use of oral corticosteroids (e.g., prednisone, prednisolone, dexamethasone); **OR**
  - Concurrent use of anticoagulants (e.g., warfarin, heparin); **OR**
  - Concurrent use of antiplatelets (e.g., aspirin including low-dose, clopidogrel); **AND**
- Documentation of failure or clinically significant adverse effects to trials of 2 preferred H2-receptor antagonists in combination with a prescription dose NSAID; **AND**
- Prescriber has provided rationale for need to use fixed-dose combination therapy with Duexis or its generic instead of taking individual products in combination**.**

INDOCIN® (INDOMETHACIN) SUSPENSION

- Patient is 14 years of age or older; **AND**
- Patient has a diagnosis of one of the following:
  - Moderate to severe rheumatoid arthritis including acute flares of chronic disease; **OR**
  - Moderate to severe ankylosing spondylitis; **OR**
  - Moderate to severe osteoarthritis; **OR**
  - Acute painful shoulder (bursitis and/or tendonitis); **OR**
  - Acute gouty arthritis; **AND**
- History of failure, contraindication, or intolerance to **two** generic NSAIDs; **OR**
- Patient has difficulty swallowing solid dosage forms or the dosage needed is not available in another formulation.

CLINICAL CRITERIA FOR RENEWAL

- Patient has demonstrated clinical improvement in response to treatment; **AND**
- Patient has not developed any contraindications or other exclusion to its continued use

VIMOVO®

- Patient is 12 years of age or older; **AND**
- Patient has a diagnosis of **one** of the following:
  - In adults: osteoarthritis, rheumatoid arthritis or ankylosing spondylitis; **OR**
  - In adolescents: juvenile idiopathic arthritis (JIA); **AND**
- Documentation that the patient has of **one** of the following risk factors for NSAID-induced adverse GI events:
  - Patient is greater than or equal to 65 years of age; **OR**
  - Prior history of peptic, gastric, or duodenal ulcer; **OR**
  - History of NSAID-related ulcer; **OR**
  - History of clinically significant GI bleeding; **OR**
  - Untreated or active H. Pylori gastritis; **OR**
  - Concurrent use of oral corticosteroids (e.g., prednisone, prednisolone, dexamethasone); **OR**
  - Concurrent use of anticoagulants (e.g., warfarin, heparin); **OR**
  - Concurrent use of antiplatelets (e.g., aspirin including low-dose, clopidogrel); **AND**
- Documentation of failure or clinically significant adverse effects to trials of 2 preferred proton pump inhibitors (PPIs) in combination with a prescription dose NSAID; **AND**
- Prescriber has provided rationale for need to use fixed-dose combination therapy with Vimovo instead of taking individual products in combination**.**

CLINICAL CRITERIA FOR RENEWAL

- Patient has demonstrated clinical improvement in response to treatment; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use

NALFON®

Patient has tried and failed two of the following: diclofenac, diclofenac CR, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmetin

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient is free of unacceptable toxicity from the drug

QMIIZ®

For patients ≥ 18 years of age:

- Patient has tried and failed **two** of the following: diclofenac, diclofenac CR, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmetin; **OR**
- Patient must have difficulty swallowing or cannot swallow tablets or capsules

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING) *(CONTINUED)*

VIVLODEX®

- Patient has a diagnosis of osteoarthritis of the hip or knee; **AND**
- Patient is 18 or older; **AND**
- Patient has tried **two** of the following: diclofenac ER, Naproxen DR, Etodolac ER, Indomethacin ER or Ketoprofen ER

ZIPSOR® (DICLOFENAC POTASSIUM)

- Patient has mild to moderate pain; **AND**
- Patient is 12 years of age or older; **AND**
- Patient has tried and failed **two** of the following: diclofenac, diclofenac CR, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmetin

ZORVOLEX®

Patient has tried and failed **two** of the following: diclofenac, diclofenac CR, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmetin

STEP THERAPY (NO GRANDFATHERING)

RELAFEN, RELAFEN DS

The patient has had a trial and failure of generic nabumetone

PRECISION FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Category A: PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA – PRECISION FORMULARY (NO GRANDFATHERING)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

INDOCIN® (INDOMETHACIN) SUSPENSION

- Patient is 14 years of age or older; **AND**
- Patient has a diagnosis of one of the following:
  - Moderate to severe rheumatoid arthritis including acute flares of chronic disease; **OR**
  - Moderate to severe ankylosing spondylitis; **OR**
  - Moderate to severe osteoarthritis; **OR**
  - Acute painful shoulder (bursitis and/or tendonitis); **OR**
  - Acute gouty arthritis; **AND**
- History of failure, contraindication, or intolerance to **two** generic NSAIDs; **OR**
- Patient has difficulty swallowing solid dosage forms or the dosage needed is not available in another formulation.

CLINICAL CRITERIA FOR RENEWAL

- Patient has demonstrated clinical improvement in response to treatment; **AND**
- Patient has not developed any contraindications or other exclusion to its continued use

NALFON®

Patient has tried and failed **two** of the following: diclofenac, diclofenac CR, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, or tolmetin

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient is free of unacceptable toxicity from the drug

VIVLODEX®

- Patient has a diagnosis of osteoarthritis of the hip or knee; **AND**
- Patient is 18 or older; **AND**
- Patient has tried **TWO** of the following: diclofenac ER, Naproxen DR, Etodolac ER, Indomethacin ER or Ketoprofen ER; **OR**
- Patient is continuing therapy

CAMBIA®/ZORVOLEX®

Cambia® and Zorvolex® are excluded and the generic NSAIDs are preferred (i.e., diflunisal, etodolac, fenoprofen, flurbiprofen, indomethacin, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmetin)

ANALGESICS: NSAIDS – RECTAL

Length of Authorization:	1 year
Initiative:	MNC: Category A: PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

INDOCIN® (INDOMETHACIN) SUPPOSITORY

Initial Criteria:

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of one of the following; **AND**
  - Moderate to severe rheumatoid arthritis including acute flares of chronic disease
  - Moderate to severe ankylosing spondylitis
  - Moderate to severe osteoarthritis
  - Acute painful shoulder (bursitis and/or tendonitis)
  - Acute gouty arthritis
- History of failure, contraindication, or intolerance to **two** generic NSAIDs; **OR**
- Provider indicates therapy with oral agents is clinically inappropriate.

CLINICAL CRITERIA FOR RENEWAL

- Patient has demonstrated clinical improvement in response to treatment; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use.

ANALGESICS: NSAIDS – TOPICAL

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Category A: PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL(NO GRANDFATHERING)

SOLARAZE® GEL (DICLOFENAC SODIUM), DICLOFENAC SODIUM 3% GEL

- Diagnosis of actinic keratoses (AK); **AND**
- Patient is 18 years of age and older

SPRIX® (KETOROLAC TROMETHAMINE) NASAL SPRAY

- Diagnosis of short term (up to 5 days) management of moderate to moderately severe pain that requires analgesia at the opioid level; **AND**
- Patient is 18 years of age and older; **AND**
- Must have a history of failure, contraindication or intolerance to **OR** is not successfully managed with a generic NSAID **AND** ketorolac (oral); **AND**
- Patient must **not** have the following or be used for the following:
  - Asthma, urticarial, or other allergic-type reactions after taking aspirin or other NSAIDs, for CABG surgery, peptic ulcer disease, recent GI bleed or perforation, prophylactic analgesic before any major surgery, advanced renal disease or at risk for renal failure due to volume depletion, suspected or confirmed cerebrovascular bleeding, hemorrhagic diathesis, incomplete hemostasis and those at high risk of bleeding, not to be used for labor and delivery

CLINICAL CRITERIA FOR RENEWAL FOR ALL AGENTS ABOVE

- The patient has benefited from the medication; **AND**
- The patient's condition has not progressed or worsened while on therapy; **AND**
- The patient has not developed any contraindications or other exclusions to continued use of the medication

STEP THERAPY (NO GRANDFATHERING)

PENNSAID® 2%

- ***The patient has had a trial and failure of generic diclofenac 1% gel***

GENERIC DICLOFENAC 1% GEL

- ***The patient has had a trial and failure of one generic prescription oral NSAID*** (diclofenac, diclofenac CR, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmetin)

LICART 1.3% PATCH

- ***The patient has had a trial and failure of both generic diclofenac epolamine 1.3% patch AND Flector patch***

PRECISION FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Category A: PA Required (IE 2462/NCPDP 75)

CLINICAL CRITERIA – PRECISION FORMULARY (NO GRANDFATHERING)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

SOLARAZE® GEL (DICLOFENAC SODIUM), DICLOFENAC SODIUM 3% GEL

- Diagnosis of actinic keratosis (AK); **AND**
- Patient is 18 years of age and older

CLINICAL CRITERIA FOR RENEWAL

- The patient has benefited from the medication; **AND**
- The patient's condition has not progressed or worsened while on therapy; **AND**
- The patient has not developed any contraindications or other exclusions to continued use of the medication

STEP THERAPY (NO GRANDFATHERING)

GENERIC DICLOFENAC 1% GEL

The patient has had a trial and failure of one generic prescription oral NSAID (diclofenac, diclofenac CR, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmetin)

ANALGESICS: SUBLOCADE (BUPRENORPHINE EXTENDED-RELEASE)

Length of Authorization: Initial 3 months; 6 months for 1st renewal; 12 months for subsequent renewals
Initiative: SPC: Opiate Abuse Treatment (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Internal note: Is the patient a member of a FULLY INSURED plan **and** is the plan written in a state that does not allow a PA for buprenorphine products (i.e., MD, NY)? If yes, please approve indefinitely. ***This does not apply to self-insured plans.***

- Does the client cover medical drugs through the pharmacy benefit?
  - If **YES**, then proceed to below. If **NO**, then product cannot be covered.
- Provider must:
  - Be certified to treat addictions under the Drug Addiction Treatment Act of 2000 (DATA 2000) waiver and provide an X-DEA number; **AND**
  - Provide verbal or written attestation of a comprehensive treatment plan between provider and patient; **AND**
  - Provide verbal or written attestation that patient has a referral **OR** active involvement in substance abuse counseling **OR** reason patient is unable to have counseling; **AND**
  - Have complied with all aspects of the REMS program; **AND**
- Patient must:
  - Be 18 years old or older; **AND**
  - Meet diagnosis of DSM-5 criteria for moderate or severe opioid use disorder; **AND**
  - Have initiated treatment and had at least 7 days of therapy on a transmucosal buprenorphine-containing product delivering the equivalent of 8 mg to 24 mg of buprenorphine daily with control of cravings and withdrawal symptoms; **AND**
  - Will discontinue therapy with transmucosal buprenorphine upon initiation of Sublocade; **AND**
  - **Not** have pre-existing moderate to severe hepatic impairment; **AND**
  - **Not** have a history of Long QT Syndrome or an immediate family member with this condition or those taking Class IA antiarrhythmic medications (e.g., quinidine, procainamide, disopyramide) or Class III antiarrhythmic medications (e.g., sotalol, amiodarone, dofetilide), or other medications that prolong the QT interval; **AND**
  - Provide verbal or written attestation that that he/she is **not** prescribed concurrent opioid medication without explanation (verified by state opioid database, if available); **AND**
  - **Not** be receiving methadone; **AND**
  - **Not** be receiving other long-acting products for the treatment of opioid abuse disorder (e.g., buprenorphine [Probuphine®] implant, naltrexone [Vivitrol®], etc.)

CLINICAL CRITERIA FOR RENEWAL

- The patient has had continued participation in substance abuse counseling **OR** reason patient is unable to have counseling **OR** no longer needs counseling; **AND**
- Patient must:
  - Meet initial request criteria with the exception of the line regarding transmucosal buprenorphine treatment as patient is already established on Sublocade therapy, **AND**
  - **Not** have adrenal insufficiency; **AND**
  - **Not** have evidence of tampering or attempts to remove the depot at the injection site; **AND**
  - Provide verbal or written attestation of regular urine drug screens including buprenorphine. (Recommendation): 1 being within the past 60 days of the renewal request, it should **not** be negative for buprenorphine or positive for opioids.

ANAPHYLAXIS AGENTS

STANDARD FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Anaphylaxis Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

- For Adrenaclick®, Auvi-Q® 0.3, and EpiPen®:
  - The patient must have a history of trial, intolerance, preference for the brand, **or** other reason why the patient cannot take the generic epinephrine
- For Auvi-Q® 0.15 mg:
  - The patient must have a history of trial, intolerance **or** other reason why the patient cannot take a generic epinephrine that is indicated for children (i.e., generic EpiPen Jr®.); **AND**
  - Patient must be between 15 and 30 kg
- For Auvi-Q® 0.1 mg:
  - Patient must be between 7.5 kg and 15 kg

PRECISION/PLUS FORMULARY CRITERIA

CORE FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Anaphylaxis Agents (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

- For Adrenaclick® and EpiPen®:
  - The patient must have a history of trial, intolerance, preference for the brand, **or** other reason why the patient cannot take the generic epinephrine

ANDROGENS

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Androgens (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Attestation of low (low or normal for renewals) testosterone levels within the last year
  - Diagnosis of Primary hypogonadism (congenital or acquired) – testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome; or orchidectomy; **OR**
  - Hypogonadotropic hypogonadism (congenital or acquired) – idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation.
    - If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in patients who develop testosterone deficiency after puberty; **OR**
  - Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every 6 months to assess the effect of treatment on the epiphyseal centers, **OR**
  - Replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone; **AND**
  - Two pre-treatment serum total testosterone levels less than 280 ng/DL (9.7nmol/L) taken at separate times (attestation of lab value and date for both levels); **AND**
  - Patient is not taking:
    - Growth hormone (e.g., Genotropin, Humatrope, Norditropin, Omnitrope, Saizen, Serostim, Zorbtive); **OR**
    - Aromatase inhibitor (e.g., Arimidex (anastrozole) Femara (letrozole), Aromasin (exemestane); **AND**
  - One of the following:
    - Significant reduction in weight (less than 90% of ideal body weight) (e.g., AIDS wasting syndrome)
    - Osteopenia
    - Osteoporosis
    - Decreased bone density
    - Decreased Libido
    - Organic cause of testosterone deficiency (e.g., injury, tumor, infection, or genetic defects)

Note: Per 2019 BEERS criteria update, testosterone should be avoided in patients greater than or equal to 65 years of age unless indicated for moderate to severe hypogonadism.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Oral testosterone agents (other than Striant®) may be approved for a diagnosis of inoperable metastatic breast cancer (postmenopausal) or if the patient had tried and failed on Danazol®.
  - A trial on the injectable dosage form is not required.

Androgens may be used secondarily in patients with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. Primary goals of therapy in these patients include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or antiestrogen therapy. This treatment has also been used in premenopausal patients with breast cancer who have benefitted from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

Contraindications:

- Known or suspected carcinoma of the prostate
- Known or suspected carcinoma of the breast
- Severe renal or cardiac disease
- Benign prostatic hyperplasia with obstruction
- Pregnancy
- Undiagnosed genital bleeding
- Breast Cancer

OXANDRIN®

- Do not have to meet other criteria above
- Diagnosis of bone pain: for the relief of bone pain frequently accompanying osteoporosis
- Diagnosis of Protein catabolism: To offset the protein catabolism associated with prolonged administration of corticosteroids
- Diagnosis of weight gain: Adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who, without definite pathophysiologic reasons, fail to gain or maintain normal weight.

STEP CRITERIA – BRAND ANDROGEL®, BRAND AXIRON®, BRAND FORTESTA®, BRAND NATESTO®, BRAND TESTIM®, BRAND VOGELXO® (NO GRANDFATHERING)

Documented trial and evidence of treatment failure of generic testosterone gel

STEP CRITERIA – BRAND ANDROID®, BRAND METHITEST™, BRAND JATENZO®, BRAND STRIANT®, BRAND TESTRED® (NO GRANDFATHERING)

If medication is being used for androgen replacement therapy:

- Documented trial and evidence of treatment failure of generic testosterone gel **and** Androderm

CLINICAL CRITERIA FOR RENEWAL

- No grandfathering, patient must meet step therapy; **AND**
- Patient has had a disease response

PRECISION FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Androgens (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL – PRECISION FORMULARY

- For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.
- Attestation of low (low or normal-for-renewals) testosterone levels within the last year
  - Diagnosis of primary hypogonadism (congenital or acquired)– testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome; or orchidectomy; **OR**
  - Hypogonadotropic hypogonadism (congenital or acquired)– idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation.
    - If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these patients who develop testosterone deficiency after puberty; **OR**
  - Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every 6 months to assess the effect of treatment on the epiphyseal centers; **OR**
  - Replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone; **AND**
  - Two pre-treatment serum total testosterone levels less than 280 ng/DL (9.7 nmol/L) taken at separate times (attestation of lab value and date for both levels); **AND**
  - Patient is not taking:
    - Growth hormone (e.g., Genotropin®, Humatrope®, Norditropin®, Omnitrope®, Saizen®, Serostim®, Zorbtive®); **OR**
    - Aromatase inhibitor (e.g., Arimidex® [anastrozole], Femara® [letrozole], Aromasin® [exemestane]); **AND**
  - One of the following:
    - Significant reduction in weight (less than 90% of ideal body weight) (e.g., AIDS wasting syndrome)
    - Osteopenia
    - Osteoporosis
    - Decreased bone density
    - Decreased Libido
    - Organic cause of testosterone deficiency (e.g., injury, tumor, infection, or genetic defects)

Note: Per 2019 BEERS criteria update, testosterone should be avoided in patients greater than or equal to 65 years of age unless indicated for moderate to severe hypogonadism.

CLINICAL CRITERIA FOR INITIAL APPROVAL – PRECISION FORMULARY *(CONTINUED)*

- Oral testosterone agents (other than Striant®) may be approved for a diagnosis of inoperable metastatic breast cancer (postmenopausal) or if the patient had tried and failed on Danazol®.
  - A trial on the injectable dosage form is not required.

Androgens may be used for patients with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. Primary goals of therapy in these patients include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or antiestrogen therapy. This treatment has also been used in premenopausal patients with breast cancer who have benefitted from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

Contraindications:

- Known or suspected carcinoma of the prostate
- Known or suspected carcinoma of the breast
- Severe renal or cardiac disease
- Benign prostatic hyperplasia with obstruction
- Pregnancy
- Undiagnosed genital bleeding
- Breast Cancer

OXANDRIN®

- Do not have to meet other criteria above
- Diagnosis of bone pain: for the relief of bone pain frequently accompanying osteoporosis
- Diagnosis of protein catabolism: To offset the protein catabolism associated with prolonged administration of corticosteroids
- Diagnosis of weight gain: Adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections or severe trauma, and in some patients who, without definite pathophysiologic reasons, fail to gain or maintain normal weight.

STEP CRITERIA –BRAND NATESTO® (NO GRANDFATHERING)

- Documented trial and evidence of treatment failure of generic testosterone gel

STEP CRITERIA – BRAND ANDROID®, BRAND METHITEST™, BRAND STRIANT®, BRAND TESTRED® (NO GRANDFATHERING)

If medication is being used for androgen replacement therapy:

- Documented trial and evidence of treatment failure of generic testosterone gel **and** Androderm.

CLINICAL CRITERIA FOR RENEWAL

- Patient has had a disease response with the medication

ANGIOTENSIN RECEPTOR BLOCKERS

Length of Authorization:	1 Year
Initiative:	MNC: Angiotensin Receptor Antagonists (IE 2462 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

- Edarbi:
  - Trial and failure of one of the following:
    - ACE Inhibitor; **OR**
    - ACE Inhibitor combinations; **OR**
    - ARB; **OR**
    - ARB combination; **OR**
    - Amlodipine-benazepril; **OR**
    - Trandolapril-verapamil
- Edarbyclor:
  - Trial and failure of one of the following:
    - ACE Inhibitor; **OR**
    - ACE Inhibitor combinations; **OR**
    - ARB; **OR**
    - ARB combination; **OR**
    - Amlodipine-benazepril; **OR**
    - Trandolapril-verapamil

ANTI-ALCOHOLIC PREPARATIONS

Length of Authorization:	1 year
Initiative:	MNC: miscellaneous pa required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA IF BENEFIT BUILDER REQUIRES PA FOR ANTI-ALCOHOLIC PREPS

- Acamprosate/Antabuse/Disulfiram
  - Diagnosis of alcohol dependence; **AND**
  - Patient is in a comprehensive management program

ANTI-ALLERGEN EXTRACTS

Length of Authorization:	1 year Palforzia- initial: 8 months, Renewal: 1 year
Initiative:	MNC: Antiallergens (IE 2462 / NCPDP 75) SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)---Palforzia, Oralair

CLINICAL CRITERIA FOR INITIAL APPROVAL

GRASTEK®, ORALAIR®, RAGWITEK®

- Diagnosis of allergic conjunctivitis or allergic rhinitis; **AND**
- Submit a positive skin test for 1 out of 5 grass pollens (i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, or Kentucky Bluegrass) or Ragweed (for Ragwitek®) for pollen-specific IgE antibodies prior to administration; **AND**
- Confirm the first dose will be in a healthcare setting to monitor for acute allergic reactions; **AND**
- Patient has a prescription for auto-injection epinephrine.

ODACTRA®

- Patient is between 18 and 65 years of age; **AND**
- Diagnosis of allergic rhinitis; **AND**
- Submit a positive laboratory test for house dust mite-specific IgE antibodies prior to administration; **AND**
- Patient has tried environmental measures to reduce dust mite exposure; **AND**
- Confirm the first dose will be in a healthcare setting to monitor for acute allergic reactions; **AND**
- Patient has a prescription for auto-injection epinephrine

PALFORZIA™

- Patient must be 4 to 17 years of age; **AND**
- Patient must have a documented clinical history of allergy to peanuts or peanut-containing foods; **AND**
- Confirmed diagnosis of peanut allergy based on:
  - Serum immunoglobulin E (IgE) *to peanut* ≥ 14 kUA/L (kilos of allergen-specific units per liter) within the past 12 months; **OR**
  - Skin prick test (SPT) *to peanut* with a mean wheal diameter of ≥ 8 mm compared to control; **OR**
  - Clinical history of systemic reaction to peanut within the last 2 years with evidence of sensitization to peanut (serum IgE ≥ 0.35 and/or peanut SPT ≥ 3 mm); **OR**
  - *Documented* reaction to peanut upon supervised oral food challenge at a dose of ≤ 100 mg peanut protein (≤ 200 mg peanut flour); **AND**
- Patient does **NOT** have any of the following**:**
  - Severe asthma (e.g., currently treated with high-dose inhaled corticosteroid/long-acting beta-agonist therapy; has forced expiratory volume in 1 second [FEV_1] < 60% of predicted); **OR**
  - Persistently uncontrolled mild to moderate asthma (defined as FEV_1 < 80% predicted; **OR**
  - Three to four of the following symptoms: daytime asthma symptoms > twice/week, and nighttime awakening due to asthma symptoms, asthma reliever medication use > twice/week [excluding reliever taken for exercise], or any activity limitation due to asthma); **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

PALFORZIA™ *(CONTINUED)*

- Patient has **NOT** received systemic corticosteroid therapy (oral, intramuscular, intravenous) for the treatment of asthma in any of the following manners:
  - Daily systemic corticosteroid for > 1 month during the past year; **OR**
  - More than 2 burst systemic corticosteroid courses in the past year with ≥ 1 week in duration; **OR**
  - Burst systemic corticosteroid course within 3 months prior to starting Palforzia™; **AND**
- Patient has **NOT** been hospitalized for asthma within 1 year prior to starting Palforzia™; **AND**
  - Patient has **NOT** had emergency department (ED) visit for an asthma exacerbation within 6 months prior to starting Palforzia™; **AND**
- Patient does **NOT** have a history of eosinophilic esophagitis, and/or other eosinophilic gastrointestinal diseases; **AND**
- Patient does **NOT** have uncontrolled atopic dermatitis; **AND**
- Patient does **NOT** have a medical condition that inhibits their ability to survive anaphylaxis, such as significantly reduced lung function, severe mast cell disorder, or cardiovascular disease; **AND**
- Patient is **NOT** currently taking medications that can alter the effects of epinephrine (e.g., beta-blockers [oral], angiotensin-converting enzyme (ACE) inhibitor; angiotensin receptor blocker [ARB], calcium channel blocker [CCB], alpha-adrenergic blocker, ergot alkaloid); **AND**
- Patient has **NOT** experienced severe anaphylaxis resulting in hypotensive shock, use of > 2 doses of epinephrine, and/or intubation within the prior 60 days; **AND**
- Palforzia™ is being requested by or in consultation with a specialist (Allergy and Immunology specialists)
- Patient has been prescribed and/or has a refill history of epinephrine auto-injector; **AND**
- Prescriber attestation for the following:
  - Patient or caregiver understand how to use injectable epinephrine; **AND**
  - Patient or caregiver must be able to recognize the signs and symptoms of a serious allergic reaction and anaphylaxis; **AND**
  - Patient or caregiver understands the importance of continual daily dosing of Palforzia to sustain desensitization and will adhere to a daily dosing regimen, including maintenance phase, of Palforzia as prescribed; **AND**
  - Patient or caregiver will **temporarily** withhold Palforzia and contact the prescriber if the patient experiences an acute asthma exacerbation; **AND**
  - Patient or caregiver understands dose timing considerations (e.g., strenuous exercise, hot shower/bath); **AND**
- Palforzia will be initiated at a REMS-certified healthcare facility; the initial dose escalation phase and the first dose of each of the 11 up-dosing phases will be given at a REMS-certified healthcare facility; **AND**
- Patient or caregiver will adhere to the complex up-dosing schedule that requires frequent visits to the administering healthcare facility

CLINICAL CRITERIA FOR RENEWAL

- The patient has had a disease response; **AND**
- The patient's condition has not progressed or worsened while on therapy; **AND**
- The patient has not developed any contraindications or other exclusions to its continued use

PALFORZIA™ RENEWAL

- Patient must continue to meet the initial criteria; **AND**
- Patient must continue to tolerate the prescribed daily doses of Palforzia™; **AND**
- Patient has not experienced recurrent asthma exacerbations; **AND**
- Patient has not have experienced any treatment-restricting adverse effects (e.g. repeated systemic allergic reaction and/or severe anaphylaxis)

ANTI-ARRHYTHMICS

Length of Authorization:	1 year
Initiative:	MNC: Anti-Arrhythmic (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Multaq® may be approved if the following clinical criteria are met:

- Patient is **not** taking any of the following anti-arrhythmics:
  - Amiodarone (Cordarone®, Pacerone®);
  - Disopyramide, Disopyramide SA (Norpace®, Norpace CR®)
  - Dofetilide (Tikosyn®)
  - Flecainide (Tambocor®)
  - Ibutilide
  - Mexiletine
  - Propafenone, Propafenone SR (Rythmol®, Rythmol SR®)
  - Quinidine gluconate, Quinidine sulfate
  - Sotalol, Sotalol AF (Betapace®, Betapace AF®); **AND**
- Patient has a diagnosis of atrial fibrillation (AF) in sinus rhythm; **AND**
  - Patient has a history of paroxysmal or persistent AF; **AND**
  - Patient does **not** have PERMANENT AF (cannot be cardioverted into normal sinus rhythm) **OR** recent decompensated heart failure (HF) requiring hospitalization **OR** NYHA Class IV HF; **AND**
  - The patient has their cardiac rhythm monitored at least once every 3 months; **AND**
  - The patient is being monitored for liver and pulmonary toxicity at least once every 3 months; **AND**
  - The patient is **not** on greater than Simvastatin 10mg; **AND**
  - The patient does **not** have severe hepatic impairment.

CLINICAL CRITERIA FOR RENEWAL

- The patient is in sinus rhythm; **AND**
- The patient does **not** have new or worsening heart failure; **AND**
- The patient does **not** have liver injury; **AND**
- The patient does **not** have signs of pulmonary toxicity (i.e., shortness of breath, unproductive cough, etc.); **AND**
- The patient does **not** have hypokalemia and hypomagnesemia; **AND**
- The patient does **not** have QT prolongation; **AND**
- Patient is free of any other unacceptable toxicity from the medication.

ANTI-PLATELET AGENTS

Length of Authorization:	1 Year
Initiative:	MNC: Platelet inhibitors (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

ZONTIVITY

- Diagnosis of MI (myocardial infarction) or PAD (peripheral arterial disease); **AND**
- Patient must not have a history of stroke, TIA, ACS, GI Bleed, or peptic ulcer due to the risk of bleeding; **AND**
- Concomitant therapy with clopidogrel, unless patient has a contraindication to clopidogrel in which case patient must have concomitant therapy with aspirin.

CLINICAL CRITERIA FOR RENEWAL

- The patient has had a disease response with the medication.

ANTIBIOTICS: GYNECOLOGICAL

Length of Authorization:	1 year
Initiative:	MNC: Antibiotics (IE 2462 / NCPDP 75)

STANDARD FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

STEP CRITERIA

BRAND CLEOCIN CREAM, CLEOCIN OVULES, NUVESSA

Trial and failure of a minimum 5-day supply of generic metronidazole 0.75% vaginal gel or a 3-day supply of generic clindamycin 2% vaginal cream

ANTIBIOTICS: CEPHALOSPORINS (TEFLARO®)

Length of Authorization:	7 days–14 days
Initiative:	MNC: Antibiotics (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

TEFLARO® (CEFTAROLINE FOSAMIL)

Diagnosis of **acute bacterial skin and skin structure infections**

- Bacterial isolates indicate susceptible strains of gram-positive and gram-negative microorganisms: Staphylococcus aureus (MRSA), Streptococcus pyogenes, Streptococcus agalactia, E Coli, Klebsiella pneumoniae, and Klebsiella oxytoca; **AND**
- Approve for 14 days

Diagnosis of **community-acquired bacterial pneumonia (CABP)**

- Bacterial isolates indicate susceptible strains of gram-positive and gram-negative microorganisms: Streptococcus pneumoniae (including cases with concurrent bacteremia), Staphylococcus aureus (MRSA), Haemophilus influenzae, Escherichia Coli, Klebsiella pneumoniae, and Klebsiella oxytoca;
- Approve for 7 days

ANTIBIOTICS: GASTROINTESTINAL

Length of Authorization:	Detailed below
Initiative:	MNC: Antibiotics: Gastrointestinal (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

DIFICID® (FIDAXOMICIN)

- Diagnosis of diarrhea due to C. Difficile (C. Diff)
- Patient is 6 months of age or older
- Length of authorization: 10 days
  - Note: Approve if patient started therapy in the hospital and request is to complete the course; criteria above do not need to be met.

ALINIA® (NITAZOXANIDE)

- Diagnosis of diarrhea caused by Giardia lamblia or cryptosporidium parvum
- Patient is at least 1 year of age for oral suspension or is at least 12 years of age for the tablets
- Length of authorization: 3 days

XIFAXAN (RIFAXIMIN)

- Diagnosis of Irritable bowel syndrome with diarrhea (IBS-D); **AND**
- The patient is 18 or older
- Length of authorization: 14 days
- Diagnosis of Hepatic Encephalopathy; **AND**
- The patient is 18 or older
- Length of authorization: 6 months
- Diagnosis of traveler's diarrhea caused by noninvasive strains of Escherichia coli; **AND**
- The patient is 12 or older
- Length of authorization: 3 days

CLINICAL CRITERIA FOR RENEWAL

- May be renewed if above criteria is met

ANTIBIOTICS: OXAZOLIDINONES

Length of Authorization:	28-day, or up to 8 weeks if appropriate for diagnosis
Initiative:	MNC: Antibiotics: Oxazolidinones (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

**If the patient is completing a course of therapy with Zyvox® which was initiated in the hospital, approve the requested medication for the remainder of the course of therapy (no other criteria needs to be addressed)

ZYVOX (BRAND TABLETS)

- Patient is being treated for one of the following infections caused by susceptible Gram-positive bacteria, **AND**:
  - Nosocomial pneumonia
  - Community-acquired pneumonia, including concurrent bacteremia
  - Complicated skin and skin structure infections
  - Vancomycin-resistant Enterococcus faecium infections, including concurrent bacteremia
  - Uncomplicated skin and skin structure infections
- Patient has tried and failed generic linezolid tablets.

ZYVOX (BRAND SUSPENSION)

- Patient is being treated for one of the following infections caused by susceptible Gram-positive bacteria, **AND**:
  - Nosocomial pneumonia
  - Community-acquired pneumonia, including concurrent bacteremia
  - Complicated skin and skin structure infections
  - Vancomycin-resistant Enterococcus faecium infections, including concurrent bacteremia
  - Uncomplicated skin and skin structure infections
- Patient must have difficulty swallowing, cannot swallow tablets, or the dosage needed is not available in tablet formulation, **AND**
- Patient has tried and failed generic linezolid oral suspension.

SIVEXTRO

**If the patient is completing a course of therapy with Sivextro® which was initiated in the hospital, approve the requested medication for the remainder of the course of therapy (no other criteria needs to be addressed)

- Approval requires patient to meet ALL of the following criteria:
  - Diagnosis of acute bacterial skin and skin structure infection; **AND**
  - Culture documenting one of the following susceptible gram-positive cocci as causative organism:
    - *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA])
    - Streptococcus agalactiae
    - Streptococcus pyogenes
    - Streptococcus anginosus group including:
      - Streptococcus constellatus
      - Streptococcus intermedius
      - Streptococcus anginosus
      - Enterococcus faecalis
  - Patient must be resistant to or have a contraindication or intolerance to all other treatment options

    Note: Documentation of culture and sensitivity should be submitted and prescriber should indicate why patient cannot use all other options culture is showing as sensitive.

ANTIBIOTICS: QUINOLONES

Length of Authorization:	3-day DOS, or up to 1 year if appropriate for diagnosis
Initiative:	MNC: Antibiotics (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

FACTIVE

- The medication may be approved if:
  - There has been a therapeutic failure to no less than a three-day trial of at least one medication within the same class not requiring prior approval; **OR**
  - The medication was started in the hospital [approve request to complete the course of therapy]; **OR**
  - There is a clinical reason the patient cannot be changed to a preferred medication. Acceptable reasons include:
    - Allergy to preferred medications
    - Contraindication to or drug-drug interaction with preferred medications
    - History of unacceptable/toxic side effects to preferred medications
    - The infection is caused by an organism resistant to the non-prior authorized quinolone medication

BAXDELA®

- ****If the patient is completing a course of therapy with Baxdela® that was initiated in the hospital, approve the medication for the remaining course of therapy (no other criteria needs to be addressed) *****
- The patient must have a diagnosis of acute bacterial skin and skin structure infection (ABSSSI) **or** a diagnosis of community-acquired bacterial pneumonia (CABP) caused by susceptible gram-positive or gram-negative bacteria, including methicillin-resistant Staphylococcus aureus (MRSA); **AND**
- The patient must be resistant to or have a contraindication or intolerance to other treatment options (i.e., trimethoprim-sulfamethoxazole (TMP-SMX), tetracyclines (i.e., doxycycline, minocycline), clindamycin)

PA IV Antibiotics:

Note: IV therapy will only be approved for patients unable to take oral medications or for patients with severe infection in which oral therapy is inappropriate.

ANTIBIOTICS: TETRACYCLINES

STANDARD FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

Length of Authorization:	1 year, except for: Nuzyra: 7-14 days; Seysara: Initial: 12 weeks, Renewal: 6 months (not to exceed 12 months use)
Initiative:	MNC: Antibiotics (IE 2462 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

ACTICLATE® (BRAND AND GENERIC), DORYX®, MONODOX®, TARGADOX®, VIBRAMYCIN®

Trial and failure of any **two** generic doxycycline products

DOXYCYCLINE HYC DR 100 MG TAB, DOXYCYCLINE HYC DR 150 MG TAB, DOXYCYCLINE HYC DR 200 MG TAB, DOXYCYCLINE HYC DR 50 MG TAB, DOXYCYCLINE HYC DR 75 MG TAB, DOXYCYCLINE HYC DR 80 MG TAB

Trial and failure of any combination of **two** of the following:

- generic immediate release (IR) tetracycline products; **OR**
- Solodyn™

MINOCYCLINE ER 45, 55, 65, 115, 90, 135 MG TABLET

Trial and failure of any combination of **two** of the following:

- generic immediate release tetracycline products; **OR**
- Solodyn™

COREMINO

Trial and failure of any combination of **two** of the following:

- generic immediate release tetracycline products; **OR**
- Solodyn™

MINOCIN®

Trial and failure of a generic minocycline IR product

MINOCYCLINE IR TABLETS

Trial and failure of generic minocycline IR ***capsules***

CLINICAL CRITERIA (NO GRANDFATHERING)

MINOLIRA™, XIMINO®, MINOCYCLINE ER 45, 90, 135 MG CAPSULE

- The patient has non-nodular moderate to severe acne vulgaris with inflammatory lesions; **AND**
- The patient has tried and failed, has a contraindication, or experienced intolerance/adverse reaction to at least **one** oral preferred tetracycline; **AND**
- The patient has tried and failed, has a contraindication, or experienced intolerance/adverse reaction to at least **two** of the following topical agents:
  - Metronidazole (i.e., MetroGel®, MetroCream®), or azelaic acid (e.g., Azelex®, Finacea®); **OR**
  - Erythromycin gel, solution, or clindamycin (e.g., Cleocin-T®, Clindagel®); **OR**
  - Sodium sulfacetamide, or benzoyl peroxide
- **For Ximino® and its generic, minocycline ER 45, 90, 135 mg capsule:** in addition to the above criteria, patient has also tried and failed Solodyn™

ORACEA®

- The patient requires treatment for inflammatory lesions (papules and pustules) of rosacea; **AND**
- The patient requires long-term therapy (greater than 3 months) with an oral antibiotic; **AND**
- The patient has tried and failed, has a contraindication or experienced intolerance/adverse reaction to at least **one** of the following topical agents:
  - Metronidazole (i.e., MetroGel®, MetroCream®); **OR**
  - Erythromycin gel, solution; **OR**
  - Soolantra®

NUZYRA® (OMADACYCLINE)

- Patient must be ≥ 18 years of age; **AND**
- If of childbearing potential, patient is **not** pregnant; **AND**
  - Patient must have a diagnosis of one of the following:
    - Community-acquired bacterial pneumonia (CABP); **OR**
    - Acute bacterial skin and skin structure infections (ABSSSI)
- If patient started Nuzyra® in the hospital and the request is to complete the course of therapy, then approve; **OR**
- If a new start or if the patient has had an inadequate response, contraindication, or intolerance to one generic formulary antibiotic

CLINICAL CRITERIA (NO GRANDFATHERING) *(CONTINUED)*

SEYSARA® (SARECYCLINE)

- Patient is 9 years of age or older; **AND**
- If of childbearing potential, patient is **not** pregnant; **AND**
- Patient has a diagnosis of non-nodular moderate to severe acne vulgaris; **AND**
- Patient has tried and failed, has a contraindication to, or experienced an intolerance/adverse reaction to an oral generic doxycycline **and** an oral generic minocycline; **AND**
- Use of sarecycline will be in combination with a topical agent (e.g., benzoyl peroxide or a topical retinoid)

CLINICAL CRITERIA FOR RENEWAL FOR SEYSARA®

- Patient continues to meet above criteria; **AND**
- Prescriber to provide verbal attestation that acne has improved; **AND**
- Patient has no treatment-limiting adverse effects (e.g., intracranial hypertension, *Clostridium difficile* associated diarrhea, severe photosensitivity, severe central nervous system adverse effects)

ZILXI® (MINOCYCLINE 1.5% FOAM)

- ***Patient has tried and failed or has a contraindication or experienced intolerance/adverse reaction to Soolantra®, Finacea® foam, or azelaic acid***

PRECISION/PLUS FORMULARY CRITERIA

Length of Authorization:	1 year, except for: Nuzyra: 7-14 days; Seysara: Initial: 12 weeks, Renewal: 6 months (not to exceed 12 months use)
Initiative:	MNC: Antibiotics (IE 2462 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

MINOCYCLINE ER 45, 55, 65, 115, 90, 135 MG TABLET

Trial and failure of any **two** generic immediate release tetracycline products

COREMINO

Trial and failure of any **two** generic immediate release tetracycline products

STEP CRITERIA (NO GRANDFATHERING) (CONTINUED)

MINOCIN®

Trial and failure of a generic minocycline IR product

MINOCYCLINE IR TABLETS

Trial and failure of generic minocycline IR CAPSULES

CLINICAL CRITERIA (NO GRANDFATHERING)

NUZYRA® (OMADACYCLINE)

- Patient must be ≥ 18 years of age; **AND**
- If of childbearing potential, patient is **not** pregnant; **AND**
  - Patient must have a diagnosis of one of the following:
    - Community-acquired bacterial pneumonia (CABP); **OR**
    - Acute bacterial skin and skin structure infections (ABSSSI)
- If patient started Nuzyra® in the hospital and the request is to complete the course of therapy, approve; **OR**
- If a new start, patient has had an inadequate response, contraindication, or intolerance to one generic formulary antibiotic.

SEYSARA® (SARECYCLINE)

- Patient is 9 years of age or older; **AND**
- If of childbearing potential, patient is **not** pregnant; **AND**
- Patient has a diagnosis of non-nodular moderate to severe acne vulgaris; **AND**
- Patient has tried and failed, has a contraindication to, or experienced an intolerance/adverse reaction to an oral generic doxycycline **and** an oral generic minocycline; **AND**
- Use of sarecycline will be in combination with a topical agent (e.g., benzoyl peroxide or a topical retinoid).

CLINICAL CRITERIA FOR RENEWAL FOR SEYSARA

- Patient continues to meet above criteria; **AND**
- Prescriber to provide verbal attestation that acne has improved; **AND**
- Patient has no treatment-limiting adverse effects (e.g., intracranial hypertension, *Clostridium difficile* associated diarrhea, severe photosensitivity, severe central nervous system adverse effects).

ZILXI® (MINOCYCLINE 1.5% FOAM)

- ***Patient has tried and failed or has a contraindication or experienced intolerance/adverse reaction to Soolantra®, Finacea® foam, or azelaic acid***

CORE FORMULARY CRITERIA

Length of Authorization:	1 year, except for: • Nuzyra: 7–14 days • Seysara: Initial: 12 weeks, Renewal: 6 months (not to exceed 12 months use)
Initiative:	MNC: Antibiotics (IE 2462 / NCPDP 75 – GSN)

STEP CRITERIA (NO GRANDFATHERING)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

COREMINO

Trial and failure of any **two** generic immediate release tetracycline products

NUZYRA® (OMADACYCLINE)

- Patient must be ≥ 18 years of age; **AND**
- If of childbearing potential, patient is **not** pregnant; **AND**
  - Patient must have a diagnosis of one of the following:
    - Community-acquired bacterial pneumonia (CABP); **OR**
    - Acute bacterial skin and skin structure infections (ABSSSI)
- If patient started Nuzyra® in the hospital and the request is to complete the course of therapy, approve; **OR**
- If a new start, patient has had an inadequate response, contraindication, or intolerance to one generic formulary antibiotic.

SEYSARA® (SARECYCLINE)

- Patient is 9 years of age or older; **AND**
- If of childbearing potential, patient is **not** pregnant; **AND**
- Patient has a diagnosis of non-nodular moderate to severe acne vulgaris; **AND**
- Patient has tried and failed, has a contraindication to, or experienced an intolerance/adverse reaction to an oral generic doxycycline **and** an oral generic minocycline; **AND**
- Use of sarecycline will be in combination with a topical agent (e.g., benzoyl peroxide or a topical retinoid).

CLINICAL CRITERIA FOR RENEWAL FOR SEYSARA

- Patient continues to meet above criteria; **AND**
- Prescriber to provide verbal attestation that acne has improved; **AND**
- Patient has no treatment-limiting adverse effects (e.g., intracranial hypertension, *Clostridium difficile* associated diarrhea, severe photosensitivity, severe central nervous system adverse effects).

ZILXI® (MINOCYCLINE 1.5% FOAM)

- ***Patient has tried and failed or has a contraindication or experienced intolerance/adverse reaction to azelaic acid, ivermectin cream, or Finacea® foam***

ANTIBIOTICS: XENLETA (LEFAMULIN)

Length of Authorization:	5 days – 7 days
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient must be ≥ 18 years of age; **AND**
- Patient must have a diagnosis of Community-Acquired Bacterial Pneumonia (CABP); **AND**
- If patient started Xenleta in the hospital and the request is to complete the course of therapy, approve; **OR**
- If a new start, patient has had an inadequate response, contraindication, or intolerance to one generic formulary antibiotic.

ANTICOAGULANTS

Length of Authorization:	1 year (Savaysa), 42 days for Bevyxxa
Initiative:	MNC: Anticoagulants (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

SAVAYSA

- Diagnosis of Non-valvular Atrial Fibrillation; **AND**
  - Patient has had a trial of Pradaxa or Xarelto
  - Patient is 18 or older
  - CrCl is **LESS** than 95 mL/min
- Diagnosis of Deep Vein Thrombosis or Pulmonary Embolism; **AND**
  - Patient has had a trial of Pradaxa or Xarelto
  - Patient is 18 or older

BEVYXXA

- Patient is 18 years of age or older**; AND**
- Hospitalized for an acute medical illness **AND** must meet one of the following criteria for increased risk of VTE in medical patients:
  - Age ≥ 55 years, Active Rheumatologic Disease, Acute MI, Cancer, Chemotherapy, CHF Class III or IV, Central venous catheters/pulmonary artery catheters, hemorrhagic cerebral vascular accident, hormone therapy, hormone replacement therapy (hormone contraceptives), ICU admission, Ischemic cerebral vascular accident, Inflammatory bowel disease, Infections, nephrotic syndrome, Obesity, paresis/paralysis of legs, Peripheral arterial insufficiency, pregnancy and puerperium, previous VTE, reduced mobility, severe respiratory disease, Thrombophilia, Varices/chronic venous insufficiency.
- Deny if the patient meets any of the following:
  - Patient has an active bleed; **OR**
  - Patient has liver dysfunction; **OR**
  - Patient has severe renal insufficiency (CrCl 15-29 mL/min) and requires concomitant use of a P-gp inhibitor.
- Bevyxxa is used for 42 days' total for treatment duration. No renewal criteria, if patient is being treated for a different event they must meet all criteria above.

CLINICAL CRITERIA FOR RENEWAL

SAVAYSA

- Patient continues to meet the initial criteria; **AND**
- The patient has benefited from therapy; **AND**
- The condition has not progressed or worsened while on therapy; **AND**
- The patient has not developed any contraindications or other exclusions to its continued use.

ANTICONVULSANTS

STANDARD FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

Length of Authorization:	1 year Diacomit: 6 months, may be renewed Fintepla: 6 months initial, renewals may be renewed 1 year
Initiative:	MNC: Anticonvulsants (IE 2462 / NCPDP 75, 50081 and 2193) SPC: Anticonvulsants (IE 2462 / NCPDP 75, 50081 and 2193)—Sabril (vigabatrin), Onfi (clobazam) suspension, Sympazan, Epidiolex, Fintepla

CLINICAL CRITERIA FOR INITIAL APPROVAL

BRIVIACT® (BRIVARACETAM)

Diagnosis of **partial onset seizures**

- Patient is 1 month of age or older; **AND**
- Patient has tried and failed one generic anticonvulsant: (i.e., levetiracetam, tiagabine, topiramate, valproic acid or zonisamide); **AND**
- Will be used as monotherapy or add-on therapy to help partial onset seizures.

Briviact® should **not** be approved if the patient meets any of the following:

- The patient has severe hepatic impairment, end stage renal disease, post kidney transplant, or is on dialysis;
- The patient is under the age of 1 month.

LYRICA® CR (PREGABALIN ER)

For Diabetic Peripheral Neuropathy and Postherpetic Neuralgia only

Diagnosis of **diabetic peripheral neuropathy** or **post-herpetic neuralgia (PHN)**

- Adequate trial/failure of or intolerance/contraindication to at least one of these first-line agents:
  - Tricyclic antidepressant (TCAs); **OR**
  - Gabapentin; **OR**
  - Lidocaine 5% patch; **AND**
- Must have trial/failure of **or** contraindication/intolerance to **or** is not successfully managed with pregabalin IR.

ONFI®, SYMPAZAN® (CLOBAZAM)

Note: Onfi (clobazam) tablets are non-specialty and use MNC: Anticonvulsants. Onfi® (clobazam) suspension and Sympazan® are specialty and use SPC: Anticonvulsants

Diagnosis of **adjunctive therapy for Lennox-Gastaut syndrome** (LGS) when used in combination with at least one other anticonvulsant

- Patient is not taking any other benzodiazepines; **AND**
- Patient is not taking an opioid.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

EPIDIOLEX® (CANNABIDIOL)

Diagnosis of **Lennox-Gastaut syndrome (LGS)** or **Dravet syndrome (DS)**

- Patient is 2 years of age or older; **AND**
- Diagnosed by a pediatric neurologist or pediatric epileptologist; if there are no specialists in the area, prescriber to provider verbal attestation, including documented history of slow (< 3.0 Hz) spike and wave electroencephalograms, may be used; **AND**
- Prescriber to provide verbal (or written) attestation that patient has refractory epilepsy (patient has failed to become seizure-free with adequate trials of 2 antiepileptic drugs [AED]); **AND**
- Prescriber to provide verbal (or written) attestation that Epidiolex will be used in adjunct to ≥ 1 antiepileptic drug; **AND**
- Prescriber to provide verbal (or written) attestation that baseline serum transaminases (ALT and AST) and total bilirubin levels have been completed; **AND**
- Prescriber to provide verbal (or written) attestation that patient is not currently using recreational or medicinal cannabis along with this product.

RENEWAL FOR EPIDIOLEX®:

- Patient continues to meet above criteria; **AND**
- Prescriber to provide verbal attestation that annual serum transaminases (ALT and AST) and total bilirubin levels have been completed.

DIACOMIT® (STIRIPENTOL)

Diagnosis of **Dravet syndrome (DS)**

- Patient is 2 years of age or older; **AND**
- Patient has been diagnosed with Dravet syndrome (DS) by a pediatric neurologist or pediatric epileptologist; if there are no specialists in the area, prescriber to provider verbal attestation may be used; **AND**
- Prescriber to provide verbal attestation that baseline serum hematologic testing has been completed; **AND**
- Prescriber to provide verbal attestation that stiripentol will be used in adjunct to ≥ 1 antiepileptic drug, including clobazam; **AND**
- If the oral powder for suspension is prescribed, the patient does not have phenylketonuria (PKU); **AND**
  - Prescriber to provide verbal attestation that patient has refractory epilepsy (patient has failed to become seizure-free with adequate trials of 2 antiepileptic drugs [AED]); **OR**
  - Patient is continuing therapy.

RENEWAL FOR DIACOMIT®

- Patient continues to meet above criteria; **AND**
- Prescriber to provide verbal attestation that every 6 months hematologic testing has been completed; **AND**
- Patient has no treatment-limiting adverse effects (e.g., thrombocytopenia, neutropenia, new onset or worsened depression; suicidal thoughts, worsened seizure control); **AND**
- Prescriber to provide verbal attestation of stiripentol effectiveness (e.g., reduced seizure frequency).

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

FELBATOL® (FELBAMATE)

Diagnosis of **Lennox-Gastaut Syndrome in children** or **partial seizures with or without generalization in patients ≥ 14 years of age**

- May be used as adjunctive therapy or monotherapy; **AND**
- History of failure, contraindication, or intolerance to **two** formulary anticonvulsants; **AND**
- Must have hematologic consultation with routine monitoring; **AND**
- Must **not** have history of hepatic dysfunction (must have normal baseline serum transaminases)

SABRIL®, VIGABATRIN, VIGADRONE®

- Diagnosis of **infantile spasms**; **OR**
- **All** of the following:
  - Diagnosis of complex partial seizures; **AND**
  - Used as adjunctive therapy; **AND**
  - History of failure, contraindication, or intolerance to **two** formulary anticonvulsants (e.g., Lamictal®, Depakene®, Dilantin®); **AND**
  - Must have baseline and periodic (every 6 months) systematic visual monitoring by an ophthalmic professional. Testing should include visual acuity and dilated fundus photography.

BANZEL® (RUFINAMIDE)

Diagnosis of **adjunctive therapy for Lennox-Gastaut Syndrome when used in combination with at least one other anticonvulsant**

- Patient is 1 year of age or older

XCOPRI® (CENOBAMATE)

INITIAL CRITERIA

Diagnosis of **partial-onset seizures**

- Patient must be ≥ 18 years of age; **AND**
- Patient does **not** have familial QT syndrome; **AND**
- Patient does **not** have severe hepatic impairment (Child-Pugh Class C); **AND**
  - Patient has tried and failed **one** generic anticonvulsant (e.g., carbamazepine, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, pregabalin, topiramate, vigabatrin, or zonisamide); **OR**
  - Request is for continuation of therapy.

CLINICAL CRITERIA FOR RENEWAL

- Continue to meet initial criteria; **AND**
- Patient is experiencing symptom improvement or maintenance; **AND**
- The patient is not experiencing any treatment-limiting adverse reactions of the medication

FINTEPLA® (FENFLURAMINE)

INITIAL CRITERIA

Diagnosis of **Dravet syndrome (DS)** by a pediatric neurologist or pediatric epileptologist; if there are no specialists in the area, prescriber to provider verbal attestation, including documented history of slow [< 3.0 Hz] spike and wave electroencephalograms, may be used.

- Patient must be ≥ 2 years of age; **AND**
- Prescriber must provide verbal attestation that patient has refractory epilepsy (patient has failed to become seizure-free with adequate trials of 2 antiepileptic drugs [AED]); **AND**
- Patient has not been treated with a monoamine oxidase inhibitor (MAOI) within 14 days of starting fenfluramine; **AND**
- Patient will undergo echocardiogram to evaluate for valvular heart disease and pulmonary arterial hypertension prior to starting fenfluramine (Fintepla) therapy and every 6 months during therapy; **AND**
- Fenfluramine (Fintepla) will be added to background antiepileptic therapy

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet initial criteria; **AND**
- Patient has documented disease response to treatment, as defined by decrease from baseline and stabilization of seizure frequency/severity; **AND**
- Patient is absent of unacceptable toxicity from therapy. Examples of unacceptable toxicity (e.g., significant weight loss, sedation, diarrhea)

STEP CRITERIA (NO GRANDFATHERING)

QUDEXY XR® (TOPIRAMATE ER)

The patient must fail a trial of topiramate ER

TROKENDI XR® (TOPIRAMATE ER)

The patient must fail a trial of topiramate IR

ELEPSIA XR® (LEVETIRACETAM ER)

The patient must fail a trial of generic levetiracetam

PRECISION/PLUS FORMULARY CRITERIA

CORE FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Anticonvulsants (IE 2462 / NCPDP 75, 50081 and 2193) SPC: Anticonvulsants (IE 2462 / NCPDP 75, 50081 and 2193)—Sabril (vigabatrin), Onfi (clobazam) suspension

CLINICAL CRITERIA FOR INITIAL APPROVAL

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

BRIVIACT® (BRIVARACETAM)

- Diagnosis of partial onset seizures, **AND**
- Patient is 4 years of age or older; **AND**
- Patient has tried and failed one generic anticonvulsant (i.e., levetiracetam, tiagabine, topiramate, valproic acid, or zonisamide); **AND**
- Will be used as monotherapy or add-on therapy to help partial onset seizures

Briviact® should **not** be approved if the patient meets any of the following:

- The patient has severe hepatic impairment, end stage renal disease, post kidney transplant, or is on dialysis;
- The patient is under the age of 4.

LYRICA CR (PREGABALIN ER) (FOR DIABETIC PERIPHERAL NEUROPATHY AND POSTHERPETIC NEURALGIA ONLY)

Diagnosis of **diabetic peripheral neuropathy** or **post-herpetic neuralgia (PHN)**

- Adequate trial/failure of or intolerance/contraindication to at least one of these first-line agents:
  - Tricyclic antidepressant (TCAs); **OR**
  - Gabapentin; **OR**
  - Lidocaine 5% patch; **AND**
- Must have trial/failure of **or** contraindication/intolerance to **or** is not successfully managed with pregabalin IR.

ONFI® (CLOBAZAM)

Note: Onfi® (clobazam) tablets are non-specialty and use MNC: Anticonvulsants. Onfi® (clobazam) suspension is specialty and uses SPC: Anticonvulsants

Diagnosis of **adjunctive therapy for Lennox-Gastaut Syndrome when used in combination with at least one other anticonvulsant**

- Patient is not taking any other benzodiazepines; **AND**
- Patients is not taking an opioid

EPIDIOLEX® (CANNABIDIOL)

Diagnosis of **Lennox-Gastaut syndrome (LGS)** or **Dravet syndrome (DS)**

- Patient is 2 years of age or older; **AND**
- Diagnosed by a pediatric neurologist or pediatric epileptologist; if there are no specialists in the area, prescriber to provider verbal attestation, including documented history of slow (< 3.0 Hz) spike and wave electroencephalograms, may be used; **AND**
- Prescriber to provide verbal (or written) attestation that patient has refractory epilepsy (patient has failed to become seizure-free with adequate trials of 2 antiepileptic drugs [AED]); **AND**
- Prescriber to provide verbal (or written) attestation that Epidiolex will be used in adjunct to ≥ 1 antiepileptic drug; **AND**
- Prescriber to provide verbal (or written) attestation that baseline serum transaminases (ALT and AST) and total bilirubin levels have been completed; **AND**
- Prescriber to provide verbal (or written) attestation that patient is not currently using recreational or medicinal cannabis along with this product.

RENEWAL FOR EPIDIOLEX®

- Patient continues to meet above criteria; **AND**
- Prescriber to provide verbal attestation that annual serum transaminases (ALT and AST) and total bilirubin levels have been completed.

DIACOMIT® (STIRIPENTOL)

Diagnosis of **Dravet syndrome (DS)**

- Patient is 2 years of age or older; **AND**
- Patient has been diagnosed with Dravet syndrome (DS) by a pediatric neurologist or pediatric epileptologist; if there are no specialists in the area, prescriber to provider verbal attestation may be used; **AND**
- Prescriber to provide verbal attestation that baseline serum hematologic testing has been completed; **AND**
- Prescriber to provide verbal attestation that stiripentol will be used in adjunct to ≥ 1 antiepileptic drug, including clobazam; **AND**
- If the oral powder for suspension is prescribed, the patient does not have phenylketonuria (PKU); **AND**
  - Prescriber to provide verbal attestation that patient has refractory epilepsy (patient has failed to become seizure-free with adequate trials of 2 antiepileptic drugs [AED]); **OR**
  - Patient is continuing therapy.

RENEWAL FOR DIACOMIT®

- Patient continues to meet above criteria; **AND**
- Prescriber to provide verbal attestation that every 6-month hematologic testing has been completed; **AND**
- Patient has no treatment-limiting adverse effects (e.g., thrombocytopenia, neutropenia, new onset or worsened depression; suicidal thoughts, worsened seizure control); **AND**
- Prescriber to provide verbal attestation of stiripentol effectiveness (e.g., reduced seizure frequency).

FELBATOL® (FELBAMATE)

Diagnosis of **Lennox-Gastaut Syndrome in children** or **partial seizures with or without generalization in patients ≥ 14 years of age**

- May be used as adjunctive therapy or monotherapy; **AND**
- History of failure, contraindication, or intolerance to **two** formulary anticonvulsants; **AND**
- Must have hematologic consultation with routine monitoring; **AND**
- Must **not** have history of hepatic dysfunction (must have normal baseline serum transaminases)

SABRIL®, VIGABATRIN, VIGADRONE®

- Diagnosis of **infantile spasms**; **OR**
- **All** of the following:
  - Diagnosis of complex partial seizures; **AND**
  - Used as adjunctive therapy; **AND**
  - History of failure, contraindication, or intolerance to **two** formulary anticonvulsants (e.g., Lamictal®, Depakene®, Dilantin®); **AND**
  - Must have baseline and periodic (every 6 months) systematic visual monitoring by an ophthalmic professional. Testing should include visual acuity and dilated fundus photography.

BANZEL® (RUFINAMIDE)

Diagnosis of **adjunctive therapy for Lennox-Gastaut Syndrome when used in combination with at least one other anticonvulsant**

- Patient is 1 year of age or older

XCOPRI® (CENOBAMATE)

INITIAL CRITERIA

Diagnosis of **partial-onset seizures**

- Patient must be ≥ 18 years of age; **AND**
- Patient does **not** have familial QT syndrome; **AND**
- Patient does **not** have severe hepatic impairment (Child-Pugh Class C); **AND**
- Patient has tried and failed **one** generic anticonvulsant (e.g., carbamazepine, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, pregabalin, topiramate, vigabatrin, or zonisamide); **OR**
- Request is for continuation of therapy.

CLINICAL CRITERIA FOR RENEWAL

- Continue to meet initial criteria; **AND**
- Patient is experiencing symptom improvement or maintenance; **AND**
- The patient is not experiencing any treatment-limiting adverse reactions of the medication

FINTEPLA® (FENFLURAMINE)

INITIAL CRITERIA

Diagnosis of **Dravet syndrome (DS)** by a pediatric neurologist or pediatric epileptologist; if there are no specialists in the area, prescriber to provider verbal attestation, including documented history of slow (< 3.0 Hz) spike and wave electroencephalograms may be used

- Patient must be ≥ 2 years of age; **AND**
- Prescriber must provide verbal attestation that patient has refractory epilepsy (patient has failed to become seizure-free with adequate trials of 2 antiepileptic drugs [AED]); **AND**
- Patient has not been treated with a monoamine oxidase inhibitor (MAOI) within 14 days of starting fenfluramine; **AND**
- Patient will undergo echocardiogram to evaluate for valvular heart disease and pulmonary arterial hypertension prior to starting fenfluramine (Fintepla) therapy and every 6 months during therapy; **AND**
- Fenfluramine (Fintepla) will be added to background antiepileptic therapy

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet initial criteria; **AND**
- Patient has documented disease response to treatment, as defined by decrease from baseline and stabilization of seizure frequency/severity; **AND**
- Patient is absent of unacceptable toxicity from therapy. Examples of unacceptable toxicity (e.g., significant weight loss, sedation, diarrhea)

STEP CRITERIA (NO GRANDFATHERING)

TROKENDI XR®

The patient has failed a trial of topiramate IR

ANTIDEPRESSANTS

Length of Authorization:	1 year
Initiative:	MNC: Antidepressants (IE 2462 / NCPDP 75)

STEP CRITERIA

TRINTELLIX® (FORMERLY BRINTELLIX)

- Diagnosis of Major Depressive Disorder
- Patient has tried and failed **two** agents at an appropriate dose (defined as: 3 weeks at the maximum tolerated dose within the recommended therapeutic range) within the following drug classes:
  - SNRI medication (i.e., Venlafaxine, Pristiq, Duloxetine, etc.)
  - SSRI medication (i.e., citalopram, sertraline, paroxetine, etc.)
  - Bupropion
  - Mirtazapine

FETZIMA

- Diagnosis of Major Depressive Disorder
  - Patient has tried and failed TWO agents at an appropriate dose (defined as: 3 weeks at the maximum tolerated dose within the recommended therapeutic range) within the following drug classes:
    - SNRI medication (i.e., Venlafaxine, Pristiq, Duloxetine, etc.).

SAVELLA

- The patient has had an adequate trial/failure or intolerance/allergy to at least one of the below first-line agents:
  - Tricyclic antidepressants (i.e., Amitriptyline, desipramine, nortriptyline, etc.); **OR**
  - Cyclobenzaprine; **OR**
  - Duloxetine; **OR**
  - Pregabalin

EMSAM

The patient tried and failed any **TWO** of the following generics: bupropion, citalopram, desvenlafaxine ER, duloxetine, escitalopram, fluoxetine, mirtazapine, paroxetine, paroxetine ER, sertraline, venlafaxine, venlafaxine ER

CLINICAL CRITERIA FOR INITIAL APPROVAL

PAXIL SUSPENSION

- The patient is unable to swallow tablets/capsules; **AND**
- Patient must not have any tablets/capsules in their claim history

PEXEVA

Must have a history of failure, contraindication, or intolerance to generic paroxetine hydrochloride **or** is not successfully managed with generic paroxetine hydrochloride

CLINICAL CRITERIA FOR RENEWAL

- The patient has benefited from therapy; **AND**
- The patient's condition has not progressed or worsened while on therapy; **AND**
- The patient has not developed any contraindications or other exclusions to its continued use.

ANTIEMETICS

Length of Authorization:	6 Months or 9 months, noted below (Sustol may not be renewed)
Initiative:	MNC: Antiemetics (IE 2462 / NCPDP 75) SPC: Miscellaneous PA required (IE 2462 / NCPDP 75), Cinvanti, Emend, Sustol, Varubi

CLINICAL CRITERIA FOR INITIAL APPROVAL

Injections: patient is unable to take oral antiemetics.

AKYNZEO® IV(FOSNETUPITANT/PALONOSETRON)

Note: Approval is 6 months, may be renewed

Prevention of chemotherapy-induced nausea and vomiting (CINV)

- Patient must be at least 18 years of age; **AND**
- Used in combination with dexamethasone; **AND**
- Patient has failed** with another generically available 5-HT_3 receptor antagonist (e.g., ondansetron, granisetron, palonosetron, etc.) in combination with a NK-1 receptor antagonist (e.g., aprepitant, fosaprepitant, rolapitant, etc.) while receiving the current chemotherapy regimen; **AND**
- Patient is receiving highly emetogenic chemotherapy (HEC) **(see table below)**; **AND**
- Akynzeo® is **not** covered for:
  - Breakthrough emesis; **OR**
  - Repeat dosing in multi-day emetogenic chemotherapy regimens; **OR**
  - CINV related to an anthracycle plus cyclophosphamide chemotherapy regimen

ALOXI IV(PALONOSETRON)

Note: Approval is 6 months, may be renewed (may not be renewed for the indication of PONV)

Prevention of chemotherapy-induced nausea and vomiting (CINV) in adults

- Patient is receiving highly emetogenic chemotherapy (HEC); **OR**
- Patient has failed** with another 5HT3-antagonist (i.e., ondansetron or granisetron) while receiving the current chemotherapy regimen; **AND**
- Palonosetron is **not** covered for:
  - Breakthrough emesis; **OR**
  - Repeat dosing in multi-day emetogenic chemotherapy regimens

** Failure is defined as:

Two or more documented episodes of vomiting attributed to the current chemotherapy regimen

Prevention of chemotherapy-induced nausea and vomiting (CINV) in pediatric patients

- Patient is at least 1 month old and less than 17 years old; **AND**
- Patient is receiving emetogenic chemotherapy; **AND**
- Palonosetron is **not** covered for:
  - Breakthrough emesis; **OR**
  - Repeat dosing in multi-day emetogenic chemotherapy regimens

Prevention of post-operative nausea and vomiting (PONV) in Adults

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

CINVANTI IV(AREPITANT)

Note: Approval is 6 months, may be renewed

Prevention of chemotherapy-induced nausea and vomiting (CINV)

- Patient is at least 18 years of age; **AND**
- Patient is receiving highly and/or moderately emetogenic chemotherapy (see Table 1 below); **AND**
- Must be used in combination with a 5-HT_3 antagonist such as ondansetron, granisetron, palonosetron, etc.; **AND**
- Must be used in combination with a corticosteroid such as dexamethasone; **AND**
- Patient is not taking pimozide concurrently.

EMEND IV (FOSAPREPITANT)

Note: Approval is 6 months, may be renewed

Prevention of chemotherapy-induced nausea and vomiting (CINV)

- Patient is 6 months old or older; **AND**
- Patient is receiving highly and/or moderately emetogenic chemotherapy (see Table 1 below); **AND**
- Must be used in combination with a 5-HT_3 antagonist such as ondansetron, granisetron, palonosetron, etc.; **AND**
- Must be used in combination with a corticosteroid such as dexamethasone; **AND**
- Patient is not taking pimozide concurrently

KYTRIL IV (GRANISETRON)

Note: Approval is 6 months, may be renewed

- Diagnosis of **prevention and treatment of post-operative nausea and vomiting in adults, breakthrough treatment for chemotherapy-induced nausea/vomiting** or **prevention of nausea and vomiting associated with radiation treatment**; **OR**
- Diagnosis of **prevention of chemotherapy induced nausea and vomiting (CINV)**; **AND**
  - Patient is receiving emetogenic chemotherapy

SANCUSO (GRANISETRON TRANSDERMAL)

Note: Approval is 6 months, may be renewed

- Patient is at least 18 years of age; **AND**
- Diagnosis of **chemotherapy-induced nausea and vomiting (CINV)**; **AND**
- Patient is receiving highly and/or moderately emetogenic chemotherapy (see Table 1 below); **AND**
- Patient has failed (see definition below) with another generically available 5-HT3 receptor antagonist (e.g., ondansetron, granisetron, or palonosetron)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

SUSTOL (GRANISETRON EXTENDED RELEASE)

Approval is for 6 months, may **not** be renewed

Prevention of chemotherapy-induced nausea and vomiting (CINV)

- Patient is at least 18 years of age; **AND**
- Must be administered in combination with dexamethasone; **AND**
- Patient is receiving highly emetogenic chemotherapy (HEC) or a regimen that is not considered to be HEC; **AND**
- Patient has failed** with palonosetron while receiving the current chemotherapy regimen; **AND**
- Sustol is **not** covered for:
  - Breakthrough emesis; **OR**
  - Repeat dosing in multi-day emetogenic chemotherapy regimens

*** Failure is defined as:*

Two or more documented episodes of vomiting attributed to the current chemotherapy regimen

VARUBI

Prevention of chemotherapy induced nausea and vomiting (CINV)

- Patient is age of 18 years or older; **AND**
- Patient is receiving moderately to highly emetogenic chemotherapy (see table 1 below); **AND**
- Must be used in combination with a 5-HT_3 receptor antagonist (e.g., ondansetron, granisetron, palonosetron); **AND**
- Must be used in combination with a corticosteroid such as dexamethasone; **AND**
- Patient is not on any concurrent CYP2D6-substrates with a narrow therapeutic index (e.g., thioridazine, pimozide)

ZOFRAN IV (ONDANSETRON)

Note: Approval is 6 months, may be renewed

- Diagnosis of **prevention of post-operative nausea and vomiting, breakthrough treatment for chemotherapy-induced nausea/vomiting**; **OR**
- Diagnosis of **prevention of chemotherapy induced nausea and vomiting (CINV)**; **AND**
  - Patient is receiving emetogenic chemotherapy

DICLEGIS AND BONJESTA – APPROVAL IS FOR 9 MONTHS

- Patient is at least 18 years of age: **AND**
- Diagnosis of **nausea and vomiting associated with pregnancy in women who do not respond to non-pharmacological interventions such as dietary and lifestyle modifications** (not indicated for severe hyperemesis); **AND**
- Documented contraindication or failure of Pyridoxine (B6), doxylamine, diphenhydramine, meclizine, metoclopramide, promethazine, prochlorperazine or ondansetron.

Note: Dietary modifications may include advice to eat smaller, more frequent meals and to avoid smells and food textures that cause nausea (i.e., spicy foods, fatty foods, strong odorous foods)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Table 1: List of highly emetogenic chemotherapy (HEC):

Highly Emetogenic Chemotherapy (HEC)			
Carboplatin	Carmustine	Cisplatin	Cyclophosphamide
Dacarbazine	Doxorubicin	Epirubicin	Ifosfamide
Mechlorethamine	Melphalan	Sacituzumab govitecan	Streptozocin
Moderately Emetogenic Chemotherapy (MEC)			
Aldesleukin > 12-15 million IU/m^2	Amifostine > 300mg/m^2	Azacitidine	Bendamustine
Busulfan	Clofarabine	Cytarabine > 200 mg/m^2	Daunorubicin Liposomal; Cytarabine Liposomal
Dinutuximab	Fam-trastuzumab deruxtecan-nxki	Irinotecan Liposomal	Lurbinectedin
Temozolomide			

The following regimens can be considered HEC:			
FOLFOX	FOLFIRI	FOLFIRINOX; FOLFOXIRI	AC (any anthracycline + cyclophosphamide)

The following chemotherapy can be considered HEC in certain patients:			
Dactinomycin	Daunorubicin	Idarubicin	Irinotecan
Methotrexate ≥ 250 mg/m^2	Oxaliplatin	Trabectedin	

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient has had a disease response; **AND**
- Patient is free of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions [anaphylaxis and bronchospasm], serotonin syndrome, gastrointestinal peristalsis, QT prolongation)

ANTIEMETICS: DELTA-9THC DERIVATIVES

Length of Authorization:	6 Months
Initiative:	MNC: Antiemetics (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

CESAMET

- Diagnosis of severe, chemotherapy induced nausea and vomiting, **AND**
- Patient has tried and failed, has a contraindication to, an intolerance, or a medical reason not to try the combination of Emend® plus a 5HT3 receptor antagonist plus a corticosteroid.

SYNDROS AND MARINOL

- The patient is 18 years of age or older; **AND**
- The patient has a diagnosis of anorexia due to AIDS; **OR**
- The patient has a diagnosis of nausea/vomiting due to chemotherapy; **AND**
  - Patient has tried and failed 1 preferred 5HT3 antagonist (i.e., granisetron, ondansetron); **AND**
- The provider must provide documentation why the patient cannot use the generic dronabinol capsule.

ANTIFUNGALS: ORAL

Length of Authorization:	FOR THE DURATION OF THE RX OR UP TO A YEAR
Initiative:	MNC: Antifungals (IE 2462 / NCPDP 75, 50081 and 2193) SPC: Miscellaneous: PA required (IE 2462/NCPDP 75)----Cresemba, Tolsura

CLINICAL CRITERIA FOR INITIAL APPROVAL

Brand Sporanox may be approved for 6 months (unless noted) if:

- Diagnosis is **febrile neutropenia**
- Diagnosis is **aspergillus**
- Diagnosis is **blastomycosis**
- Diagnosis is **histoplasmosis**
- Diagnosis is **cryptococcosis**
- Diagnosis is **coccidiomycosis**
- Diagnosis is **oropharyngeal/esophageal candidiasis**
- Diagnosis is **any candida krusei infection** Diagnosis is Any candida krusei infection
- Diagnosis is **any other systemic fungal infections** including (but not limited to) chronic mucocutaneous candidiasis, allescheriosis, chromomycosis, paracoccidioidomycosis, sporotrichosis
- Diagnosis of **onychomycosis**
- Injections: Patient is unable to take oral medications

BRAND SPORANOX® (STEP THERAPY)

For this indication only: treatment of onychomycosis due to dermatophytes (tinea unguium) in immunocompetent patients, patient must have a trial and failure of a topical antifungal agent or oral terbinafine or oral itraconazole

BREXAFEMME – APPROVAL FOR 30 DAYS

- Patient is post-menarchal and female ≥ 12 years of age; **AND**
- Diagnosis of vulvovaginal candidiasis (VVC); **AND**
- Women of child-bearing age must have negative pregnancy test prior to treatment; **AND**
- Patient will avoid concomitant use with moderate and strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, long-acting barbiturates, bosentan, efavirenz, etravirine); **AND**
- Patient must have an adequate trial and failure, contraindication, intolerance, or resistance to oral fluconazole

CRESEMBA® – APPROVAL ONE YEAR

- Diagnosis of **aspergillosis**:
  - Patient cannot tolerate voriconazole or amphotericin B due to renal dysfunction
- Diagnosis of **mucormycosis**:
  - Approve

ONMEL® – APPROVAL IS FOR 6 MONTHS

- Diagnosis of onychomycosis of the toenail caused by trichophyton rubrum or T. mentagrophytes; **AND**
- Cannot tolerate treatment with oral terbinafine or fail to respond to terbinafine; **AND**
- Has a medical reason why the generic itraconazole cannot be used.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

TOLSURA® APPROVAL ONE YEAR

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of one of the following:
  - blastomycosis (pulmonary and extrapulmonary); **OR**
  - histoplasmosis (including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis); **OR**
  - aspergillosis (pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy) ; **AND**
- If patient started Tolsura in the hospital and the request is to complete the course of therapy, consult with the provider to see if s/he is willing to change to generic itraconazole.
  Note: Tolsura is **not** interchangeable or substitutable with other itraconazole products due to the differences in the dosing between Tolsura and other itraconazole products; OR
- If a new start, patient must have an inadequate response or intolerance to the generic itraconazole capsule.

ANTIFUNGALS: TOPICAL

Length of Authorization:	6 months or duration of therapy, LUZU initial and reauthorization: 2 weeks Ciclopirox 8% solution, Jublia and Kerydin: 48 weeks
Initiative:	MNC: Antifungals (IE 2462 / NCPDP 75)

STANDARD FORMULARY CRITERIA

JUBLIA, KERYDIN

- Diagnosis of onychomycosis of the toenail(s) due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*; **AND**
- For patients ages 6 years through 11 years, approve; **OR**
- For patients ages 12 years through 17 years:
  - Trial and failure of ciclopirox 8% nail lacquer for 48 weeks; **OR**
- For patients at least 18 years of age:
  - Patient has tried and failed to exhibit an adequate response to oral terbinafine (Lamisil®); **OR** has a clinical reason oral terbinafine cannot be used (document reason and forward to RPh for review); **AND**
  - Trial and failure of ciclopirox 8% nail lacquer for 48 weeks.

LUZU AND GENERIC LULICONAZOLE

- Diagnosis of interdigital tinea pedis, tinea cruris, and tinea corporis due to Trichophyton rubrum **or** Epidermophyton floccosum
- Patient is at least 12 years of age for tinea pedis and tinea cruris
- Patient is at least 2 years of age for tinea corporis
- Trial and failure of one generic topical antifungal
- Re-Authorization Duration: 2 weeks
- Criteria:
  - Must meet criteria above
  - The condition has not progressed or worsened while on therapy; **AND**
  - Has not developed any contraindications or other exclusions to its continued use.

EXELDERM, SULCONAZOLE NITRATE, NAFTIN, NAFTIFINE, OXISTAT, OXICONAZOLE, ECOZA, ERTACTZO

- The patient has failed a trial of one of the following: ciclopirox, clotrimazole, econazole, ketoconazole, luliconazole, or OTC antifungals (butenafine, miconazole, terbinafine, tolnaftate)
- Approve x 1 year

CLOTRIMAZOLE-BETAMETHASONE LOTION

- The patient has failed a trial of clotrimazole-betamethasone cream
- Approve x 1 year

LOPROX TOPICAL SUSPENSION

- The patient has failed a trial of generic ciclopirox suspension
- Approve x 1 year

EXTINA 2% FOAM

- The patient has failed a trial of generic ketoconazole foam, cream or shampoo
- Approve x 1 year

PRECISION FORMULARY CRITERIA

Length of Authorization:	LUZU and generic luliconazole, initial and reauth: 2 weeks
Initiative:	MNC: Antifungals (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

GENERIC LULICONAZOLE

- Diagnosis of interdigital tinea pedis, tinea cruris, and tinea corporis due to Trichophyton rubrum and Epidermophyton floccosum
- Patient is at least 12 years of age for tinea pedis and tinea cruris
- Patient is at least 2 years of age for tinea corporis
- Trial and failure of one generic topical antifungal
- Re-authorization duration: 2 weeks
- Criteria:
  - Must meet criteria above
  - The condition has not progressed or worsened while on therapy; **AND**
  - Has not developed any contraindications or other exclusions to its continued use.

KERYDIN

- Diagnosis of onychomycosis of the toenail(s) due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*; **AND**
- For patients ages 6 years through 11 years, approve; **OR**
- For patients ages 12 years through 17 years:
  - Trial and failure of ciclopirox 8% nail lacquer for 48 weeks; **OR**
- For patients at least 18 years of age:
  - Patient has tried and failed to exhibit an adequate response to oral terbinafine (Lamisil®); **OR** has a clinical reason oral terbinafine cannot be used (document reason and forward to RPh for review); **AND**
  - Trial and failure of ciclopirox 8% nail lacquer for 48 weeks

NAFTIN, OXICONAZOLE

- The patient has failed a trial of one of the following: ciclopirox, clotrimazole, econazole, ketoconazole, luliconazole, or OTC antifungals (butenafine, miconazole, terbinafine, tolnaftate)
- Approve x 1 year

ANTIHISTAMINE PRODUCTS

Length of Authorization:	1 year
Initiative:	MNC: Miscellaneous: PA required (IE 2462 / NCPDP 75, 50081 and 2193)

STEP CRITERIA (NO GRANDFATHERING)

RYVENT

- The patient has failed a trial of carbinoxamine or a preferred antihistamine (i.e., diphenhydramine, hydroxyzine, promethazine, cetirizine, fexofenadine, etc.).

CLINICAL CRITERIA FOR INITIAL APPROVAL

CLARINEX SYRUP

- The patient is unable to swallow tablets/capsules; **AND**
- The patient must not be currently taking any tablets/capsules (per claim history)

ANTIHYPERKINESIS MEDICATIONS (STIMULANTS AND RELATED MEDICATIONS)

Length of Authorization:	1 Year
Initiative:	MNC: CNS Stimulants (IE 2462 / NCPDP 75, 50081, 2194, and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

All agents except Vyvanse®, Nuvigil®, and Provigil®:

- Diagnosis of narcolepsy, ADHD, or ADD; **AND**
- Step criteria met below (if the medication requires step, please refer to formulary lookup for agents that require a step).

VYVANSE®:

- Diagnosis of narcolepsy, ADHD, or ADD; or binge-eating

NUVIGIL® (ARMODAFINIL) OR PROVIGIL® (MODAFINIL):

For Brand products, must have a trial and failure of its generic (for Nuvigil® – armodafinil, for Provigil® – modafinil)

- Diagnosis of narcolepsy; **OR**
- Diagnosis of obstructive sleep apnea- with CPAP; **OR**
- Diagnosis of shift work disorder; **OR**
- Diagnosis of hypersomnia, **OR**
- Diagnosis of fatigue related to cancer; **OR**
- Diagnosis of fatigue related to multiple sclerosis

For renewal:

- Patient continues to meet the above criteria; **AND**
- Patient has demonstrated clinical improvement or maintenance in response to treatment; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use.

SUNOSI (SOLRIAMFETOL)

INITIAL CRITERIA:

Diagnosis of Narcolepsy

- Diagnosis of narcolepsy as confirmed by sleep study (unless prescriber provides justification confirming that sleep study would not be feasible); **AND**
- **Both** of the following:
  - Trial and failure, contraindication, or intolerance to ONE of the following: generic modafinil OR armodafinil

  AND
  - **One** of the following:
    - Trial and failure, contraindication, or intolerance to amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate-based stimulant

      OR
    - History of or potential for substance use disorder

Diagnosis of Obstructive sleep apnea (OSA)

- Prescriber attestation that patient is compliant with and will continue using OSA therapy (e.g., PAP, oral appliance) or has a history of surgical intervention to treat underlying obstruction or rationale why they are not receiving OSA therapy; **AND**
- Prescriber has excluded any other identifiable causes for patient's sleepiness (e.g., non-compliance with PAP, improperly fitted PAP mask, insufficient sleep, poor sleep hygiene, depression, and/or other sleep disorders); **AND**
- Trial and failure, contraindication, or intolerance to ONE of the following: generic modafinil OR armodafini

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet the above criteria; **AND**
- Patient has demonstrated clinical improvement in response to treatment; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use

STEP CRITERIA

- There has been a therapeutic failure to at least **two** preferred CNS stimulants or related medications (that are generics [except Methylphenidate ER capsules] and Vyvanse®). Please refer to formulary lookup for agents that require a step.
- Exceptions:
  - Brand Intuniv®: Must try equivalent generic for at least 60-day supply.
  - Brand Strattera®: Must try equivalent generic for at least 60-day supply

ANTIMALARIALS

Length of Authorization:	1 Year
Initiative:	MNC: Antimalarials (IE 2462/NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

ATOVAQUONE/PROGUANIL (GENERIC FOR MALARONE)

- Diagnosis of Malaria (P. falciparum) or Prophylaxis of Malaria
  - The patient has had a trial and failure of chloroquine or the patient is resistant to chloroquine or is traveling to an area with known chloroquine resistance.

CLINICAL CRITERIA FOR INITIAL APPROVAL

QUALAQUIN (QUININE SULFATE)

- Diagnosis of Malaria (P. falciparum)
  - The patient has had a trial and failure of chloroquine or the patient is resistant to chloroquine or is traveling to an area with known chloroquine resistance.
- Diagnosis of **leg cramps**.

Technicians: Diagnosis is not approved by the FDA. Escalate to RPh for denial (risk of QT prolongation).

CLINICAL CRITERIA FOR INITIAL APPROVAL

MEPRON

- For the treatment **or** prevention of Pneumocystis jirovecii pneumonia (PCP):
  - Patient must be 13 years of and older; **AND**
  - Patient cannot tolerate trimethoprim-sulfamethoxazole
- For the treatment of **Babesiosis; AND**
  - Must be used in combination with azithromycin
- For the treatment **or** prevention of Toxoplasma encephalitis in HIV patients:
  - Patient cannot tolerate trimethoprim-sulfamethoxazole

CLINICAL CRITERIA FOR INITIAL APPROVAL

ARAKODA

- Patient is 18 years of age or older; **AND**
- Patient must have a need for malaria prophylaxis; **AND**
- Glucose-6-phosphate dehydrogenase (G6PD) deficiency or unknown G6PD status is a contraindication. Patient must be tested for G6PD deficiency prior to prescribing.
- **Note:** Pregnancy testing is recommended for females of reproductive potential prior to initiation.

ANTIMIGRAINE MEDICATIONS: TRIPTANS

Length of Authorization:	1 Year
Initiative:	MNC: Antimigraine Medications (IE 2462 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

- Patient must have had a trial and failure of **two** preferred agents in this class (i.e., Almotriptan, Naratriptan, Rizatriptan, Sumatriptan, Zolmitriptan, etc.)

ONZETRA XSAIL AND ZEMBRACE

- May be approved if the patient has tried two preferred triptans

CLINICAL CRITERIA FOR INITIAL APPROVAL

IMITREX INJECTABLE PRODUCTS (PLAN MAY REQUIRE A PA)

- The patient has failed an oral triptan first

MIGRANAL/DHE 45/DIHYDROERGOTAMINE

- Diagnosis of acute treatment of severe migraine headaches with or without aura; **OR**
- Diagnosis of Acute treatment of cluster headache episodes; **AND**
- Patient is 18 years or older; **AND**
- Must not be coadministered with potent CYP3A4 inhibitors (ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin, ketoconazole, itraconazole); **AND**
- Should not be used within 24 hours of a triptan (5-HT1 agonists), ergotamine-containing or ergot type medications or methysergide; **AND**
- Patient must **not** have any of the following:
  - Ischemic heart disease (angina pectoris, history of MI, documented silent ischemia)
  - Symptomatic coronary artery vasospasm (including Prinzmetal's variant angina),
  - Uncontrolled hypertension,
  - Peripheral arterial disease,
  - Sepsis,
  - Severe hepatic or renal impairment
  - Should not be administered to patients with hemiplegic or basilar migraine
  - Must not be pregnant; **AND**
- Patient must have had a trial and failure of **TWO** generic Triptans (5-HT1 agonists)

TREXIMET (BRAND ONLY)

- Patient is 12 years of age or older; **AND**
- Patient has a diagnosis of migraine with or without aura**; AND**
- May be approved if the patient has tried any preferred NSAID (e.g., ibuprofen, naproxen, etc.) **and** oral sumatriptan

QUANTITY LIMIT SPECIFIC CRITERIA

- Patient has a diagnosis of severe migraine headaches with or without aura; **OR**
- Patient has a diagnosis of cluster headaches (except Migranal); **AND**
- Prescribed by neurologist or pain management specialists; **AND**
- Patient is experiencing two or more headaches monthly; **AND**
- Currently receiving prophylactic therapy with at least one of the following:
  - Antidepressants (e.g., amitriptyline, venlafaxine IR/ER)
  - Antihistamines (e.g., cyproheptadine)
  - Antiepileptics (e.g., divalproex sodium, topiramate)
  - ACE inhibitors (e.g., lisinopril)
  - ARBs (e.g., candesartan)
  - Beta-blockers (e.g., propranolol, timolol, metoprolol)

ANTIPARASITICS

Length of Authorization:	1 month or length of therapy for parasite, eligible for renewal
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Albenza (and generic albendazole) will be approved for: Hydatid disease caused by *Echinococcus granulosus* and Neurocysticercosis caused by *Taenia solium*
- Stromectol (and generic ivermectin) will be approved for: intestinal (i.e., non-disseminated) strongyloidiasis due to nematode parasite, strongyloides stercoralis and onchocerciasis due to the nematode parasite Onchocerca volvulus
- Biltricide (and generic praziquantel) will be approved for infections caused by the following: all species of Schistosoma (e.g., Schistosoma mekongi, S. japonicum, S. mansoni, S. hematobium) and the liver flukes, Clonorchis sinensis/Opisthorchis viverrini, tape worms and cysticercoids

STEP CRITERIA: NATROBA, ULESFIA, EURAX, SKLICE, OVIDE (NO GRANDFATHERING)

- Patient has had a trial and failure of permethrin

ANTIPSYCHOTICS

Length of Authorization:	1 Year Injectables: initial 16 weeks, renewal see below Abilify MyCite: Initial: 30 days, Renewal: 30 days, not to exceed 90 days per calendar year
Initiative:	MNC: Antipsychotics (IE 2462 / NCPDP 75, 50081, and 2193)

PA required for patients under the **Age Edit** (override criteria below):

- Perphenazine/amitriptyline, loxapine, Adasuve®, Rexulti®, Clozaril®, Fazaclo®, Fanapt®, Vraylar®, Zyprexa Relprevv®, Geodon® (ziprasidone), Invega Sustenna®, Invega Trinza®, Risperdal Consta®, Abilify Maintena®, Aristada®, Aristada Initio®, Perseris™, Abilify MyCite®, Secuado®, Caplyta®
  - Not approvable for patients under the age of 18 years
- Zyprexa®, olanzapine
  - Not approvable for patients under the age of 13 years
- Invega®, paliperidone ER, perphenazine
  - Not approvable for patients under the age of 12 years
- Saphris®, Symbyax™, olanzapine/fluoxetine, Seroquel®, quetiapine, Seroquel® XR, quetiapine XR, Latuda®
  - Not approvable for patients under the age of 10 years
- Abilify®, aripiprazole, Abilify® injection
  - Not approvable for patients under the age of 6 years
- Risperdal®, risperidone
  - Not approvable for patients under the age of 5 years

AGE EDIT OVERRIDE CRITERIA

- Member has FDA-approved diagnosis for use; **AND**
  - Patient must have received developmentally-appropriate, comprehensive psychiatric assessment with diagnoses, impairments, treatment target and treatment plans clearly identified and documented; **AND**
- Dose is within FDA-approved range for use; **AND**
- Provider must be one of the following: psychiatrist, neurologist, developmental/behavioral pediatrician; **OR**
  - If not, provider must supply proof of a consultation or assessment by a psychiatrist, neurologist, or a developmental/behavioral pediatrician; **AND**
- Member must have tried therapy and/or behavior modification techniques; **AND**
- Baseline weight and metabolic labs (blood glucose/HgA1c, LDL) must be provided; **OR**
- May approve continuation of therapy without meeting above criteria –document pertinent clinical details and rationale for therapy; **OR**
- Approvable for continuation of therapy beginning during in-patient hospitalization.

Important Notes:

- Only approve one antipsychotic at a time. Exception: tapering off one agent while titrating another
- Labs needed should be cholesterol panel or LDL, HbA1c, or glucose
- For approval: Member meets FDA approved age for use **or** meets all the criteria above and has documented clinical justification for this drug

STEP CRITERIA—VRAYLAR®

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

Patient has tried a generic antipsychotic

STEP CRITERIA— CLOZARIL, FANAPT®, INVEGA, ZYPREXA ZYDIS

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

Patient has tried any TWO of the following: generic antipsychotics, Latuda, or Vraylar

STEP CRITERIA—ABILIFY, RISPERDAL, SAPHRIS, SECUADO, SEROQUEL, SEROQUEL XR, ZYPREXA

STANDARD FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

Patient has tried any TWO of the following: generic antipsychotics, Latuda, or Vraylar

STEP CRITERIA—GEODON

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

Patient has tried any TWO of the following: generic antipsychotics, Latuda, or Vraylar

ABILIFY MAINTENA®, ARISTADA®, ARISTADA INITIO®, INVEGA SUSTENNA®, INVEGA TRINZA®, PERSERIS™, RISPERDAL CONSTA®, ZYPREXA RELPREV®

INITIAL CRITERIA (APPROVAL IS 16 WEEKS)

- Patient has a diagnosis of schizophrenia (or bipolar disorder for Risperdal Consta® and Abilify Maintena®, or schizoaffective disorder for Invega Sustenna®); **AND**
- Patient must be at least 18 years of age; **AND**
- Patient has a documented history of receiving an oral atypical antipsychotic of the same chemical entity without experiencing any clinically significant side effects
- **Note:** For Invega Trinza® the patient must be established on Invega Sustenna® for at least 4 months with adequate response and acceptable tolerance

CLINICAL CRITERIA FOR RENEWAL (APPROVAL IS 12 MONTHS)

- The requested medication may be reauthorized for the FDA approved indication if use of the medication has clinically improved or stabilized the member and the member is successfully tolerating the medication
- If all of the above conditions are met, the request will be approved with 16-week duration; however, for patients stable on a dose (e.g., > 6 months) can be approved for 12-month duration

ABILIFY MYCITE®

- Patient must:
  - Be ≥ 18 years of age; **AND**
  - Have tolerability to oral aripiprazole with suboptimal effects (as assessed by prescriber) that may be due to adherence problems; **AND**
  - Have a smart phone compatible with the device or be enrolled in the manufacturer's loanable device program; **AND**
  - Give consent to a healthcare provider and caregiver (if applicable) to monitor the portal; **AND**
  - There is a documented intervention or intervention plan by prescriber if nonadherence is detected; **AND**
  - Patient has not received Abilify MyCite for ≥ 90 days/calendar year.

CLINICAL CRITERIA FOR RENEWAL

- Continue to meet initial criteria; **AND**
- Have prescriber attestation that patient benefited from therapy; **AND**
- Have prescriber attestation that there is a continued need for device (e.g., continued suboptimal effects and/or compliance); **AND**
- Have a healthcare provider and caregiver (if applicable) agree to continue to monitor device; **AND**
- Not have worsened target symptoms; **AND**
- Not have had any treatment-limited adverse effects (e.g., hypersensitivity, suicidality, neuroleptic malignant syndrome, tardive dyskinesia, metabolic changes, pathological gambling and other compulsive behaviors, orthostatic hypotension, falls, seizures, cognitive and motor impairment, dysphagia, disruption in body temperature regulation, and leukopenia, neutropenia, and agranulocytosis); **AND**
- Have a healthcare provider state reason why the patient cannot use long acting injectable atypical antipsychotic if there is continued nonadherence.

CAPLYTA®

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

- Patient is ≥ 18 years old; **AND**
- Patient must have a diagnosis of schizophrenia; **AND**
- Patient does not have dementia-related psychosis; **AND**
- Patient does **not** have moderate to severe hepatic impairment (Child-Pugh classes B or C); **AND**
- Patient is **not** taking any of the following drugs with clinically relevant interactions:
  - Cytochrome P450 3A4 (CYP3A4) inducers (e.g., carbamazepine, phenytoin, rifampin, efavirenz, etravirine, modafinil, armodafinil, pioglitazone, prednisone); **OR**
  - Moderate to strong CYP3A4 inhibitors (e.g., amprenavir, ciprofloxacin, cyclosporine, diltiazem, fluvoxamine, verapamil); **OR**
  - UGT inhibitors (e.g., valproic acid, probenecid); **AND**
- Patient has tried and failed or has a contraindication or intolerance to any TWO of the following: generic antipsychotics, Latuda, or Vraylar.

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet initial criteria; **AND**
- Patient is experiencing symptom improvement or maintenance; **AND**
- The patient is not experiencing any treatment-limiting adverse reactions of the medication

NUPLAZID®

- Patient has a diagnosis for Parkinson's disease psychosis; **AND**
- Diagnosis of psychosis was made after the Parkinson's disease diagnosis was established; **AND**
- Patient is 18 years of age or older; **AND**
- Trial of dose adjustment or withdrawal of antiparkinson medications (i.e., anticholinergics, amantadine, dopamine agonists, COMT inhibitors, selegiline) prior to treatment with Nuplazid®
- Medication is **not** covered for psychosis not related to Parkinson's disease

REXULTI®

- Patient has a diagnosis of schizophrenia or major depressive disorder with concurrent use of antidepressant therapy; **AND**
- Patient is 18 years of age or older; **AND**
- Does not have a diagnosis of dementia-related psychosis; **AND**
- Patient has failed a trial of aripiprazole and quetiapine

APOKYN® (APOMORPHINE)

Length of Authorization:	1 Year
Initiative:	SPC: Parkinson's Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of advanced Parkinson's disease for acute, intermittent treatment of hypomobility, 'off' episodes associated with advanced Parkinson's disease. Adjunct to other medications; **AND**
- Patient is unable to control "Off" symptoms with adequate combinations of convention oral therapy (e.g., Comtan® [entacapone], Mirapex® [pramipexole], Requip® [ropinirole], Sinemet® [carbidopa/levodopa], Stalevo® [carbidopa/levodopa/entacapone], Symmetrel® [amantadine], Tasmar® [tolcapone]); **AND**
- Used in combination with a non-5HT3 antagonists antiemetic (e.g., Tigan® (trimethobenzamide) 300 mg po TID for initial therapy; **AND**
- For intermittent subcutaneous injection only

CLINICAL CRITERIA FOR RENEWAL

- Patient is currently receiving Apokyn® via Magellan MRx Management benefit **or** member has previously met initial approval criteria and is continuing therapy; **AND**
- Patient is considered to have clinically meaningful response to treatment; **AND**
- Patient is free of unacceptable toxicity from the drug.

Note: Apokyn® is contraindicated with 5-HT3 antagonist (e.g., Aloxi® [palonosetron], Anzemet® [dolasetron], Kytril® [granisetron], Lotronex® [alosetron], and Zofran® [ondansetron]).

ARCALYST® (RILONACEPT)

Length of Authorization:	6 months and may be renewed
Initiative:	SPC: Immunomodulators: Systemic (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS)

- Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**
- Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., canakinumab, anakinra*, etc.) [***Note:** *For DIRA, anakinra must be discontinued 24 hours prior to starting Arcalyst*]; **AND**
- Patient is not on concurrent treatment with another TNF inhibitor, biologic response modifier or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib); **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient is at least 12 years of age; **AND**
- Used as a single agent; **AND**
- Patient has documented baseline serum levels of inflammatory proteins (C-Reactive Protein [CRP] and/or Serum Amyloid A [SAA], etc.); **AND**
- Patient has documented laboratory evidence of a genetic mutation in the Cold-Induced Auto-inflammatory Syndrome 1 (CIAS1), also known as NLRP3; **AND**
  - Documented diagnosis of Familial Cold Autoinflammatory Syndrome (FCAS); **OR**
  - Documented diagnosis of Muckle-Wells Syndrome (MWS); **AND**
- Patient has two or more of any of the CAPS-typical symptoms:
  - Urticaria-like rash
  - Cold-triggered episodes
  - Sensorineural hearing loss
  - Musculoskeletal symptoms
  - Chronic aseptic meningitis
  - Skeletal abnormalities

CLINICAL CRITERIA FOR INITIAL APPROVAL (CONTINUED)

Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

- Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment;; **AND**
- Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., canakinumab, anakinra*, etc.) [***Note:** *For DIRA, anakinra must be discontinued 24 hours prior to starting Arcalyst*]; **AND**
- Patient is not on concurrent treatment with another TNF inhibitor, biologic response modifier, or other non-biologic immunomodulating agent (e.g., apremilast, tofacitinib, baricitinib); **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient weighs at least 10 kg; **AND**
- Patient has a confirmed diagnosis of DIRA as evidenced by a mutation in the *IL1RN* gene; **AND**
- Used as maintenance of remission in patients who have previously experienced clinical benefit from anakinra therapy for the treatment of DIRA

Diagnosis of Recurrent Pericarditis (RP)

- Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment;; **AND**
- Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., canakinumab, anakinra*, etc.) [***Note:** *For DIRA, anakinra must be discontinued 24 hours prior to starting Arcalyst*]; **AND**
- Patient is not on concurrent treatment with another TNF inhibitor, biologic response modifier, or other non-biologic immunomodulating agent (e.g., apremilast, tofacitinib, baricitinib); **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient is at least 12 years of age; **AND**
- Used for the treatment of recurrent pericarditis and/or reducing the recurrence of disease; **AND**
- Patient has documented baseline serum levels of inflammatory proteins (C-Reactive Protein [CRP], etc.); **AND**
- Patient has failed standard therapy (e.g., NSAID, colchicine, corticosteroids, etc.)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, serious infections [including but not limited to tuberculosis], lipid profile changes); **AND**

Cryopyrin-Associated Periodic Syndromes

- Disease response as indicated by improvement in patient's symptoms from baseline AND improvement in serum levels of inflammatory proteins (e.g. CRP and/or SAA, etc.) from baseline

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

- Disease response as indicated by improvement in patient's symptoms (e.g., fever, skin rash, bone pain), inflammatory markers (e.g., CRP, ESR), and/or radiological evidence of active bone lesions compared to baseline

Recurrent Pericarditis (RP)

- Disease response as indicated by improvement in patient's symptoms (e.g., pericarditis pain, etc.), inflammatory markers (e.g., CRP, etc.), and/or decreased rate of recurrence of disease compared to baseline

ARIKAYCE® (AMIKACIN LIPOSOMAL INHALATION)

Length of Authorization:	Initial: 3 months, Renewal: 6 months
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of *Mycobacterium avium* complex (MAC) lung disease

- Patient is ≥ 18 years of age; **AND**
- Chest radiography or high-resolution computed tomography (HRCT) scan; **AND**
- At least 2 positive sputum cultures; **AND**
- Other conditions such as tuberculosis and lung malignancy have been ruled out; **AND**
- Patient has failed a multi-drug regimen with a macrolide (clarithromycin or azithromycin), rifampin, and ethambutol. (Failure is defined as continual positive sputum cultures for MAC while adhering to a multi-drug treatment regimen for a minimum duration of 6 months); **AND**
- Patient has documented failure or intolerance to aerosolized administration of amikacin solution for injection, including pretreatment with a bronchodilator; **AND**
- Arikayce will be prescribed in conjunction with a multi-drug antimycobacterial regimen

CLINICAL CRITERIA FOR RENEWAL

- Patient has demonstrated response to therapy with the addition of Arikayce, as defined as 3 consecutive monthly negative sputum cultures starting by month 6 of treatment; **AND**
- Patient has not experienced toxicity to amikacin treatment (e.g., ototoxicity, renal toxicity, neuromuscular blockade)

ARRANON® (NELARABINE)

Length of Authorization:	6 months and may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma (adult-young adult (AYA) and adults)**

- Patient is 18 years or older (unless otherwise specified); **AND**
  - Patient has not responded to or has relapsed following treatment with two or more chemotherapy regimens; **OR**
  - Used as consolidation therapy as a component of COG AALL0434 regimen (daunorubicin, vincristine, prednisone, and pegaspargase); **AND**
    - Patient is 15 years or older; **AND**
    - Patient is Philadelphia chromosome-negative; **OR**
  - Used for relapsed/refractory disease; **AND**
    - Patient has Philadelphia chromosome-negative disease; **AND**
      - Used as a single agent; **OR**
      - Used in combination with etoposide and cyclophosphamide; **OR**
    - Patient is Philadelphia chromosome-positive; **AND**
      - Patient is refractory to tyrosine kinase inhibitor therapy (e.g., imatinib, dasatinib, ponatinib, nilotinib, bosutinib); **AND**
        - Used as a single agent; **OR**
        - Used in combination with etoposide and cyclophosphamide

Diagnosis of **pediatric acute lymphoblastic leukemia**

- Patient is 1 year or older; **AND**
  - Patient has not responded to or has relapsed following treatment with two or more chemotherapy regimens (*Note: includes T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma*); **OR**
  - Used as consolidation therapy as a component of COG AALL0434 regimen (daunorubicin, vincristine, prednisone, and pegaspargase); **OR**
  - Used for relapsed or refractory disease in combination with etoposide and cyclophosphamide

CLINICAL CRITERIA FOR RENEWAL

- Disease stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular complete response), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH; **AND**
- Absence of unacceptable toxicity from the drug (e.g., any severe neurologic [central and/or peripheral] adverse reactions, severe anemia/leukopenia/anemia/thrombocytopenia, tumor lysis syndrome)

ARZERRA® (OFATUMUMAB)

Length of Authorization:	6 months, may be renewed • CLL/SLL (first-line) may be renewed to allow for a total of 12 cycles • CLL/SLL (relapsed or refractory) may not be renewed (unless the provisions for extended treatment have been met) • CLL/SLL (extended treatment) may be renewed to provide for a total of 2 years of therapy • NHL/FL may be renewed to provide up to a total of 8 doses • Waldenström's Macroglobulinemia/Lymphoplasmacytic lymphoma may be renewed to allow for up to a total of 3 cycles
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma** (SLL)

- Patient is 18 years or older; **AND**
- Patient must be screened for HBV infection (i.e., HBsAg and anti-HBc) prior to initiating therapy; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Used as first-line therapy in combination with chlorambucil; **OR**
- Used as first-line therapy in combination with bendamustine; **AND**
  - Patient does not have del(17p)/TP53 mutation; **AND**
  - Patient is not considered to be frail with significant comorbidities; **OR**
- Used for relapsed or refractory disease; **AND**
  - Used as a single agent; **OR**
  - Used in combination with fludarabine and cyclophosphamide (FC); **OR**
- Used as extended treatment in patients with complete or partial response after 2 or more lines of therapy; **AND**
  - Used as a single agent

Diagnosis of **B-Cell Lymphomas**

- Patient is 18 years or older; **AND**
- Patient must be screened for HBV infection (i.e., HBsAg and anti-HBc) prior to initiating therapy; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Used as a substitute for rituximab or obinutuzumab in patients experiencing rare complications such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient has any of the following:
  - Follicular Lymphoma (low grade 1-2)
  - MALT Lymphoma (Gastric or Non-Gastric)
  - Marginal Zone Lymphoma (Splenic or Nodal)
  - Diffuse Large B-Cell Lymphoma (DLBCL)
  - Histologic Transformation of Nodal Marginal Zone Lymphoma to DLBCL
  - Mantle Cell Lymphoma
  - High Grade B-Cell Lymphomas
  - Burkitt Lymphoma
  - AIDS Related B Cell Lymphomas
  - Post-Transplant Lymphoproliferative Disorders
  - Castleman's Disease

Diagnosis of **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma**

- Patient is 18 years or older; **AND**
- Patient must be screened for HBV infection (i.e., HBsAg and anti-HBc) prior to initiating therapy; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Used as a single agent OR as part of combination therapy; **AND**
- Patient is intolerant to rituximab; **AND**
  - Patient has previously failed primary therapy; **OR**
  - Patient has progressive or relapsed disease

CLINICAL CRITERIA FOR RENEWAL

Coverage can be renewed based upon the following criteria:

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hepatitis B virus reactivation/infection, progressive multifocal leukoencephalopathy, severe infusion reactions, tumor lysis syndrome, cytopenias [neutropenia, anemia, and thrombocytopenia])

ASPARLAS® (CALASPARGASE PEGOL-MKNL)

Length of Authorization:	6 months and may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 1 month to 21 years of age; **AND**
- Patient must not have a history of serious hypersensitivity reactions with pegylated L-asparaginase therapy; **AND**
- Patient must not have a history of serious hypersensitivity, pancreatitis, severe hepatic impairment, thrombosis, or hemorrhagic events with prior L-asparaginase therapy; **AND**
- Used as a component of a multi-agent chemotherapy regimen

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hypersensitivity reactions (including anaphylaxis), serious thrombotic events, hemorrhage, severe hepatotoxicity, pancreatitis, etc.; **AND**
- Disease stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular CR), complete hematologic response, or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

AVASTIN® (BEVACIZUMAB), MVASI™ (BEVACIZUMAB-AWWB), ZIRABEV™ (BEVACIZUMAB-BVZR)

Length of Authorization:	6 months, May be renewed. For CNS cancers (symptom management), coverage will be provided for 12 weeks and may **not** be renewed.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

STANDARD FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Avastin® - For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of either MVASI™ or Zirabev™

Note: For Core Formulary, all bevacizumab products are non-formulary.

Diagnosis of **Colorectal Cancer (CRC)**

- Patient is at least 18 years of age; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** any grade 3-4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Will not be used as part of adjuvant treatment; **AND**
  - Patient's disease is metastatic, unresectable, or advanced; **AND**
    - Used as first-line or subsequent therapy in combination with a fluoropyrimidine- (e.g., 5-fluorouracil/5-FU or capecitabine) or irinotecan-based regimen; **OR**
  - Used in combination with a fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based regimen (if not used first line) as second-line therapy for metastatic disease that has progressed on a first-line bevacizumab containing regimen; **OR**
  - Used in combination with trifluridine and tipiracil as subsequent therapy for advanced or metastatic disease after progression on all available regimens

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Non-Squamous Non-Small Cell Lung Cancer** (NSCLC):

- Patient is at least 18 years of age; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3-4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Used as first-line therapy for recurrent, locally advanced, unresectable, or metastatic disease in combination with carboplatin and paclitaxel; **OR**
- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **AND**:
    - Used for one of the following:
      - Patients with performance status (PS) ≤ 1 who have tumors that are negative for actionable molecular markers* and PD-L1 expression < 1%; **OR**
      - PD-L1 expression positive tumors (PD-L1 ≥ 1%) that are negative for actionable molecular markers*****; **OR**
      - Patients with PS ≤ 1 who are positive for one of the following molecular markers: BRAF V600E-mutation, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation, or RET rearrangement; **AND**
    - Used in combination with:
      - Pemetrexed and either carboplatin or cisplatin in patients with contraindications**¥** to PD-1 or PD-L1 inhibitors *(excluding use in patients with PD-L1 ≥ 1%)*; **OR**
      - Atezolizumab, carboplatin, and paclitaxel *(excluding use in patients with RET rearrangement positive tumors)*; **OR**
  - Used as subsequent therapy in patients with PS ≤ 1; **AND**
    - Used for one of the following:
      - EGFR (e.g., exon 19 deletion or L858R), ALK, or ROS1 positive tumors and prior targeted therapy; **OR**
      - BRAF V600E-mutation, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation, or RET rearrangement positive tumors; **OR**
      - PD-L1 expression-positive (PD-L1 ≥ 1%) tumors that are negative for actionable molecular markers ***** with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-doublet chemotherapy; **AND**
    - Used in combination with:
      - Carboplatin and paclitaxel in patients with contraindications**¥** to PD-1 or PD-L1 inhibitors; **OR**
      - Pemetrexed and either carboplatin or cisplatin in patients with contraindications**¥** to PD-1 or PD-L1 inhibitors; **OR**
      - Atezolizumab, carboplatin, and paclitaxel *(excluding use in patients who have received prior PD-1/PD-L1 inhibitor therapy or who have EGFR, ALK, and RET rearrangement positive tumors)*; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Non-Squamous Non-Small Cell Lung Cancer** (NSCLC) (continued):

- Used as continuation maintenance therapy (*bevacizumab must have been included in patient's first-line chemotherapy regimen*) in patients with PS ≤ 2 who achieved a tumor response or stable disease after first-line systemic therapy; **AND**
  - Used as a single agent; **OR**
  - Used in combination with pemetrexed following a first-line bevacizumab/pemetrexed/platinum chemotherapy regimen; **OR**
  - Used in combination with atezolizumab following a first-line atezolizumab/carboplatin/paclitaxel/bevacizumab regimen; **OR**
- Used in combination with erlotinib for sensitizing EGFR mutation positive disease (e.g., exon 19 deletion or L858R); **AND**
  - Used as first-line therapy; **OR**
  - Used as continuation of therapy following disease progression on erlotinib with bevacizumab for asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited metastases.

***** Note: Actionable molecular genomic biomarkers include EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, and RET rearrangement. If there is insufficient tissue to allow testing for all of EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET, and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*
¥ Note: Contraindications for treatment with PD-1/PD-L1 inhibitors may include active or previously documented auto-immune disease and/or current use of immunosuppressive agents, or presence of an oncogene (e.g., EGFR [exon 19 deletions, p.L858R point mutation in exon 21], ALK rearrangements, RET rearrangements), which would predict lack of benefit.

Diagnosis of **Cervical Cancer**:

- Patient is at least 18 years of age; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Used in combination with paclitaxel **and** either cisplatin, carboplatin, or topotecan; **AND**
- Patient has persistent, recurrent, or metastatic disease; **AND**
  - Patient's disease has adenocarcinoma, adenosquamous, or squamous cell carcinoma histology; **OR**
  - Used as second-line therapy for small cell neuroendocrine carcinoma of the cervix (NECC)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Breast Cancer:**

- Patient is at least 18 years of age; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Patient has recurrent unresectable or metastatic disease OR inflammatory disease with no response to preoperative systemic therapy; **AND**
- Patient has a high tumor burden, rapidly progressive disease and visceral crisis; **AND**
- Used in combination with paclitaxel; **AND**
- Patient must be human epidermal growth factor receptor 2 (HER2) negative; **AND**
  - Disease is hormone receptor negative; **OR**
  - Disease is hormone receptor positive with visceral crisis or refractory to endocrine therapy.

Diagnosis of **Renal Cell Carcinoma (RCC):**

- Patient is at least 18 years of age; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Used in combination with interferon alfa for metastatic disease; **OR**
- Patient must have metastatic or relapsed disease; **AND**
  - Used as a single agent in patients with non-clear cell histology; **OR**
  - Used in combination with everolimus in patients with non-clear cell histology; **OR**
  - Used in combination with erlotinib in patients with non-clear cell histology advanced papillary disease including hereditary leiomyomatosis and renal cell carcinoma (HLRCC).

Diagnosis of **Central Nervous System (CNS) Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Used for symptom management related to radiation necrosis, poorly controlled vasogenic edema or mass effect as single-agent short-course therapy**; AND**
- Patient has a diagnosis of one of the following other CNS cancers:
  - Low-Grade (WHO Grade 1 or 2) Glioma; **OR**
  - Primary CNS lymphoma; **OR**
  - Meningiomas**; OR**
  - Brain or spine metastases**; OR**
  - Medulloblastoma**; OR**
  - Glioblastoma; **OR**
  - Anaplastic gliomas**; OR**
  - Intracranial or spinal ependymoma (excluding subependymoma)**; OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Central Nervous System (CNS) Cancer** *(Continued)*

- Used as a single agent **or** in combination with one of the following: carmustine, lomustine, or temozolomide in patients with recurrent anaplastic gliomas or recurrent glioblastoma; **OR**
- Used as a single agent for progressive or recurrent intracranial and spinal ependymoma (excluding subependymoma) after prior radiation therapy; **OR**
- Used as a single agent for patients with surgically inaccessible recurrent or progressive meningioma when radiation is not possible.

Diagnosis of **Ovarian Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Patient has malignant stage II–IV granulosa cell sex cord-stromal tumors; **AND**
  - Used as single agent therapy for relapsed disease; **OR**
- Patient has epithelial ovarian or fallopian tube or primary peritoneal cancer; **AND**
  - Patient has persistent or recurrent disease; **AND**
    - Bevacizumab has not been used previously; **AND**
    - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **AND**
      - Patient has platinum sensitive disease; **AND**
        - Used as a single agent; **OR**
        - Used in combination niraparib; **OR**
        - Used in combination with carboplatin **and** either gemcitabine, paclitaxel**,** or PEGylated liposomal-doxorubicin; **OR**
      - Patient has platinum resistant disease; **AND**
        - Used as a single agent; **OR**
        - Used in combination with one of the following: oral cyclophosphamide, PEGylated liposomal doxorubicin, paclitaxel, or topotecan; **OR**
  - Used in combination with paclitaxel and carboplatin for rising CA-125 levels or clinical relapse in patients who have received no prior chemotherapy; **OR**
  - Used as maintenance therapy; **AND**
    - Used following primary therapy including bevacizumab; **AND**
      - Used as a single agent in patients that are BRCA1/2 wild-type or unknown and homologous recombination (HR) proficient or status unknown; **OR**
      - Used in combination with olaparib; **AND**
        - Patient is BRCA1/2 wild-type or unknown and HR deficient; **OR**
        - Patient has a germline or somatic BRCA1/2 mutation; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Ovarian Cancer** *(Continued)*

- Used as a single agent following recurrence therapy with chemotherapy plus bevacizumab for platinum-sensitive disease; **OR**
- Used in combination with paclitaxel and carboplatin for stable disease following neoadjuvant therapy as continued maintenance therapy; **OR**
- Used as neoadjuvant therapy for endometrioid or serous histology in combination with paclitaxel and carboplatin; **AND**
  - Patient is a poor surgical candidate or has a low likelihood of optimal cytoreduction; **OR**
- Used as adjuvant therapy in combination with paclitaxel and carboplatin; **AND**
  - Patient has pathologic stage II–IV disease; **OR**
  - Patient is a poor surgical candidate or has a low likelihood of optimal cytoreduction; **AND**
    - Patient has endometrioid or serous histology; **AND**
    - Used after interval debulking surgery (IDS) in patients with a response or stable disease to neoadjuvant therapy.

Diagnosis of **Soft Tissue Sarcoma**:

- Patient is at least 18 years of age; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Used as a single agent for angiosarcoma; **OR**
- Used in combination with temozolomide for solitary fibrous tumor

Diagnosis of **Endometrial Carcinoma (Uterine Neoplasms)**:

- Patient is at least 18 years of age; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Used as single agent therapy for disease that has progressed on prior cytotoxic chemotherapy; **OR**
- Used in combination with carboplatin and paclitaxel for advanced and recurrent disease.

Diagnosis of **Malignant Pleural* Mesothelioma (MPM):**

- Patient is at least 18 years of age; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Patient has unresectable disease OR clinical stage IIIB or IV disease, sarcomatoid, or medically inoperable tumors; **AND**
- Used in combination with pemetrexed and cisplatin or carboplatin as first-line therapy, followed by single-agent maintenance bevacizumab

*peritoneal, pericardial, and tunica vaginalis testis mesothelioma will be evaluated on a case-by-case basis

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Vulvar Cancer**:

- Patient is at least 18 years of age; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Used in combination with paclitaxel and cisplatin for squamous cell carcinoma; **AND**
- Patient has unresectable locally advanced, metastatic, or recurrent disease.

Diagnosis of **Small Bowel Adenocarcinoma/Advanced Ampullary Cancer**:

- Patient is at least 18 years of age; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Patient has advanced or metastatic disease; **AND**
- Used in combination with a fluoropyrimidine-based regimen
  - Used as initial therapy; **OR**
  - Used as subsequent therapy after prior initial therapy with nivolumab or pembrolizumab

Diagnosis of **Hepatocellular Carcinoma (HCC)**:

- Patient is at least 18 years of age; **AND**
- Patient has no recent history of hemoptysis (i.e., the presence of ≥ 2.5 mL of blood in sputum) **or** grade 3–4 hemorrhage; **AND**
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**
- Used as first-line therapy in combination with atezolizumab; **AND**
- Patient has Child-Pugh Class A disease **; AND**
- Patient has unresectable or metastatic disease, inoperable (*e.g., by performance status, comorbidity or with minimal or uncertain extrahepatic-disease*) liver-confined disease, or extensive liver tumor burden

For ophthalmic use, refer to ophthalmics: specialty section.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., gastrointestinal perforations and fistulae, surgical/wound healing complications, hemorrhage, arterial and venous thromboembolic events [ATE & VTE], uncontrolled hypertension, posterior reversible encephalopathy syndrome [PRES], nephrotic syndrome, proteinuria, severe infusion reactions, ovarian failure, congestive heart failure [CHF])

DIAGNOSIS-SPECIFIC CLINICAL CRITERIA FOR RENEWAL

CNS cancers – symptom management (short-course therapy):

- May not be renewed

Colorectal Cancer (after first-line bevacizumab-containing regimen):

- Refer to initial criteria

Malignant Mesothelioma – (maintenance therapy):

- Refer to initial criteria

Non-Squamous Non-Small Cell Lung Cancer (maintenance therapy OR continuation therapy in combination with erlotinib):

- Refer to initial criteria

Ovarian Cancer (maintenance therapy):

- Refer to initial criteria

AVEED® (TESTOSTERONE UNDECANOATE)

Length of Authorization:	6 months, renewal 12 months
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Primary or Secondary (hypogonadotropic) hypogonadism in males**

- Patient is at least 18 years of age; **AND**
- The prescriber is enrolled in the AVEED REMS Program; **AND**
- Patient does not have carcinoma of the breast or known or suspected carcinoma of the prostate; **AND**
- Patient does not have a prostate specific antigen (PSA) level of > 4.0 ng/mL; **AND**
- Prescribed by, or in consultation with, an endocrinologist or urologist; **AND**
- The patient will be receiving only one androgen or anabolic agent; **AND**
- Patient does not have "age-related hypogonadism"; **AND**
- Patient PSA, hemoglobin, hematocrit, and lipid concentrations are measured at baseline and monitored periodically, during treatment; **AND**
- Pre-treatment morning total testosterone of less than 300 ng/dL (or below lower limit of normal by the testing laboratory); **AND**
- Patient has signs and symptoms consistent with hypogonadism (e.g., low libido, decreased morning erections, loss of body hair, low bone mineral density, gynecomastia, small testes, etc.); **AND**
- Diagnosis is confirmed by one of the following:
  - Repeat morning total testosterone test (as above); **OR**
  - Pre-treatment free testosterone of less than 50 pg/mL (or below lower limit of normal by the testing laboratory); **AND**
- Patient had an inadequate response (or contraindication or intolerance) to a 3 or more-month trial with a topical agent such as testosterone gel, testosterone patch, bio-adhesive buccal testosterone, testosterone nasal gel, testosterone topical solution, etc.; **AND**
- Patient had an inadequate response (or contraindication or intolerance) to a 3 or more-month trial with an alternative injectable agent (i.e., testosterone cypionate or testosterone enanthate)

Primary hypogonadism	Secondary (hypogonadotropic) hypogonadism
• Testicular failure due to cryptorchidism • Bilateral torsion • Orchitis • Vanishing testes syndrome • Orchiectomy • Klinefelter's Syndrome • Chemotherapy • Toxic damage from alcohol or heavy metals.	• Gonadotropic or LHRH deficiency • Pituitary hypothalamic injury due to trauma, radiation, or tumor

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: serious pulmonary oil microembolism (POME) reactions, prostatic hypertrophy/carcinoma, polycythemia, venous thromboembolism, azoospermia, myocardial infarction and stroke, edema with/without congestive heart failure in those with preexisting cardiac/renal/hepatic disease, hepatic dysfunction (e.g., jaundice), sleep apnea, severe changes in lipid profile, hypercalcemia, signs of abuse or dependence, etc.; **AND**
- Patient's testosterone levels (within the preceding 28 days) do not exceed the upper limit of the normal range for the testing laboratory (generally mid-range is targeted); **AND**
- Patient has an improvement in signs and symptoms; **AND**
- Patient has not had a PSA increase of > 1.4 ng/mL above baseline or an absolute level > 4.0 ng/mL

AYVAKIT® (AVAPRITINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is 18 years of age or older; **AND**
- Used as a single agent; **AND**
- Patient will avoid concomitant use with moderate or strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, bosentan, etc.); **AND**
- Patient will avoid concomitant use with moderate or strong CYP3A inhibitors (e.g., itraconazole, fluconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient's BCR-ABL KD mutational analysis contains the presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutations; **AND**
  - Patient has the presence of a D842V mutation in the PDGFRA gene; **AND**
    - Patient has unresectable or metastatic disease; **OR**
    - Used as primary treatment for recurrent disease; **OR**
    - Used for persistent microscopic residual disease (R1 resection) or gross residual disease (R2 resection); **OR**
    - Used as continued treatment for limited progression ; **OR**
    - Patient's PDGFRA exon 18 mutations are insensitive to imatinib; **AND**
      - Used as neoadjuvant treatment for resectable disease with significant morbidity; **OR**
      - Used as primary treatment for resectable disease with significant morbidity; **OR**
  - Patient has unresectable, recurrent, or metastatic disease; **AND**
    - Disease has progressed on prior treatment with a 3-month or longer trial of at least ONE of the following: imatinib, regorafenib, sunitinib, sorafenib, nilotinib, dasatinib, or pazopanib.

Diagnosis of **Advanced Systemic Mastocytosis (AdvSM)**

- Patient is 18 years of age or older; **AND**
- Used as a single agent; **AND**
- Patient will avoid concomitant use with moderate or strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, bosentan, etc.); **AND**
- Patient will avoid concomitant use with moderate or strong CYP3A inhibitors (e.g., itraconazole, fluconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has a confirmed diagnosis of one of the following: aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL); **AND**
- Patient has a platelet count ≥ 50 X 10^9/L obtained within the last 4 weeks and is not receiving platelet transfusions

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**

- Patient is 18 years of age or older; **AND**
- Used as a single agent; **AND**
- Patient will avoid concomitant use with moderate or strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, bosentan, etc.); **AND**
- Patient will avoid concomitant use with moderate or strong CYP3A inhibitors (e.g., itraconazole, fluconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has eosinophilia and FIP1L1-PDGFRA gene rearrangement; **AND**
- Patient has the presence of a D842V mutation in the PDGFRA gene that is resistant to imatinib

CLINICAL CRITERIA FOR RENEWAL

Coverage can be renewed based upon the following criteria:

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include serious intracranial hemorrhages, cognitive effects, etc.; **AND**

Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes only

- Disease response as evidenced by at least one of the following:
  - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
  - Stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

Gastrointestinal Stromal Tumors (GIST) only

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread.

Advanced Systemic Mastocytosis (AdvSM) only

- Disease stabilization or improvement as evidenced by a complete remission, partial remission, or clinical improvement shown by bone marrow biopsy, extracutaneous organ biopsy, serum tryptase level, CBC, or resolution of organ damage

AZEDRA® (IOBENGUANE I-131) IV

Length of Authorization:	6 months (3 doses only, one imaging dosimetric dose followed by two therapeutic doses at least 90 days apart), may **not** be renewed
Initiative:	SPC: Oncology agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Pheochromocytoma/Paraganglioma**

- Patient is at least 12 years old; **AND**
- Patient has a negative pregnancy test (in females of reproductive potential); **AND**
- Patient's disease is iobenguane scan-positive (e.g., on CT-scan or MRI) in at least one tumor site**; AND**
- Patient is receiving appropriate thyroid blockade (i.e., inorganic iodine) starting at least 24 hours before and continuing for 10 days after each Azedra dose**; AND**
- Patient has not received any form of radiation therapy, including systemic radiotherapy, whole-body radiation or external beam radiotherapy to > 25% of bone marrow; **AND**
- Patient has locally advanced, unresectable or metastatic disease; **AND**
- Patient's disease requires systemic chemotherapy; **AND**
- Patient has failed prior therapy for pheochromocytoma/paraganglioma or are not candidates for chemotherapy or other curative therapies; **AND**
- Patient has a life expectancy of at least 6 months; **AND**
- Patient has a Karnofsky Performance Status score ≥ 60; **AND**
- Patient does not have uncontrolled/unstable hypertension.

RENEWAL CRITERIA

May not be renewed

BALVERSA® (ERDAFITINIB)

Length of Authorization:	6 months, and renewable
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Bladder Cancer/Urothelial Carcinoma**

- Patient must be at least 18 years old; **AND**
- Patient has had a baseline serum phosphate level measurement and it is within normal limits; **AND**
- Patient has received ophthalmological examinations (i.e., assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography) at baseline and will be examined periodically throughout therapy; **AND**
- Patient phosphate intake is restricted to less than 800 mg per day; **AND**
- Patient will avoid concomitant use with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will implemented:
  - Moderate CYP2C9 inhibitors (e.g., amiodarone, fluvoxamine, miconazole, etc.)
  - Strong CYP3A4 inhibitors (e.g., clarithromycin, cobicistat, ketoconazole, etc.)
  - Moderate CYP2C9 or CYP3A4 inducers (e.g., carbamazepine, rifampin, bosentan, modafinil, etc.); **AND**
- Patient will not be on concomitant therapy with any of the following:
  - Strong CYP2C9 or CYP3A4 inducers (e.g., rifampicin)
  - Serum phosphate level-altering agents before the initial dose increase period based on serum phosphate levels (e.g., potassium phosphate supplements, vitamin D supplements, antacids, phosphate-containing enemas or laxatives, certain medications); **AND**
- Must be used as a single agent; **AND**
- Patient has a susceptible gene mutation or fusions in the FGFR-2 or FGFR-3 (fibroblast growth factor receptor) gene, as determined by an FDA-approved or CLIA-compliant test; **AND**
- Patient has one of the following diagnoses:
  - Locally advanced or metastatic urothelial carcinoma; **OR**
  - Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder; **OR**
  - Metastatic or local bladder cancer recurrence post-cystectomy; **OR**
  - Metastatic upper genitourinary tract tumors; **OR**
  - Metastatic urothelial carcinoma of the prostate; **OR**
  - Metastatic or recurrent primary carcinoma of the urethra; **AND**
    - Patient does not have recurrence of stage T3-4 disease or palpable inguinal lymph nodes; **AND**
- Used as subsequent therapy after first-line platinum-containing chemotherapy followed by avelumab maintenance therapy; **OR**

- Used as second-line therapy after one of the following:
  - After at least one prior line of platinum-containing chemotherapy*; **OR**
  - After at least one prior line of checkpoint inhibitor-containing chemotherapy; **OR**
  - After first-line therapy other than platinum or an immune checkpoint inhibitor

*** Note:**

- If platinum treatment occurred greater than 12 months ago, the patient should be re-treated with platinum-based therapy if the patient is still platinum eligible (see below for cisplatin- or carboplatin-ineligible comorbidities).
  - Cisplatin-ineligible comorbidities may include GFR < 60 mL/min, PS ≥ 2, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, or grades ≥ 2 peripheral neuropathy. Carboplatin may be substituted for cisplatin particularly in those patients with a GFR <60 mL/min or a PS of 2.
  - Carboplatin-ineligible comorbidities may include CrCl < 30 mL/min, PS ≥ 3, grade ≥ 3 peripheral neuropathy, or NYHA class ≥ 3.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., central serous retinopathy/retinal pigment epithelial detachment [CSR/RPED], severe hyperphosphatemia); **AND**
- Patient serum phosphate level is < 7.0 mg/dL

BAVENCIO® (AVELUMAB)

Length of Authorization:	6 months, and renewable
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Merkel Cell Carcinoma (MCC)**

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, dostarlimab, atezolizumab, durvalumab, cemiplimab) unless otherwise specified; **AND**
- Patient is at least 12 years of age; **AND**
- Used as a single agent**; AND**
- Patient has metastatic or recurrent disseminated disease.

Diagnosis of **Urothelial Carcinoma (bladder cancer)**

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, dostarlimab, atezolizumab, durvalumab, cemiplimab) unless otherwise specified; **AND**
- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
  - Used as subsequent therapy after previous platinum* or other treatment; **AND**
    - Patient has a diagnosis of **one** of the following:
      - Locally advanced or metastatic urothelial carcinoma; **OR**
      - Local muscle invasive bladder cancer recurrence or persistent disease in a preserved bladder; **OR**
      - Local or metastatic bladder cancer recurrence post-cystectomy; **OR**
      - Metastatic upper genitourinary (GU) tract tumors; **OR**
      - Metastatic urothelial carcinoma of the prostate; **OR**
      - Recurrent or metastatic primary carcinoma of the urethra; **AND**
        - Patient does not have recurrent stage T3-4 disease or palpable inguinal lymph node; **OR**
  - Used as first-line maintenance treatment; **AND**
    - Patient has locally advanced or metastatic urothelial carcinoma (inclusive of the bladder, upper GU tract, urethra, and/or prostate); **AND**
    - Patient has not progressed with first-line platinum-containing chemotherapy

*** Note:**

- *If patient was progression-free for > 12 months after platinum therapy, consider re-treatment with platinum-based therapy if the patient is still platinum eligible (see below for cisplatin- or carboplatin-ineligible comorbidities).*
  - *Cisplatin-ineligible comorbidities may include the following: CrCl < 60 mL/min, PS ≥ 2, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, grade ≥ 2 peripheral neuropathy, or NYHA class ≥ 3. Carboplatin may be substituted for cisplatin particularly in those patients with a CrCl < 60 mL/min or a PS of 2.*
  - *Carboplatin-ineligible comorbidities may include the following: CrCl < 30 mL/min, PS > 3, grade > 3 peripheral neuropathy, or NYHA class > 3, etc.*

Diagnosis of **Renal Cell Carcinoma**

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, dostarlimab, atezolizumab, durvalumab, cemiplimab) unless otherwise specified; **AND**
- Patient is at least 18 years of age; **AND**
- Used in combination with axitinib; **AND**
- Used as first line therapy; **AND**
- Used for the treatment of advanced, relapsed, or stage IV disease with clear cell histology

Diagnosis of **Gestational Trophoblastic Neoplasia**

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, dostarlimab, atezolizumab, durvalumab, cemiplimab) unless otherwise specified; **AND**
- Patient is at least 18 years of age; **AND**
- Used as single-agent therapy for multiagent chemotherapy resistant disease; **AND**
  - Patient has intermediate placental site trophoblastic tumor (PSTT) or epithelioid trophoblastic tumor (ETT); **AND**
    - Patient has recurrent or progressive disease; **AND**
    - Patient was previously treated with a platinum/etoposide-containing regimen; **OR**
  - Patient has high-risk disease (i.e., prognostic score ≥ 7 **OR** FIGO stage IV disease)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe infusion reactions, hepatotoxicity, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatitis/skin adverse reactions), major adverse cardiovascular events (MACE) when used in combination with axitinib, etc.

BELEODAQ® (BELINOSTAT)

Length of Authorization:	6 months, and renewable
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

T-CELL LYMPHOMAS

Diagnosis of **Peripheral T-Cell Lymphoma (PTCL)** (Including: Angioimmunoblastic T-cell lymphoma; peripheral T-cell lymphoma not otherwise specified, Anaplastic large cell lymphoma; enteropathy-associated T-cell lymphoma; Monomorphic epitheliotropic intestinal T-cell lymphoma; Nodal peripheral T-cell lymphoma with TFH phenotype; or Follicular T-cell lymphoma)

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Used as subsequent therapy for relapsed or refractory disease; **OR**
- Used as initial palliative intent therapy in transplant ineligible patients

Diagnosis of **Adult T-Cell Leukemia/Lymphoma**

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Used as subsequent therapy for non-responders to first-line therapy for acute or lymphoma subtypes.

Diagnosis of **Extranodal NK/T-Cell Lymphoma (nasal type)**

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Patient has relapsed or refractory disease; **AND**
- Patient has previously received at least 2 different prior lines of therapy including an asparaginase based combination chemotherapy regimen.

Diagnosis of **Hepatosplenic Gamma-Delta T-cell Lymphoma**

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Used as subsequent therapy for refractory disease after two first-line therapy regimens.

Diagnosis of **Breast Implant-Associated Anaplastic Large Cell Lymphoma (ALCL)**

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Used as subsequent therapy for relapsed or refractory disease

Diagnosis of **Primary Cutaneous Lymphomas**

- Mycosis fungoides (MF)/Sézary syndrome; **AND**
  - Patient is at least 18 years of age; **AND**
  - Used as a single agent; **AND**
  - Patient has relapsed, persistent, or refractory disease; **OR**
  - Used as primary treatment for stage IV non Sézary or visceral disease (solid organ): **OR**
  - Used as primary treatment for large cell transformation (LCT) with generalized cutaneous or extra-cutaneous lesions
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders; **AND**
  - Patient is at least 18 years of age; **AND**
  - Used as a single agent; **AND**
  - Patient has relapsed or refractory disease; **AND**
    - Patient has primary cutaneous anaplastic large cell lymphoma (pcALCL) with multifocal lesions; **OR**
    - Patient has cutaneous ALCL with regional nodes (excludes systemic ALCL).

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hematologic toxicity [e.g., thrombocytopenia, leukopenia, and/or anemia], severe infections, hepatotoxicity, tumor lysis syndrome, severe gastrointestinal toxicity)

BENDAMUSTINE (TREANDA®, BENDEKA™, BELRAPZO™)

Length of Authorization:	• Non-Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL), Waldenström's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL), Classic Hodgkin Lymphoma (cHL): 6 months; may **not** be renewed • Multiple Myeloma: Coverage will be provided for eight months and may NOT be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Hodgkin's Lymphoma (NHL):**

- Patient is at least 18 years of age; **AND**
- Patient must not have received bendamustine in a previous line of therapy; **AND**
- Coverage is provided for B-cell lymphomas when:
  - Used as subsequent therapy; **AND**
    - In combination with rituximab for:
      - AIDS-related B-cell lymphomas (i.e., DLBCL, primary effusion, HHV8-positive DLBCL, NOS)
      - Follicular lymphoma
      - Gastric MALT lymphoma
      - High-grade B-cell lymphomas
      - Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma (DLBCL) after 2 or more prior therapies
      - Mantle cell lymphoma
      - Nodal marginal zone lymphoma
      - Non-gastric MALT lymphoma
      - Monomorphic post-transplant lymphoproliferative disorder (B-cell type)
      - Splenic marginal zone lymphoma; **OR**
    - Used as a single agent for:
      - AIDS-related B-cell lymphomas (i.e., DLBCL, primary effusion, HHV8-positive DLBCL, and NOS, or plasmablastic lymphomas in non-candidates for transplant)
      - Follicular lymphoma
      - Histologic transformation of follicular lymphoma to DLBCL without translocations of MYC and BCL2 and/or BCL6 after 2 or more prior therapies
      - High-grade B-cell lymphomas
      - Histologic transformation of nodal marginal zone lymphoma to DLBCL after 2 or more prior therapies
      - Monomorphic post-transplant lymphoproliferative disorder (B-cell type); **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL (CONTINUED)

- In combination with obinutuzumab for:
  - Follicular lymphoma
  - Gastric MALT lymphoma
  - Non-gastric MALT lymphoma
  - Nodal marginal zone lymphoma
  - Splenic marginal zone lymphoma; **OR**
- In combination with polatuzumab after 2 or more prior therapies for:
  - Histologic transformation of follicular lymphoma to DLBCL without translocations of MYC and BCL2 and/or BCL6
  - Follicular lymphoma
  - Histologic transformation of nodal marginal zone lymphoma to DLBCL
  - Monomorphic post-transplant lymphoproliferative disorder (B-cell type); **OR**
- In combination with polatuzumab for:
  - Histologic transformation of follicular lymphoma to DLBCL without translocations of MYC and BCL2 and/or BCL6 in patient who have received minimal or no chemotherapy prior to histologic transformation and have no response or progressive disease after chemoimmunotherapy
  - Follicular Lymphoma
  - AIDS-Related B-Cell Lymphomas (i.e., DLBCL, primary effusion, HHV8-positive DLBCL, NOS, or plasmablastic lymphomas in non-candidates for transplant)
  - DLBCL
  - High-grade B-cell Lymphomas; **OR**

– Used as first-line therapy; **AND**
- In combination with rituximab for:
  - Follicular lymphoma
  - Gastric MALT lymphoma
  - Mantle cell Lymphoma
  - Nodal marginal zone lymphoma
  - Non-gastric MALT lymphoma
  - Splenic marginal zone lymphoma; **OR**
- In combination with obinutuzumab for:
  - Follicular lymphoma
  - Nodal Marginal Zone Lymphoma

CLINICAL CRITERIA FOR INITIAL APPROVAL (CONTINUED)

- Coverage is provided for the following T-cell lymphomas:
  - Adult T-cell leukemia/lymphoma
    - Used as subsequent therapy for non-responders to first-line therapy as a single agent for acute or lymphoma subtypes
  - Peripheral T-cell lymphoma *(includes anaplastic large cell, peripheral T-cell not otherwise specified, angioimmunoblastic T-cell, enteropathy-associated T-cell, monomorphic epitheliotropic intestinal T-cell, nodal peripheral T-cell with TFH phenotype, or follicular T-cell lymphomas)*
    - Used as a single agent; AND
      - Used as subsequent therapy for relapsed or refractory disease; **OR**
      - Used as initial palliative intent therapy in transplant ineligible patients
  - Mycosis fungoides (MF)/Sézary syndrome (SS)
    - Used as a single agent; **AND**
      - Used as systemic therapy, as primary treatment (excluding Sézary syndrome); **OR**
      - Used for relapsed, persistent, or refractory disease
  - Primary cutaneous CD30+ T-cell lymphoproliferative disorders
    - Used as a single agent for relapsed or refractory disease; **AND**
      - Patient has primary cutaneous anaplastic large cell lymphoma (pcALCL) with multifocal lesions; **OR**
      - Patient has cutaneous ALCL with regional nodes (excludes systemic ALCL)
  - Hepatosplenic gamma-delta T-cell lymphoma
    - Used as subsequent therapy as a single agent for refractory disease after two first-line therapy regimens
  - Breast Implant-Associated Anaplastic Large Cell Lymphoma (ALCL)
    - Used as subsequent therapy as a single agent for relapsed or refractory disease

Diagnosis of **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)**

- Patient is at least 18 years of age; **AND**
- Patient must not have received bendamustine in a previous line of therapy; **AND**
- Used as first-line therapy; **AND**
  - Used as a single agent**; OR**
  - Used in combination with a CD20-directed agent (i.e., rituximab, ofatumumab, obinutuzumab, etc.) for disease without del(17p)/TP53 mutations *(excluding use in frail patients[i.e., not able to tolerate purine analogs])*; **OR**
- Used as subsequent therapy in combination with rituximab for disease without del(17p)/TP53 mutations in patients < 65 years without significant comorbidities.

Diagnosis of **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL)**

- Patient is at least 18 years of age; **AND**
- Patient must not have received bendamustine in a previous line of therapy; **AND**
- Used as a single agent; **OR**
- Used in combination with rituximab.

CLINICAL CRITERIA FOR INITIAL APPROVAL (CONTINUED)

Diagnosis of **Adult Hodgkin Lymphoma(cHL)**

- Patient is at least 18 years of age; **AND**
- Patient must not have received bendamustine in a previous line of therapy; **AND**
- Patient has classic Hodgkin Lymphoma; **AND**
  - Used as second-line or subsequent therapy for relapsed or refractory disease; **AND**
    - Used in combination with gemcitabine and vinorelbine; **OR**
    - Used in combination with brentuximab vedotin; **OR**
  - Used as third-line or subsequent therapy for relapsed or refractory disease; **AND**
    - Used as a single agent; **OR**
    - Used in combination with carboplatin and etoposide; **OR**
  - Used as palliative therapy as a single agent for relapsed or refractory disease in patients > 60 years old

Diagnosis of **Pediatric Hodgkin Lymphoma (pHL)**

- Patient is 18 or younger*; **AND**
- Patient must not have received bendamustine in a previous line of therapy; **AND**
- Used as re-induction therapy or subsequent therapy (if not previously used) for relapsed or refractory disease; **AND**
- Used in combination with brentuximab vedotin

* Pediatric Hodgkin Lymphoma may be applicable to adolescent and young adult (AYA) patients up to the age of 39 years.

Diagnosis **of Multiple Myeloma**

- Patient is at least 18 years of age; **AND**
- Patient must not have received bendamustine in a previous line of therapy; **AND**
- Used for relapsed or progressive disease; **AND**
  - Used as a single agent; **OR**
  - Used in combination with dexamethasone and either lenalidomide or bortezomib

CLINICAL CRITERIA FOR RENEWAL

- May **not** be renewed.

BESPONSA® (INOTUZUMAB OZOGAMICIN)

Length of Authorization:	Coverage will be provided for 6 months (for up to a maximum of 6 cycles) and may not be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Adult B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)**

- Baseline electrocardiogram (ECG) is within normal limits; **AND**
- Patient has not previously received inotuzumab ozogamicin; **AND**
- Patient is at least 18 years of age; **AND**
- Patient has CD22-positive disease; **AND**
- Patient has relapsed or refractory disease; **AND**
  - Used as single agent therapy or in combination with mini-hyper CVD (cyclophosphamide, dexamethasone, vincristine, methotrexate, cytarabine); **AND**
    - Patient is Philadelphia chromosome (Ph)-negative; **OR**
    - Patient is Philadelphia chromosome (Ph)-positive and is intolerant or refractory to prior tyrosine kinase inhibitor therapy (e.g., imatinib, dasatinib, ponatinib, nilotinib, bosutinib, etc.); **OR**
  - Used in combination with bosutinib; **AND**
    - Patient is Philadelphia chromosome (Ph)-positive; **OR**
  - Used as induction therapy in patients ≥ 65 years of age or with substantial comorbidities; **AND**
    - Used in combination with mini-hyper CVD; **AND**
    - Patient is Philadelphia chromosome (Ph)-negative

Diagnosis of **Pediatric B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)**

- Baseline electrocardiogram (ECG) is within normal limits; **AND**
- Patient has not previously received inotuzumab ozogamicin; **AND**
- Patient is at least 2 years of age; **AND**
- Patient has CD22-positive disease; **AND**
- Patient has relapsed or refractory disease; **AND**
- Used as single agent therapy; **AND**
  - Patient is Philadelphia chromosome (Ph)-negative; **OR**
  - Patient is Philadelphia chromosome (Ph)-positive and is intolerant or refractory to prior tyrosine kinase inhibitor therapy (e.g., imatinib, dasatinib, etc.)

CLINICAL CRITERIA FOR RENEWAL

- Coverage may **not** be renewed

BETA BLOCKER

Length of Authorization:	1 year
Initiative:	MNC: Antihypertensive Medications (IE 2462 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

INNOPRAN XL® AND INDERAL® XL

- Trial and failure of any propranolol ER generic

BILE ACID AGENTS

Length of Authorization:	Ocaliva: 1 year, may be renewed Cholbam: 3 months on initial, 6 months on renewal
Initiative:	SPC: Miscellaneous: PA required (IE 2462/NCPDP 75)

OCALIVA

Diagnosis of **Primary biliary cholangitis** and patient is meeting **two** of the following:

- Alkaline phosphatase (ALP) ≥ 1.5x ULN;
- Presence of antimitochondrial antibodies (AMA);
- Histologic evidence of nonsuppurative destructive cholangitis and destruction of interlobular bile ducts;
  AND
- Contraindication/unable to tolerate ursodeoxycholic acid (Ursodiol); **OR**
- Trial of Ursodiol for at least one year

CHOLBAM

- Patient is 3 weeks of age or older; **AND**
- Patient is **not** receiving treatment for extrahepatic manifestations of bile acid synthesis disorders (i.e., neurologic symptoms); **AND**
- Assessment of liver function (AST, ALT, & bilirubin) has been performed initially and with each renewal; **AND**
- Patient will not be on concomitant therapy with Bile Salt Efflux Pump (BSEP) Inhibitors (e.g., cyclosporine, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reactions; **AND**
- **Bile Acid Synthesis Disorders due to Single Enzyme Defects (SEDs)**
  - Diagnosis has been confirmed using mass spectrometry (FAB-SM) of serum or urinary bile acid levels; **AND**
  - Patient has a diagnosis of one of the following single enzyme defects:
    - 3-beta-hydoxysteroid dehydrogenase (3-β-HSD) deficiency
    - Aldo-keto reductase 1D1 (AKR1D1)
    - Cerebrotendinous xanthomatosis (CTX)
    - Alpha-methylacyl-CoA racemase (AMACR) deficiency; **OR**
- **Peroxisomal Disorder (PDs) Including Zellweger Spectrum Disorders**
  - Diagnosis has been confirmed by one of the following molecular and biochemical findings:
    - Detection of abnormalities using mass spectrometry (FAB-MS) of serum or urinary bile acid levels; **OR**
    - Detection of pathogenic variants of the PEX gene by molecular genetic testing; **AND**
  - Patient has a diagnosis of one of the following:
    - Neonatal Adrenoleukodystrophy
    - Generalized Peroxisomal Disorder
    - Refsum Disease
    - Zellweger Syndrome
    - Peroxisomal Disorder, Type Unknown; **AND**
  - Patient exhibits one or more of the following:
    - Manifestations of liver disease
    - Steatorrhea
    - Complications from decreased fat-soluble vitamin absorption

RELTONE

- Trial and failure of generic ursodiol

CLINICAL CRITERIA FOR RENEWAL

CHOLBAM

Disease response as indicated by **ALL** the following:

- Reduction in ALT or AST to less than 50 U/L, or an 80% reduction from baseline
- Reduction in total bilirubin to 1 mg/dL or less
- Reduction in steatorrhea and/or jaundice
- Body weight increased by 10% or remains stable at greater than the 50th percentile
- Patient has not developed cholestasis; **AND**
- Absence of unacceptable toxicity from the drug (e.g., exacerbation of liver impairment)

OCALIVA

- The patient has had an improvement with therapy; **AND**
- The patient's condition has not progressed or worsened while on therapy; **AND**
- The patient has not developed any contraindications or other exclusions to its continued use

BIOLOGICAL AGENTS – OTHER ALLERGENIC EXTRACT AGENTS – BENEFIT BUILDER

Length of Authorization: 6 months

Initiative: MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

Biologicals are a benefit builder category, Check CRM. For the client which chooses to prior auth these agents see below:

- For the allergen extract sublingual tablets: Grastek, Oralair, and Ragwitek (refer to PA criteria under Anti-allergen extracts)

For the rest of the products, approve if

- Patient has tested positive for allergen; **AND**
- Request is from a related specialist (examples: ENT, allergist, dermatologist)

Product List	
Brand Name	**Generic Name**
American elm	Allergenic extract tree pollen – American elm
Standard Bermuda grass pollen	Allergenic extract, grass pollen – Bermuda, standard
Standardized orchard grass	Allergenic extract, grass pollen – orchard grass, standard
Standard mixed mite extract	Allergenic extract, mite-d. farinae – d. pteronyssinus, standard
Standardized June grass pollen	Allergenic extract, grass pollen – June (Kentucky blue), standard
Standardized red top grass	Allergenic extract, grass pollen – redtop, standard
Standardized timothy grass	Allergenic extract, grass pollen – timothy, standard
D. Pteronyssinus mite extract	Allergenic extract, mite – Dermatophagoides pteronyssinus, standard
Acremonium	Allergenic extract – acremonium strictum
Alternaria	Allergenic extract – Alternaria alternata
American cockroach extract	Allergenic extract – American cockroach
Aspergillus fumigatus	Allergenic extract – aspergillus fumigatus
Mixed aspergillus	Allergenic extract – aspergillus, mixed
Aureobasidium	Allergenic extract – Aureobasidium pullulans
Botrytis	Allergenic extract – botrytis cinerea
Candida albicans	Allergenic extract – candida albicans
Cattle epithelium	Allergenic extract – cattle epithelium
Cladosporium cladosporioides	Allergenic extract – cladosporium cladosporioides
Cladosporium sphaerospermum	Allergenic extract – cladosporium sphaerospermum
Mixed cockroach	Allergenic extract – cockroach (American and German)
Corn smut	Allergenic extract – corn smut
Corn pollen	Allergenic extract – cultivated crop pollen-corn
Curvularia	Allergenic extract – Curvularia
Dog epithelium extract	Allergenic extract – dog epithelium
Drechslera	Allergenic extract – Drechslera sorokiniana
Epicoccum	Allergenic extract – Epicoccum nigrum

Product List	
Brand Name	**Generic Name**
Fire ant	Allergenic extract – fire ant
Fusarium	Allergenic extract – fusarium oxysporum
German cockroach	Allergenic extract – German cockroach
Bahia	Allergenic extract – grass pollen – Bahia
Johnson grass	Allergenic extract – grass pollen – Johnson
Standardized meadow fescue	Allergenic extract – grass pollen – meadow fescue, standardized
Standard rye grass pollen	Allergenic extract – grass pollen – perennial rye, standard
Quack grass	Allergenic extract – grass pollen – quack
Brome	Allergenic extract – grass pollen – smooth brome
Horse epithelium	Allergenic extract – horse epithelium
Mixed feathers	Allergenic extract – mixed feathers, chicken, duck, goose
Mixed ragweed extract	Allergenic extract – mixed weed pollen – short and tall ragweed
Mosquito	Allergenic extract – mosquito
Mouse epithelium	Allergenic extract – mouse epithelium
Mucor	Allergenic extract – mucor plumbeus
Penicillium notatum	Allergenic extract – penicillium notatum
Phoma	Allergenic extract – phoma herbarum
Rabbit epithelium	Allergenic extract – rabbit epithelium
Rhizopus	Allergenic extract – rhizopus oryzae
Saccharomyces cerevisiae	Allergenic extract – saccharomyces cerevisiae
Standard sweet vernal grass	Allergenic extract – sweet vernal, standardized
Acacia	Allergenic extract – tree pollen – acacia
Alder	Allergenic extract – tree pollen – alder white
American beech	Allergenic extract – tree pollen – American beech
American sycamore	Allergenic extract – tree pollen – American sycamore
Arizona cypress	Allergenic extract-tree pollen – Arizona cypress
Australian pine	Allergenic extract – tree pollen – Australian pine
Bald cypress	Allergenic extract – tree pollen – bald cypress
Bayberry	Allergenic extract – tree pollen – bayberry
Black walnut pollen	Allergenic extract – tree pollen – black walnut
Black willow	Allergenic extract – tree pollen – black willow
Box elder	Allergenic extract – tree pollen – box elder
Eastern cottonwood	Allergenic extract – tree pollen – Eastern cottonwood
Cedar elm	Allergenic extract – tree pollen – elm, cedar
Hackberry	Allergenic extract – tree pollen – hackberry

Product List	
Brand Name	**Generic Name**
Western juniper	Allergenic extract – tree pollen – juniper, Western
Kapok	Allergenic extract – tree pollen – kapok
Melaleuca	Allergenic extract – tree pollen – melaleuca
Mesquite	Allergenic extract – tree pollen – mesquite
Mountain cedar	Allergenic extract – tree pollen – mountain cedar
Red mulberry	Allergenic extract – tree pollen – mulberry, red
White mulberry	Allergenic extract – tree pollen – mulberry, white
Olive tree	Allergenic extract – tree pollen – olive
Queen palm	Allergenic extract – tree pollen – palm, queen
Pecan pollen	Allergenic extract – tree pollen – pecan
California pepper tree	Allergenic extract – tree pollen – pepper tree, California
White pine	Allergenic extract – tree pollen – pine, white
Privet	Allergenic extract – tree pollen – privet
Red birch	Allergenic extract – tree pollen – red birch
Red cedar	Allergenic extract – tree pollen – red cedar
Red maple	Allergenic extract – tree pollen – red maple
Red oak	Allergenic extract – tree pollen – red oak
Shagbark hickory	Allergenic extract – tree pollen – shagbark hickory
Sweetgum	Allergenic extract – tree pollen – sweet gum
Virginia live oak	Allergenic extract – tree pollen – Virginia live oak
White ash	Allergenic extract – tree pollen – white ash
White birch	Allergenic extract – tree pollen – white birch
White oak extract	Allergenic extract – tree pollen – white oak
Trichophyton	Allergenic extract – trichophyton mentagrophytes
Honey bee venom protein	Allergenic extract – venom – honey bee
Mixed vespid venom protein	Allergenic extract – venom – mixed vespid protein
Wasp venom protein	Allergenic extract – venom – wasp protein
White faced hornet venom	Allergenic extract – venom – white-faced hornet protein
Yellow hornet venom protein	Allergenic extract – venom – yellow hornet protein
Yellow jacket venom protein	Allergenic extract – venom – yellow jacket protein
Carelessweed	Allergenic extract – weed pollen – carelessweed
Cocklebur	Allergenic extract – weed pollen – cocklebur
Dog fennel	Allergenic extract – weed pollen – dog fennel
English plantain	Allergenic extract – weed pollen – English plantain
Tall ragweed	Allergenic extract – weed pollen – giant (tall) ragweed

Product List	
Brand Name	**Generic Name**
Goldenrod	Allergenic extract – weed pollen – goldenrod
Kochia	Allergenic extract – weed pollen – kochia (firebush)
Lamb's quarters	Allergenic extract – weed pollen – lambsquarters
Mugwort	Allergenic extract – weed pollen – mugwort
Rough pigweed	Allergenic extract – weed pollen – rough pigweed
Russian thistle	Allergenic extract – weed pollen – Russian thistle
Sagebrush	Allergenic extract – weed pollen – sagebrush
Sheep sorrel	Allergenic extract – weed pollen – sheep sorrel
Sheep sorrel-yellow dock	Allergenic extract – weed pollen – sheep sorrel, yellow dock
Ragwitek	Allergenic extract – weed pollen – short ragweed
Short ragweed	Allergenic extract – weed pollen – short ragweed
Spiny pigweed	Allergenic extract – weed pollen – spiny pigweed
Rough marsh elder	Allergenic extract – weed pollen – true marsh elder
Western ragweed	Allergenic extract – weed pollen – western ragweed
Yellow dock	Allergenic extract – weed pollen – yellow dock
Almond	Almond extract
Avocado	Avocado extract
Beef	Beef extract
Candin	Candida albicans skin test
Cantaloupe	Cantaloupe extract
Standardized cat hair	Cat hair standardized allergenic extract
Chicken meat	Chicken meat extract
Cocoa bean	Cocoa extract
Sweet corn	Corn extract
Crab	Crab extract
Infanrix dtap	Diphtheria, pertussis (acell), tetanus pediatric vaccine/pf
Infanrix dtap	Diphtheria, pertussis (acell), tetanus ped vacc/pf
Kinrix	Diphtheria, pertussis (acell), tetanus, polio vaccine/pf
Pentacel dtap-ipv component	Diphtheria, pertussis (acell), tetanus, polio vaccine/pf
Quadracel dtap-ipv	Diphtheria, pertussis (acell), tetanus, polio vaccine/pf
Adacel tdap	Diphtheria, pertussis (acell), tetanus vaccine/pf
Pentacel	Diphtheria, pertussis (acell), tetanus, polio/haemophilus b/pf
Boostrix tdap	Diphtheria, pertussis (acellular), tetanus vaccine
Whole egg	Egg extract
Egg white	Egg white extract

Product List	
Brand Name	**Generic Name**
Oralair	Grass pollen-orchard/sweet vernal/rye/Kentucky/timothy, standard
Pediarix	Hep b virus, rcmb/dipth, pertus (acell), tet, polio vaccine/pf
Hyqvia hy component	Hyaluronidase, human recomb.
Hyqvia ig component	Immune globulin, gamm (igg)/glycine/iga greater than 50 mcg/ml
D. Farinae mite extract	Mite-dermatophagoides farinae, standardized
Oat grain	Oats extract
Orange	Orange extract
Peanut	Peanut extract
Pecan nut	Pecan extract
Adagen	Pegademase bovine
Pistachio nut	Pistachio nut extract
Pork	Pork extract
Rice	Rice extract
Sesame seed	Sesame seed extract
Shrimp	Shrimp extract
Soybean	Soybean extract
Spherusol	Spherule-derived coccidioides antigen skin test
Strawberry	Strawberry extract
Tenivac	Tetanus and diphtheria toxoids, adsorbed, adult/pf
Tetanus diphtheria toxoids	Tetanus and diphtheria toxoids, adult
Diphtheria-tetanus toxoids-ped	Tetanus, diphtheria toxoid ped/pf
Kitabis pak	Tobramycin/nebulizer
Aplisol	Tuberculin, purified protein derivative
Tubersol	Tuberculin, purified protein derivative

BISPHOSPHONATES

Length of Authorization:	1 year
Initiative:	MNC: Osteoporosis Agents (IE 2462 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

Atelvia:

- Patient must have a trial and failure of alendronate or alendronate solution

BLENREP® (BELANTAMAB MAFODOTIN-BLMF)

Length of Authorization:	6 months, and renewable
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma**

- Patient must be at least 18 years old; **AND**
- Patient has an ophthalmic exam (i.e., visual acuity and slit lamp) at baseline, prior to each dose and as needed; **AND**
- Both patient AND prescriber are enrolled in the BLENREP REMS program**; AND**
- Therapy will be used in combination with preservative-free lubricant eye drops; **AND**
- Patient does not have current corneal epithelial disease *(Note: excludes mild punctate keratopathy)*; **AND**
- Patient has not had a prior allogeneic stem cell transplant; **AND**
- Patient does not have any of the following comorbidities:
  - Symptomatic amyloidosis
  - Active POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, myeloma protein, and skin changes)
  - Active plasma cell leukemia; **AND**
- Will be used as single-agent therapy; **AND**
- Patient has relapsed or refractory disease; **AND**
- Patient had disease progression on at least **four** prior anti-myeloma treatment regimens which must have included one or more agents from each of the following categories:
  - Patient is refractory to a proteasome inhibitor (e.g., bortezomib, ixazomib, carfilzomib, etc.); **AND**
  - Patient is refractory to an immunomodulatory agent (IMiD) (e.g., thalidomide, lenalidomide, pomalidomide, etc.); **AND**
  - Patient is refractory or intolerant to an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab-irfc, etc.)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: ophthalmic toxicity, severe infusion related reactions, thrombocytopenia, etc.

BLINCYTO® (BLINATUMOMAB)

Length of Authorization:	Relapsed or Refractory B-Cell Precursor Acute Lymphocytic Leukemia (ALL) • Initial coverage will be provided for 30 weeks for a total of five cycles (2 cycles of induction followed by 3 cycles of consolidation) • Continued coverage will be provided every 24 weeks for a maximum of two additional authorizations (4 cycles of continued therapy) MRD+ B-Cell Precursor Acute Lymphocytic Leukemia (ALL) • Initial coverage will be provided for 24 weeks for a total of four cycles (1 cycle of induction followed by 3 cycles of consolidation) • Continued coverage may not be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **B-Cell Precursor Acute Lymphocytic Leukemia (ALL)**

- Patient is at least 1 month old; **AND**
- Patient has not received a live vaccine within 2 weeks prior to initiating therapy and will not receive concurrent treatment with lives vaccine while on therapy; **AND**
- Used as a single agent; **AND**
- Patient has relapsed or refractory disease (Philadelphia chromosome [Ph]-positive patients must be TKI intolerant/refractory); **OR**
- Used as consolidation therapy in patients with minimal residual disease positive (MRD+) following a complete response/remission to induction therapy; **OR**
- Used in patients that are MRD+ after consolidation therapy; **OR**
- Used in patients that are Ph-positive with less than complete response after induction therapy

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: cytokine release syndrome (CRS), neurological toxicities, serious infections, pancreatitis, tumor lysis syndrome, neutropenia/febrile neutropenia, elevated liver enzymes, leukoencephalopathy, etc.; **AND**
- Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH; **AND**
- Patient has not exceeded 4 cycles of continued therapy or 9 total cycles of therapy for the treatment of relapsed or refractory disease; **OR**
  - Continued therapy for use in the treatment of MRD+ ALL may not be renewed

BLOOD FORMATION MODIFIERS – COLONY STIMULATORY FACTORS (CSF)

Length of Authorization:	• 4 months and may be renewed (unless noted below) • Mozobil: Coverage will be one treatment cycle or four days and will be eligible for renewal for one additional treatment cycle. • Leukine: see approval lengths below
Initiative:	SPC: Blood Modifiers (IE 2462 / NCPDP 75)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

NEULASTA®, FULPHILA®, UDENYCA®, ZIEXTENZO®, NYVEPRIA®

Notes:

Standard Formulary and Precision/Plus Formulary: For Fulphila, Udenyca, and Ziextenzo: Patient must have a contraindication or intolerance to a trial of Neulasta AND Nyvepria

Core Formulary: For Fulphila, Neulasta, and Udenyca: Patient must have a contraindication or intolerance to a trial of Nyvepria AND Ziextenzo

Indication	Approval length
Bone marrow transplantation (BMT) failure or engraftment delay	Coverage will be provided for 1 dose only and may not be renewed
Peripheral blood progenitor cell (PBPC) mobilization and transplant	Coverage will be provided for 1 dose only and may not be renewed
All other indications	Coverage will be provided for four months and may be renewed unless otherwise specified

- **Prophylactic use in patients with non-myeloid malignancy**
  - Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20%[§]; **OR**
  - Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% to 20%[§] **and** one or more of the following co-morbidities:
    - Age > 65 years receiving full dose intensity chemotherapy
    - Extensive prior exposure to chemotherapy
    - Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
    - Persistent neutropenia (ANC ≤ 1000/mm^3)
    - Bone marrow involvement by tumor

CLINICAL CRITERIA FOR RENEWAL

NEULASTA®, FULPHILA®, UDENYCA®, ZIEXTENZO®, NYVEPRIA® *(CONTINUED)*

- Patient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts)
- Recent surgery and/or open wounds
- Poor performance status
- Renal dysfunction (creatinine clearance < 50 mL/min)
- Liver dysfunction (i.e., elevated bilirubin > 2.0 mg/dL)
- Chronic immunosuppression in the post-transplant setting including organ transplant

Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.

- **Patients who experienced a neutropenic complication from a prior cycle of the same chemotherapy**

  Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen
- **Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS])**
- Bone marrow **transplantation (BMT) failure or engraftment delay**
- Peripher**al blood progenitor cell (PBPC) mobilization and transplant**
- **Wilms Tumor (nephroblastoma)**
  - Patient has favorable histology disease; **AND**
  - Used in combination with a cyclophosphamide-based chemotherapy regimen (i.e., Regimen M or I only)

***Febrile neutropenia is defined as:**
– **Temperature:** a single temperature ≥ 38.3 °C orally or ≥ 38.0 °C over 1 hour; **AND** – **Neutropenia**: < 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours
§ Expected incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the NCCN Hematopoietic Growth Factors Clinical Practice Guideline at NCCN.org

Note: Coverage for use in BMT failure or engraftment delay and PBPC mobilization and transplant may **not** be renewed.

Coverage for all other indications can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in initial section; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: splenic rupture, acute respiratory distress syndrome (ARDS), serious allergic reactions/anaphylaxis, sickle cell crisis, glomerulonephritis, leukocytosis, thrombocytopenia, capillary leak syndrome, potential for tumor growth stimulation of malignant cells, aortitis, myelodysplastic syndrome and acute myeloid leukemia, etc.

NEUPOGEN®, NIVESTYM®, ZARXIO®, GRANIX® (NO GRANDFATHERING)

Notes:

Standard Formulary and Precision/Plus Formulary: for Granix and Zarxio, patient must have a contraindication or intolerance to a trial of Neupogen® or Nivestym®

Core Formulary: for Granix, Neupogen, and Zarxio, patient must have a contraindication or intolerance to a trial of Nivestym®

- **Bone marrow transplant (BMT)**
- **Peripheral blood progenitor cell (PBPC) mobilization and transplant**
- **Prophylactic use in patients with non-myeloid malignancy**
  - Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of greater than 20%[§]; **OR**
  - Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of 10% or to 20%[§] **and** one or more of the following co-morbidities:
    - Age > 65 years receiving full dose intensity chemotherapy
    - Extensive prior exposure to chemotherapy
    - Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
    - Pre-existing neutropenia (ANC ≤ 1000/mm^3)
    - Bone marrow involvement with tumor
    - Patient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts)
    - Recent surgery and/or open wounds
    - Poor performance status
    - Renal dysfunction (creatinine clearance < 50 mL/min)
    - Liver dysfunction (elevated bilirubin > 2.0 mg/dL)
    - Chronic immunosuppression in the post-transplant setting including organ transplant.

Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

NEUPOGEN® NIVESTYM®, ZARXIO®, GRANIX® *(CONTINUED)*

- **Treatment of chemotherapy-induced febrile neutropenia**
  - Patient has been on prophylactic therapy with filgrastim or tbo-filgrastim ***(Note:** therapy should not be used concomitantly with pegfilgrastim)*; **OR**
  - Patient has not received prophylactic therapy with a granulocyte colony stimulating factor; **AND**
    - Patient has one or more of the following risk factors for developing infection-related complications:
      - Sepsis syndrome
      - Age greater than 65 years
      - Absolute neutrophil count [ANC] less than 100/mcL
      - Duration of neutropenia expected to be greater than 10 days
      - Pneumonia or other clinically documented infections
      - Invasive fungal infection
      - Hospitalization at the time of fever
      - Prior episode of febrile neutropenia
- **Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy**

  Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.
- **Acute myeloid leukemia (AML)**
  - Used in patients receiving induction/consolidation or re-induction chemotherapy; **OR**
  - Used for relapsed or refractory disease
- **Bone marrow transplantation (BMT) failure or engraftment delay**
- **Severe chronic neutropenia**
  - Patient must have an absolute neutrophil count (ANC) < 500/mm^3; **AND**
  - Patient must have a diagnosis of one of the following:
    - Congenital neutropenia; **OR**
    - Cyclic neutropenia; **OR**
    - Idiopathic neutropenia
- **Myelodysplastic syndrome**
  - Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
  - Patient has lower risk disease (i.e., defined as IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]); **AND**
  - Used for treatment of symptomatic anemia with no del(5q) mutation; **AND**
  - Patient is receiving concurrent therapy with erythropoiesis stimulating agents (ESAs)
- **Patients acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome)**
- **Management of CAR T-cell related toxicity**
  - Patient has been receiving therapy with CAR T-cell therapy (e.g., tisagenlecleucel, axicabtagene ciloleucel, brexucabtagene autoleucel, lisocabtagene maraleucel, etc.); **AND**
  - Patient is experiencing neutropenia related to their therapy
- **Wilms Tumor (Nephroblastoma)**
  - Patient has favorable histology disease; **AND**
  - Used in combination with a cyclophosphamide-based chemotherapy regimen (i.e., Regimen M or I only)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

NEUPOGEN®, NIVESTYM®, ZARXIO®, GRANIX® *(CONTINUED)*

***Febrile neutropenia is defined as:**
– **Temperature**: a single temperature ≥ 38.3 °C orally or ≥ 38.0 °C over 1 hour; **AND** – **Neutropenia**: < 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours
§ Expected incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the NCCN Hematopoietic Growth Factors Clinical Practice Guideline at NCCN.org

CLINICAL CRITERIA FOR RENEWAL

Absence of unacceptable toxicity from the drug (e.g., splenic rupture, acute respiratory distress syndrome [ARDS], serious allergic reactions/anaphylaxis, sickle cell crisis, glomerulonephritis, leukocytosis, capillary leak syndrome, potential for tumor growth stimulation of malignant cells, aortitis, alveolar hemorrhage and hemoptysis, thrombocytopenia, cutaneous vasculitis)

LEUKINE

LENGTH OF AUTHORIZATION

High Risk Neuroblastoma:

- When used in combination with dinutuximab, coverage will be provided for five months and may not be renewed.
- When used in combination with naxitamab, coverage will be provided for six months and may be renewed.

All other indications:

- Coverage will be provided for four months and may be renewed.

Covered for the following:

- Myeloid reconstitution after autologous or allogeneic bone marrow transplant (BMT)
- Peripheral blood progenitor cell (PBPC) mobilization and transplant
- Acute myeloid leukemia (AML) following induction or consolidation chemotherapy
- Bone marrow transplantation (BMT) failure or engraftment delay
- Patients acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS])

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Treatment of chemotherapy-induced febrile neutropenia
  - Used for the treatment of chemotherapy induced febrile neutropenia in patients who have not received prophylactic therapy with a granulocyte colony stimulating factor; **AND**
  - Patient has one or more of the following risk factors for developing infection-related complications:
    - Sepsis syndrome
    - Age greater than 65 years
    - Absolute neutrophil count (ANC) less than 100/mcL
    - Duration of neutropenia expected to be greater than 10 days
    - Pneumonia or other clinically documented infections
    - Invasive fungal infection
    - Hospitalization at the time of fever
    - Prior episode of febrile neutropenia
- High-Risk Neuroblastoma
  - Used in combination with GD2-binding monoclonal antibodies (i.e., naxitamab, dinutuximab, etc.) for the treatment of high-risk neuroblastoma

CLINICAL CRITERIA FOR RENEWAL

High-Risk Neuroblastoma

- Use in combination with dinutuximab may not be renewed.
- Used in combination with naxitamab; **AND**
  - Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
  - Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hypersensitivity reactions, severe effusions and capillary leak syndrome, severe supraventricular arrythmias, etc

All Other Indications

- Same as initial prior authorization policy criteria.

MOZOBIL®

Coverage for Mozobil® (plerixafor) is provided in the following conditions:

Peripheral mobilization of stem cells for transplantation:

- Patient is at least 18 years of age; **AND**
- Used in the autologous transplant setting; **AND**
  - Used in combination with filgrastim (or its biosimilars) or tbo-filgrastim; **OR**
  - Used in combination with pegfilgrastim; **OR**
  - Used in combination with sargramostim and cyclophosphamide; **OR**
- Used in the allogeneic transplant setting; **AND**
  - Used as additional therapy in combination with filgrastim following single-agent filgrastim therapy, for insufficient collection of stem cells

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions/anaphylaxis, hematologic effects [e.g., leukocytosis, thrombocytopenia], splenic enlargement/rupture, tumor cell mobilization); **AND**
- Patient has had only one previous treatment cycle

Approve a one-time course of therapy (up to 4 days of therapy), which will be eligible for renewal for one additional treatment cycle.

Reference dosing:

Mozobil® – Recommended dose: [1]	• Begin treatment with Mozobil® after the patient has received G-CSF once daily for 4 days • Administer daily morning doses of G-CSF 10 mcg/kg for 4 days prior to the first evening dose of Mozobil® and on each day prior to apheresis • Administer Mozobil® approximately 11 hours prior to initiation of each apheresis for up to 4 consecutive days at the following dose: – 20 mg fixed dose or 0.24 mg/kg actual body weight for patients weighing ≤ 83 kg • 0.24 mg/kg actual body weight for patients weighing > 83 kg; not to exceed 40 mg/day

NPLATE®

Approval is for 3 months and may be renewed, except for Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS) cannot be renewed.

Coverage for Nplate® (romiplostim) is provided in the following conditions:

- **Diagnosis of immune (idiopathic) thrombocytopenic purpura (ITP)**
  - Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., lusutrombopag, eltrombopag, avatrombopag etc.) or fostamatinib; **AND**
  - Must not be used in an attempt to normalize platelet counts; **AND**
  - Laboratory value for platelet count is current (i.e., drawn within the previous 28 days); **AND**
  - The patient is at increased risk for bleeding as indicated by platelet count less than 30×10^9/L (30,000/mm^3); **AND**
  - Patient has acute ITP; **AND**
    - Patient is at least 18 years of age; **AND**
    - Patient has previously failed one of the following treatments for ITP:
      - Patient has failed previous therapy with corticosteroids; **OR**
      - Patient has failed previous therapy with immunoglobulins; **OR**
      - Patient has had splenectomy; **OR**
  - Patient with chronic ITP for at least 6 months (or meets the corticosteroid requirement below); **AND**
    - Patient is 1 year of age or older; **AND**
    - Patient has previously failed one of the following treatments for ITP:
      - Patient has failed previous therapy with corticosteroids (i.e., patient had no response to at least a 3-month trial or is corticosteroid-dependent); **OR**
      - Patient has failed previous therapy with immunoglobulins; **OR**
      - Patient has had a splenectomy

- Diagnosis of **Myelodysplastic Syndromes (MDS)**
  - Patient is at least 18 years of age; **AND**
  - Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., lusutrombopag, eltrombopag, avatrombopag etc.) or fostamatinib; **AND**
  - Must not be used in an attempt to normalize platelet counts; **AND**
  - Laboratory value for platelet count is current (i.e., drawn within the previous 28 days); **AND**
  - Patient has lower risk disease [i.e., IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very Low, Low, Intermediate)]; **AND**
  - Patient has severe or refractory thrombocytopenia (i.e., platelet count < 20 x 10^9/L or higher with a history of bleeding); **AND**
  - Patient progressed or had no response to hypomethylating agents (e.g., azacitidine, decitabine,), immunosuppressive therapy, or clinical trial
- Diagnosis of **Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS)**
  - Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., lusutrombopag, eltrombopag, avatrombopag etc.) or fostamatinib; **AND**
  - Must not be used in an attempt to normalize platelet counts; **AND**
  - Laboratory value for platelet count is current (i.e., drawn within the previous 28 days); **AND**
  - Patient has suspected or confirmed exposure to radiation levels greater than 2 gray (Gy)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., thrombotic/thromboembolic complications, risk of progression of myelodysplastic syndromes to acute myelogenous leukemia); **AND**
  - **ITP**
    - Disease response indicated by the achievement and maintenance of a platelet count of at least 50 × 10^9/L (not to exceed 400 x 10^9/L) as necessary to reduce the risk for bleeding; **OR**
  - **HS-ARS**
    - Coverage cannot be renewed
  - **MDS**
    - Patient has not developed acute myeloid leukemia (AML) (**Note**: romiplostim induces an increase in immature white blood cells and peripheral blasts which is not indicative of development of AML); **AND**
    - Disease response indicated by an increase in platelet count compared to pretreatment baseline (not to exceed 450 x 10^9/L), reduction in bleeding events, or reduction in platelet transfusion requirements

BLOOD PRESSURE SUPPLIES – BENEFIT BUILDER

Length of Authorization:	1 year
Initiative:	**MNC:** miscellaneous pa required (IE 2462 / NCPDP 75)

BLOOD PRESSURE SUPPLIES are a benefit builder category, Check CRM. For the client which chooses to prior auth these agents see below

May approve requested blood pressure supply if the patient meets one of the following;

- Patient is on a blood pressure (antihypertension) medication (drugs in the HIC3's below); **OR**
- Patient is on other medications that may affect blood pressure (examples: anticholinergics, prednisone); **OR**
- Patient has a disease state in which the blood pressure fluctuates

Antihypertensive Classes by HIC3	
FDB HIC3	**HIC3 DESCRIPTION**
A4A	ANTIHYPERTENSIVES, VASODILATORS
A4B	ANTIHYPERTENSIVES, SYMPATHOLYTIC
A4C	ANTIHYPERTENSIVES, GANGLIONIC BLOCKERS
A4D	ANTIHYPERTENSIVES, ACE INHIBITORS
A4F	ANTIHYPERTENSIVES, ANGIOTENSIN RECEPTOR ANTAGONIST
A4Y	ANTIHYPERTENSIVES, MISCELLANEOUS

BLOOD PRODUCTS

Length of Authorization:	See below
Initiative:	SPC: Blood Modifiers (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

ALPHANINE SD, ALPROLIX, BENEFIX, IDELVION, IXINITY, MONONINE, PROFILNINE, REBINYN AND RIXUBIS

Note: initial authorization will be provided for 3 months and may be renewed (unless noted below)

Coverage is provided in the following conditions:

Hemophilia B (congenital factor IX deficiency aka Christmas disease)

- Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing; **AND**
- Therapy NOT used for induction of immune tolerance in patients with Hemophilia B [ONLY the following products]:
  - Alprolix
  - Rixubis
  - Ixinity
  - Idelvion
  - Rebinyn
  - AlphaNine SD
  - Mononine
  - BeneFix; **AND**
- Used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*Authorizations valid for 1 month); **OR**;
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes (excluding Rebinyn); **AND**
    - Patient must have severe hemophilia B (factor IX level of < 1%); **OR**
    - Patient has at least two documented episodes of spontaneous bleeding into joints.

RENEWAL

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, etc.), thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), nephrotic syndrome, etc.; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (i.e., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization;

Treatment of acute bleeding episodes/Treatment of Spontaneous and trauma-induced bleeding episodes/On-demand treatment of bleeding episodes

- Renewals will be approved for a 6-month authorization period

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Prevention of acute bleeding episodes/Routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12-month authorization period; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

ALPHANATE, HUMATE-P ONLY

Note: Initial authorization will be provided for 3 months and may be renewed (unless noted below)

Coverage is provided in the following conditions:

Hemophilia A (congenital factor VIII deficiency)

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Used as treatment in one of the following:
  - Control and prevention of bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management *(*Authorization is valid for 1 month)*; **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
    - Patient must have severe hemophilia A (factor VIII level of <1%); **OR**
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**

von Willebrand disease (vWD)

- Diagnosis of von Willebrand disease has been confirmed by blood coagulation and von Willebrand factor testing; **AND**
- Used as treatment in one of the following:
  - Spontaneous and trauma-induced bleeding episodes; **OR**
  - Surgical bleeding prophylaxis during major or minor procedures in patients with vWD in whom desmopressin is either ineffective or contraindicated *(*Authorization valid for 1 month)*; **AND**
- Alphanate is not indicated for patients with severe (type 3) vWD undergoing major surgery **or** treatment of spontaneous/trauma-induced bleeding episodes.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

RENEWAL

Coverage can be renewed based upon the following criteria:

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug (e.g., symptoms of allergic-anaphylactic reactions [anaphylaxis, dyspnea, rash], thromboembolic events [thromboembolism, pulmonary embolism], and development of neutralizing antibodies [inhibitors]); **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (i.e., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization;

Treatment of acute bleeding episodes/Treatment of Spontaneous and trauma-induced bleeding episodes/On-demand treatment of bleeding episodes

- Renewals will be approved for a 6-month authorization period

Prevention of acute bleeding episodes/Routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12-month authorization period; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

ADVATE, ADYNOVATE, AFSTYLA, ELOCTATE, ESPERCOT, HEMOFIL M, KOATE, KOATE-DVI, KOGENATE FS, KOVALTRY, NOVOEIGHT, NUWIQ, RECOMBINATE, XYNTHA/XYNTHA SOLOFUSE, AND JIVI

Note: Initial authorization will be provided for 3 months and may be renewed (unless noted below)

Coverage is provided in the following conditions:

Hemophilia A (congenital factor VIII deficiency)

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- The patient must be 12 years of age or older (Jivi only); **AND**
- Will not be used for the treatment of von Willebrand's disease; **AND**
- Used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*Authorizations valid for 1 month); **OR**
  - Used for routine prophylaxis; **AND**
    - Used to prevent or reduce the frequency of bleeding episodes; **OR**
    - Used to prevent or reduce the frequency of bleeding episodes and reduce the risk of joint damage in children without pre-existing joint damage (KOGENATE-FS **only**); **AND**
      - Patient must have severe hemophilia A (factor VIII level of < 1%); **OR**
      - Patient has at least two documented episodes of spontaneous bleeding into joints
- If the request is for Eloctate, Adynovate, Jivi, or Esperoct, the following criteria should be met in addition to above:
  - Patient is not a suitable candidate for a standard non- EHL factor VIII product.
  - A half-life study must be scheduled to determine the appropriate dose and dosing interval of the EHL product when initiated.
  - Prior to switching to Eloctate, Adynovate, Jivi, or Esperoct a half-life study should also be performed on current non- EHL factor VIII product to ensure that a clinical benefit will be achieved.

RENEWAL

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, etc.), thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), etc.; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (i.e., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization

Treatment of acute bleeding episodes/Treatment of Spontaneous and trauma-induced bleeding episodes/On-demand treatment of bleeding episodes

- Renewals will be approved for a 6-month authorization period

Prevention of acute bleeding episodes/Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

- Renewals will be approved for a 12-month authorization period; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

OBIZUR

Note: Initial authorization will be provided for 3 months and may be renewed (unless noted below)

Coverage is provided in the following conditions:

Acquired Hemophilia A (acquired factor VIII deficiency)

- Diagnosis of acquired factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Used as on-demand treatment and control of bleeding episodes; **AND**
- Is **not** being used for congenital Hemophilia A or von Willebrand disease

RENEWAL

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, etc.), thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), etc.; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on hand for the treatment of acute bleeding episodes as needed for the duration of the authorization

Treatment of acute bleeding episodes/Treatment of spontaneous and trauma-induced bleeding episodes/On-demand treatment of bleeding episodes

- Renewals will be approved for a 6-month authorization period

Prevention of acute bleeding episodes/Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

- Renewals will be approved for a 12-month authorization period; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

FEIBA NF/FEIBA VF

Note: initial authorization will be provided for 3 months and may be renewed every 12 months thereafter (unless noted below)

Hemophilia A (congenital factor VIII deficiency)

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation the patient has inhibitors to Factor VIII; **AND**
- Used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*Authorizations valid for 1 month); **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
  - Patient has a documented trial and failure of Immune Tolerance Induction (ITI); **AND**
    - Patient has a documented trial and failure or contraindication to emicizumab-kxwh therapy

Hemophilia B (congenital factor IX deficiency aka Christmas disease)

- Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation the patient has inhibitors to Factor IX; **AND**
- Used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*Authorizations valid for 1 month); **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
  - Patient has a documented trial and failure of Immune Tolerance Induction (ITI)

RENEWAL

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, etc.), thromboembolic events (venous thrombosis, pulmonary embolism, myocardial infarction, stroke, etc.), development of neutralizing antibodies (inhibitors), etc.; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (i.e., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; **AND**
- Treatment of acute bleeding episodes/Treatment of Spontaneous and trauma-induced bleeding episodes/On-demand treatment of bleeding episodes
  - Renewal will be approved for a 6-month authorization period
- Prevention of acute bleeding episodes/Routine prophylaxis to prevent or reduce the frequency of bleeding episode
  - Renewals will be approved for a 12-month authorization period; **AND**
  - Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

NOVOSEVEN RT

Note: initial authorization will be provided for 3 months and may be renewed, unless noted below

Coverage is provided in the following conditions:

Hemophilia A (congenital factor VIII deficiency)

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation patient has acquired inhibitors to Factor VIII; **AND**
- Used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*Authorizations valid for 1 month); **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes when the following criteria are also met:
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
    - Patient has documented trial and failure of Immune Tolerance Induction (ITI); **AND**
      - Patient has documented trial and failure or contraindication to Hemlibra

Acquired Hemophilia

- Diagnosis of acquired hemophilia has been confirmed by blood coagulation testing; **AND**
- Used as treatment for one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*Authorizations valid for 1 month)

Hemophilia B (congenital factor IX deficiency aka Christmas disease)

- Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation patient has acquired inhibitors to Factor IX; **AND**
- Used as treatment for one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*Authorizations valid for 1 month); **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes when the following criteria are also met
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
    - Patient has documented trial and failure of Immune Tolerance Induction (ITI)

Congenital Factor VII Deficiency

- Diagnosis of congenital factor VII deficiency has been confirmed by blood coagulation testing; **AND**
- Used as treatment for one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*Authorizations valid for 1 month)

Glanzmann's Thrombasthenia

- Diagnosis of Glanzmann Thrombasthenia has been confirmed by blood coagulation testing; **AND**
- Used as treatment for one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Perioperative management (*Authorizations valid for 1 month); **AND**
- The use of platelet transfusions is known or suspected to be ineffective or contraindicated

RENEWAL

- Patient continues to meet initial criteria; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, etc.), thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), etc.; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization;

Treatment of acute bleeding episodes/Treatment of Spontaneous and trauma-induced bleeding episodes/On-demand treatment of bleeding episodes

- Renewals will be approved for a 6-month authorization period

Prevention of acute bleeding episodes/Routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12-month authorization period; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

SEVENFACT®

Note: The initial authorization will be provided for 3 months and may be renewed, unless noted below.

Coverage is provided in the following conditions:

Hemophilia A (Congenital Factor VIII Deficiency)/Hemophilia B (Congenital Factor IX Deficiency)

- Patient is 12 years of age or older; **AND**
- Diagnosis of congenital factor VIII or IX deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation patient has hemophilia A (Factor VIII) inhibitors or hemophilia B (Factor IX) inhibitors; **AND**
- Used as treatment and control of acute bleeding episodes (episodic treatment of acute hemorrhage); **AND**
- Will not be used for the treatment of congenital factor VII deficiency

RENEWAL

- Patient continues to meet initial criteria; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, etc.), thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), etc.; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization;

Treatment of Acute Bleeding Episodes/Treatment of Spontaneous and Trauma-Induced Bleeding Episodes/On-Demand Treatment of Bleeding Episodes

- Renewals will be approved for a 6-month authorization period

TRETTEN®

Initial authorization: 3 months, renewal: 12 months (unless noted below)

Coverage is provided in the following conditions:

Congenital Factor XIII A-subunit deficiency

- Diagnosis of congenital factor XIII A-subunit deficiency has been confirmed by blood coagulation testing; **AND**
- Used for routine prophylaxis of bleeding

RENEWAL

Coverage can be renewed based upon the following criteria:

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, etc.), thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), etc.; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (i.e., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization

Prevention of acute bleeding episodes/Routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12-month authorization period; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

COAGADEX

Initial authorization: 3 months, renewal: 6 months (unless noted below)

Hereditary Factor X Deficiency

- Diagnosis of congenital factor X deficiency has been confirmed by blood coagulation testing; **AND**
- Used as treatment in one of the following:
  - On-demand treatment and control of bleeding episodes; **OR**
  - Routine prophylaxis to reduce the frequency of bleeding episodes; **AND**:
    - Patient must have severe factor X deficiency (factor X level of < 1%); **OR**
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
  - Perioperative management of surgical bleeding in patients with mild and moderate deficiency *(*Authorizations valid for 1 month)*

RENEWAL

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, etc.), thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), etc.; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy) ; **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; **AND**

Treatment of Acute Bleeding Episodes/Treatment of Spontaneous and Trauma-Induced Bleeding Episodes/On-Demand Treatment of Bleeding Episodes

- Renewals will be approved for a 6-month authorization period

Prevention of acute bleeding episodes/Routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 6-month authorization period; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

CORIFACT

Initial authorization: 3 months, renewal: 12 months (unless noted below)

Coverage is provided in the following conditions:

Congenital Factor XIII deficiency

- Diagnosis of congenital factor XIII deficiency has been confirmed by blood coagulation testing; **AND**
- Used for routine prophylactic treatment; **OR**
- Used for perioperative management of surgical bleeding *(*Authorizations valid for 1 month)*

RENEWAL

Coverage can be renewed based upon the following criteria:

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, etc.), thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), etc.; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (i.e., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; **AND**

Prevention of acute bleeding episodes/Routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12-month authorization period; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

WILATE

Initial authorization: 3 months, may be renewed (unless noted below)

Coverage is provided in the following conditions:

von Willebrand disease (vWD)

- Diagnosis of von Willebrand disease has been confirmed by blood coagulation and von Willebrand factor testing; **AND**
- Used as treatment in one of the following;
  - Perioperative management of bleeding *(*Authorization valid for 1 month)*; **OR**
  - Used as treatment of spontaneous and trauma-induced bleeding episodes in at least one of the following:
    - Patients with severe vWD; **OR**
    - Patients with mild or moderate vWD in whom the use of desmopressin is known or suspected to be ineffective or contraindicated

Hemophilia A (congenital factor VIII deficiency)

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Used as treatment in one of the following:
  - Control and prevention of bleeding episodes (episodic treatment of acute hemorrhage); **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
    - Patient must have severe hemophilia A (factor VIII level of < 1%); **OR**
    - Patient has at least two documented episodes of spontaneous bleeding into joints

RENEWAL

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug (e.g., symptoms of allergic-anaphylactic reactions [anaphylaxis, dyspnea, rash], thromboembolic events [thromboembolism, pulmonary embolism], and development of neutralizing antibodies [inhibitors]); **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (e.g., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; **AND**

Treatment of acute bleeding episodes/Treatment of Spontaneous and trauma-induced bleeding episodes/On-demand treatment of bleeding episodes

- Renewals will be approved for a 6-month authorization period

Prevention of acute bleeding episodes/Routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12-month authorization period; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

VONVENDI

Initial authorization: 3 months, may be renewed (unless noted below)

Diagnosis of von Willebrand Disease (vWD)

- Patient is 18 years or older**; AND**
- Diagnosis of von Willebrand disease has been confirmed by blood coagulation and von Willebrand factor testing; **AND**
  - Used as treatment of spontaneous and trauma-induced bleeding episodes in at least one of the following:
    - Patients with severe vWD; **OR**
    - Patients with mild or moderate vWD in whom the use of desmopressin is known or suspected to be ineffective or contraindicated; **OR**
  - Perioperative Management (**Note:** authorizations are for 1 month); **AND**
- Will **NOT** be used for routine prophylactic treatment of spontaneous bleeding episodes

RENEWAL

- Patient continues to meet criteria identified in initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, etc.), thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), etc; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (i.e., weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; **AND**

Treatment of acute bleeding episodes/Treatment of Spontaneous and trauma-induced bleeding episodes/On-demand treatment of bleeding episodes

- Renewals will be approved for a 6-month authorization period

HEMLIBRA (APPROVAL LENGTH: 3 MONTHS INITIAL, 12 MONTHS RENEWAL)

Hemophilia A (congenital factor VIII deficiency) with inhibitors

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Patient has confirmed inhibitors to Factor VIII; **AND**
- Used as routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- Not used in combination with Immune Tolerance Induction (ITI); **AND**
  - Patient has had at least two documented episodes of spontaneous bleeding into joints; **OR**
  - Patient had a documented trial and failure of Immune Tolerance Induction (ITI); **OR**
  - Patient had a documented trial and failure of, or is currently on, routine prophylaxis with a bypassing agent (i.e., NovoSeven, Feiba)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Hemophilia A (congenital factor VIII deficiency) without inhibitors

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Must be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- Used as treatment in one of the following:
  - Patient must have severe hemophilia A (factor VIII level of < 1%): **OR**
  - Patient has had at least two documented episodes of spontaneous bleeding into joints; **AND**
- Patient is not a suitable candidate for treatment with shorter half-life Factor VIII (Recombinant) products at a total weekly dose of 100 IU/kg or less (as attested by the prescribing physician with appropriate clinical rational)

RENEWAL

- Patient continues to meet criteria for initial approval; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include thrombotic microangiopathy and thrombotic events, symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, etc.), thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), etc.; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

CLINICAL CRITERIA FOR RENEWAL

- See criteria under specific medications above

BONIVA® (IBANDRONATE) IV

Length of Authorization:	12 months, may be renewed (unless otherwise specified)
Initiative:	SPC: Miscellaneous: PA required (IE 2462/NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Treatment of Women with Postmenopausal Osteoporosis**

- Patient is at least 18 years old; **AND**
  - Confirmation patient is receiving calcium and vitamin D supplementation if dietary intake is inadequate; **AND**
  - Patient must not have hypocalcemia; **AND**
  - Patient must have creatinine clearance ≥ 30 mL/min; **AND**
  - Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
    - Hip DXA (femoral neck or total hip) or lumbar spine T-score ≤-2.5 and/or forearm DXA 33% (one-third) radius; **OR**
    - T-score ≤-1 or low bone mass **and** a history of fragility fracture to the hip or spine; **OR**
    - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; **AND**
  - Patient must be at a high risk for fracture**; **AND**
    - Documented treatment failure or ineffective response± to a minimum (12) month trial on previous therapy with oral bisphosphonates such as alendronate, risedronate, or ibandronate; **OR**
    - Patient has a documented contraindication* or intolerance to oral bisphosphonates such as alendronate, risedronate, or ibandronate

Note: patients discontinuing treatment with denosumab due to a reduction in fracture risk (i.e., no longer high or very high risk) require subsequent antiresorptive therapy in order to prevent accelerated bone mineral density loss and increase in fracture risk. Coverage is provided for **one year** for this use prior to temporary discontinuation of intravenous antiresorptive therapy

±Ineffective response is defined as one or more of the following:
• Decrease in T-score in comparison with baseline T-score from DXA scan • Patient has a new fracture while on bisphosphonate therapy
****High risk for fractures includes, but are not limited to, one or more of the following:**
• History of an osteoporotic fracture as an adult • Parental history of hip fracture • Low BMI • Rheumatoid arthritis • Alcohol intake (3 or more drinks per day) • Current smoking • History of oral glucocorticoids ≥ 5 mg per day of prednisone (or equivalent) for > 3 months (ever)
***Examples of contraindications to oral bisphosphonate therapy include the following:**
• Documented inability to sit or stand upright for at least 30 minutes • Documented pre-existing gastrointestinal disorder such as inability to swallow, Barrett's esophagus, esophageal stricture, dysmotility, or achalasia

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., hypocalcemia, anaphylaxis, renal toxicity, severe bone joint or muscle pain, atypical femur fracture, osteonecrosis of jaw [ONJ]); **AND**
- Disease response as indicated by one or more of the following:
  - Absence of fractures
  - Increase in bone mineral density compared to pretreatment baseline
- Patients who have received 3 years of bisphosphonate therapy should be re-evaluated with a DXA or serum marker for bone turnover (i.e., serum C-terminal crosslinking telopeptide [CTX]); **AND**
  - Those patients at low-to-moderate risk of fractures should be considered for a temporary discontinuation of bisphosphonate for up to 5 years (re-assess risk at 2 to 4 year intervals to determine if earlier re-initiation is necessary)

BOSULIF® (BOSUTINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myelogenous Leukemia (CML)**

- Patient is at least 18 years old; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with moderate or strong CYP3A inhibitors (e.g., itraconazole, fluconazole, clarithromycin, etc.); **AND**
  - Coadministration with proton pump inhibitors (e.g., lansoprazole, esomeprazole, omeprazole); **AND**
- Patient's disease is confirmed by either a Philadelphia chromosome-positive (Ph+) or *BCR-ABL1* positive laboratory test result; **AND**
- Patient does not have any of the following *BCR-ABL1* mutations: T315I, V299L, G250E, or F317L (****Note:** This does **not** apply to patients receiving first-line or continued therapy); **AND**
  - Patient is resistant, intolerant, or had an inadequate response to prior therapy consisting of a 3-month or longer trial with a tyrosine kinase inhibitor (e.g., imatinib, dasatinib, ponatinib, nilotinib, etc.); **AND**
    - Patient has chronic, accelerated, or blast phase disease; **OR**
  - Used post-allogeneic hematopoietic stem cell transplant (HCT) ; **AND**
    - Used as follow-up therapy in patients with molecular relapse (BCR-ABL1 transcript positive) following complete cytogenetic response (CCyR); **OR**
    - Used for at least one year in patients with prior CCyR for accelerated or blast phase disease; **OR**
    - Used as follow-up therapy in patients with relapse or those who are not in CCyR; **OR**
  - Used as primary treatment ; **AND**
    - Used as a single agent for newly diagnosed chronic or accelerated or myeloid blast phase disease; **OR**
    - Used in combination with corticosteroids for lymphoid blast phase disease; **OR**
    - Used in combination with induction chemotherapy for disease in lymphoid blast phase or myeloid blast phase; **OR**
  - Used as switch therapy ; **AND**
    - Patient received primary treatment with one of the following: imatinib, dasatinib, or nilotinib; **AND**
    - Patient has *BCR-ABL1* transcript levels:
      - > 1% to 10% at 12 months; **OR**
      - > 0.1% to 1% at 12 months (if treatment goal is treatment-free remission); **OR**
      - > 10% at any response milestone; **OR**
  - Used as continued therapy ; **AND**
    - Patient has *BCR-ABL1* transcript levels
      - ≤ 10% at any response milestone; **OR**
      - > 10% at 3 months

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 18 years old; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with moderate or strong CYP3A inhibitors (e.g., itraconazole, fluconazole, clarithromycin, etc.); **AND**
  - Coadministration with proton pump inhibitors (e.g., lansoprazole, esomeprazole, omeprazole); **AND**
- Patient's disease is Philadelphia chromosome-positive (Ph+); **AND**
- Patient does not have any of the following *BCR-ABL1* mutations: T315I, V299L, G250E, or F317L; **AND**
  - Used for relapsed or refractory disease; **AND**
    - Used as a single agent; **OR**
    - Used in combination with an induction therapy not previously used; **OR**
    - Used in combination inotuzumab ozogamicin in patients who are TKI intolerant/refractory; **OR**
    - Used in combination with blinatumomab; **OR**
  - Used as maintenance therapy; **AND**
    - Used in combination with vincristine and prednisone with or without methotrexate and mercaptopurine; **OR**
    - Used post-hematopoietic stem cell transplant; **OR**
  - Patient is at least 15 years of age and < 65 years of age; **AND**
    - Used in a multiagent chemotherapy regimen for induction or consolidation therapy; **OR**
    - Used in combination with a corticosteroid for induction or consolidation therapy; **OR**
    - Used in combination with vincristine and dexamethasone for induction therapy; **OR**
    - Used in combination with blinatumomab as consolidation therapy for persistent/rising minimal residual disease following a complete response (CR) to induction therapy; **OR**
  - Patient is ≥ 65 years of age or with substantial comorbidities; **AND**
    - Used as induction therapy as part of one of the following regimens:
      - As a single agent or in combination with a corticosteroid; **OR**
      - In combination with vincristine and dexamethasone; **OR**

        In combination with a multiagent chemotherapy regimen
    - Used as consolidation therapy; **AND**:
      - Patient has persistent/rising minimal residual disease following a complete response (CR) to induction therapy; **AND**
      - Used in combination with blinatumomab

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes only**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with moderate or strong CYP3A inhibitors (e.g., itraconazole, fluconazole, clarithromycin, etc.); **AND**
  - Coadministration with proton pump inhibitors (e.g., lansoprazole, esomeprazole, omeprazole); **AND**
- Patient has eosinophilia and ABL1 rearrangement; **AND**
  - Patient has chronic phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

Please continue below for additional formulary specific criteria.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hepatic toxicity, renal toxicity, fluid retention, myelosuppression, gastrointestinal toxicity, cardiovascular toxicity (cardiac failure, left ventricular dysfunction, cardiac ischemic events), etc.; **AND**
- Patient has been adherent to therapy; **AND**
- **Chronic myelogenous leukemia (CML) only**:
  - Treatment response as indicated by one of the following *BCR-ABL1* (IS) transcript levels:
    - > 0.1% to 10% at 3 months or 6 months; **OR**
    - > 0.1% to 1% at 12 months and beyond (if treatment goal is long-term survival); **OR**
    - ≤ 0.1% at 12 months and beyond (if treatment goal is treatment-free remission)

Note: Cytogenetic assessment of response may be used if quantitative RT-PCR (QPCR) using International Scale (IS) for *BCR-ABL1* is not available

- **Acute lymphoblastic leukemia (ALL) only**:
  - Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR or FISH
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes only:**
  - Disease response as evidenced by at least one of the following:
    - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
    - Stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular complete response CR), complete hematologic response, or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

Please continue below for additional formulary specific criteria.

CORE FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myelogenous Leukemia (CML)**

- ***For new starts only***: Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic imatinib*** (***following the NCCN guidelines surrounding genetic mutations)

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with moderate or strong CYP3A inhibitors (e.g., itraconazole, fluconazole, clarithromycin, etc.); **AND**
  - Coadministration with proton pump inhibitors (e.g., lansoprazole, esomeprazole, omeprazole); **AND**
- Patient's disease is confirmed by either a Philadelphia chromosome-positive (Ph+) or *BCR-ABL1* positive laboratory test result; **AND**
- Patient does not have any of the following *BCR-ABL1* mutations: T315I, V299L, G250E, or F317L (****Note:** This does **not** apply to patients receiving first-line or continued therapy); **AND**
  - Patient is resistant, intolerant, or had an inadequate response to prior therapy consisting of a 3-month or longer trial with a tyrosine kinase inhibitor (e.g., imatinib, dasatinib, ponatinib, nilotinib, etc.); **AND**
    - Patient has chronic, accelerated, or blast phase disease; **OR**
  - Used post-allogeneic hematopoietic stem cell transplant (HCT) ; **AND**
    - Used as follow-up therapy in patients with molecular relapse (BCR-ABL1 transcript positive) following complete cytogenetic response (CCyR); **OR**
    - Used for at least one year in patients with prior CCyR for accelerated or blast phase disease; **OR**
    - Used as follow-up therapy in patients with relapse or those who are not in CCyR; **OR**
  - Used as primary treatment ; **AND**
    - Used as a single agent for newly diagnosed chronic or accelerated or myeloid blast phase disease; **OR**
    - Used in combination with corticosteroids for lymphoid blast phase disease; **OR**
    - Used in combination with induction chemotherapy for disease in lymphoid blast phase or myeloid blast phase; **OR**
  - Used as switch therapy ; **AND**
    - Patient received primary treatment with one of the following: imatinib, dasatinib, or nilotinib; **AND**
    - Patient has *BCR-ABL1* transcript levels:
      - > 1% to 10% at 12 months; **OR**
      - > 0.1% to 1% at 12 months (if treatment goal is treatment-free remission); **OR**
      - > 10% at any response milestone; **OR**
  - Used as continued therapy ; **AND**
    - Patient has *BCR-ABL1* transcript levels
      - ≤ 10% at any response milestone; **OR**
      - > 10% at 3 months

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with moderate or strong CYP3A inhibitors (e.g., itraconazole, fluconazole, clarithromycin, etc.); **AND**
  - Coadministration with proton pump inhibitors (e.g., lansoprazole, esomeprazole, omeprazole); **AND**
- Patient's disease is Philadelphia chromosome-positive (Ph+); **AND**
- Patient does not have any of the following *BCR-ABL1* mutations: T315I, V299L, G250E, or F317L; **AND**
  - Used for relapsed or refractory disease; **AND**
    - Used as a single agent; **OR**
    - Used in combination with an induction therapy not previously used; **OR**
    - Used in combination inotuzumab ozogamicin in patients who are TKI intolerant/refractory; **OR**
    - Used in combination with blinatumomab; **OR**
  - Used as maintenance therapy; **AND**
    - Used in combination with vincristine and prednisone with or without methotrexate and mercaptopurine; **OR**
    - Used post-hematopoietic stem cell transplant; **OR**
  - Patient is at least 15 years of age and < 65 years of age; **AND**
    - Used in a multiagent chemotherapy regimen for induction or consolidation therapy; **OR**
    - Used in combination with a corticosteroid for induction or consolidation therapy; **OR**
    - Used in combination with vincristine and dexamethasone for induction therapy; **OR**
    - Used in combination with blinatumomab as consolidation therapy for persistent/rising minimal residual disease following a complete response (CR) to induction therapy; **OR**
  - Patient is ≥ 65 years of age or with substantial comorbidities; **AND**
    - Used as induction therapy as part of one of the following regimens:
      - As a single agent or in combination with a corticosteroid; **OR**
      - In combination with vincristine and dexamethasone; **OR**
      - In combination with a multiagent chemotherapy regimen; **OR**
    - Used as consolidation therapy; **AND**
      - Patient has persistent/rising minimal residual disease following a complete response (CR) to induction therapy; **AND**
      - Used in combination with blinatumomab

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes only**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with moderate or strong CYP3A inhibitors (e.g., itraconazole, fluconazole, clarithromycin, etc.); **AND**
  - Coadministration with proton pump inhibitors (e.g., lansoprazole, esomeprazole, omeprazole); **AND**
- Patient has eosinophilia and ABL1 rearrangement; **AND**
  - Patient has chronic phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hepatic toxicity, renal toxicity, fluid retention, myelosuppression, gastrointestinal toxicity, cardiovascular toxicity (cardiac failure, left ventricular dysfunction, cardiac ischemic events), etc.; **AND**
- Patient has been adherent to therapy; **AND**
- **Chronic myelogenous leukemia (CML) only**:
  - Treatment response as indicated by one of the following *BCR-ABL1* (IS) transcript levels:
    - > 0.1% to 10% at 3 months or 6 months; **OR**
    - > 0.1% to 1% at 12 months and beyond (if treatment goal is long-term survival); **OR**
    - ≤ 0.1% at 12 months and beyond (if treatment goal is treatment-free remission)

Note: Cytogenetic assessment of response may be used if quantitative RT-PCR (QPCR) using International Scale (IS) for *BCR-ABL1* is not available

- **Acute lymphoblastic leukemia (ALL) only**:
  - Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR or FISH
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes only:**
  - Disease response as evidenced by at least one of the following:
    - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
    - Stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular complete response CR), complete hematologic response, or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH)

BOTOX® (ONABOTULINUMTOXINA)

Length of Authorization:	6 months, may be renewed Preoperative use in ventral hernia may **not** be renewed
Initiative:	SPC: Botulinum toxin (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

NOTE: FOR ANY COSMETIC PURPOSE, REFER TO THE MAIN CRITERIA DOCUMENT "COSMETIC AGENTS – BENEFIT BUILDER"

NOTE: For denials due to quantity requests over the FDA limit, please use the following initiative and reason code:

- SPC: Botulinum Toxin

DCDD: Denial: Does not Meet FDA criteria for Diagnosis and Dose

Note*: **For all shared FDA approved indications with Dysport®, the patient must have a documented failure, contraindication, or intolerance to Dysport® prior to the consideration of Botox®***

Note: For Core Formulary, all botulinum toxin products are non-formulary.

Diagnosis of **Blepharospasm**

- Patient is 12 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (i.e., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB)

Diagnosis of **Cervical Dystonia**

- Patient is 16 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (i.e., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient has a history of recurrent involuntary contraction of one or more muscles in the neck; **AND**
  - Patient has sustained head tilt; **OR**
  - Abdominal posturing with limited range of motion in neck; **AND**
- ***If the patient is 18 years of age or older, the patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Dysport®***

Diagnosis of **Strabismus**

- Patient is 12 years of age or older; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (i.e., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Spastic Conditions**

- Patient is 18 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (i.e., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient has one of the following diagnosis:
  - Upper/lower limb spasticity in adults (i.e., used post-stroke for spasms)
    - ***Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Dysport®.***
  - Pediatric upper limb spasticity in patients 2 years of age or older (i.e., used post-stroke for spasms or for spasms related to cerebral palsy)
  - Pediatric lower limb spasticity in patients 2 years of age or older
  - Spasticity due to multiple sclerosis or Schilder's disease
  - ***Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Dysport®.***
  - Acquired spasticity secondary to spinal cord or brain injuries
    - ***Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Dysport®***
  - Spastic plegic conditions including monoplegia, diplegia, hemiplegia, paraplegia (including hereditary spastic paraplegia), and quadriplegia
  - Hemifacial spasm

Diagnosis of **Severe Primary Axillary Hyperhidrosis**

- Patient is 18 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- **Documentation (e.g., clinical notes) is required to be submitted to demonstrate appropriate trials of required alternative medications and failures**
- Patient has tried and failed ≥ 1-month trial of a topical agent (e.g., aluminum chloride, glycopyrronium); **AND**
- Patient has history of medical complications such as skin infections or significant functional impairments; **OR**
- Patient has had a significant burden of disease or impact to activities of daily living due to condition (e.g., impairment in work performance/productivity, frequent change of clothing, difficulty in relationships and/or social gatherings).

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Prophylaxis of Chronic Migraines**

- Patient is 18 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB.)*;* **AND**
- Not used in combination with prophylactic calcitonin gene-related peptide (CGRP) inhibitors (e.g., eptinezumab, erenumab, galcanezumab, fremanezumab) (*NOTE: This does not include CGRP inhibitors used for acute treatment [i.e., ubrogepant])*; **AND**
- Patient is utilizing prophylactic intervention modalities (e.g., pharmacotherapy, behavioral therapy, or physical therapy); **AND**
- Patient has 15 or more headache (tension-type-like and/or migraine-like) days per month for at least 3 months (**supported through clinical documentation/clinical notes**); **AND**
  - Patient has had at least five attacks with features consistent with migraine (with and/or without aura); **AND**
  - On at least 8 days per month for at least 3 months:
    - Headaches have characteristics and symptoms consistent with migraine; **OR**
    - Patient suspected migraines are relieved by a triptan or ergot derivative medication; **AND**
- **Documentation (e.g., clinical notes) is required to be submitted to demonstrate appropriate trials of required alternative medications and failures.**
- Patient has failed at least an 8-week trial of any two oral medications (a total of 16 weeks) for the prevention of migraines:
  - Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline)
  - Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol)
  - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan)
  - Anti-epileptics (e.g., divalproex, valproate, topiramate)
  - Calcium channels blockers (e.g., verapamil)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

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Migraine Features
Migraine without aura: • At least five attacks have the following: – Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated) – Headache has at least two of the following characteristics: • Unilateral location • Pulsating quality • Moderate or severe pain intensity • Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs); **AND** – During headache, at least one of the following: • Nausea and/or vomiting • Photophobia and phonophobia
Migraine with aura: • At least two attacks have the following: – One or more of the following fully reversible aura symptoms: ▪ Visual ▪ Sensory ▪ Speech and/or language ▪ Motor ▪ Brainstem ▪ Retinal; **AND** – At least three of the following characteristics: ▪ At least one aura symptom spreads gradually over ≥ 5 minutes ▪ Two or more symptoms occur in succession ▪ Each individual aura symptom lasts 5 to 60 minutes ▪ At least one aura symptom is unilateral ▪ At least one aura symptom is positive (e.g., scintillations and pins and needles) ▪ The aura is accompanied, or followed within 60 minutes, by headache

Diagnosis of **Esophageal Achalasia**

- Patient is age 18 or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient is at high risk of complication from pneumatic dilation, surgical myotomy, or peroral endoscopic myotomy (POEM); **OR**
- Patient has had treatment failure with pneumatic dilation, surgical myotomy, or POEM; **(supported with clinical documentation/clinical notes)**; **OR**
- Patient has had perforation from pneumatic dilation; **OR**
- Patient has an epiphrenic diverticulum or hiatal hernia; **OR**
- Patient has esophageal varices.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Focal Dystonias**

- Patient is 18 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Focal upper limb dystonia
  - Patient has functional impairment; **OR**
  - Patient has pain as a result.
- Laryngeal dystonia
- Oromandibular dystonia
  - Patient has functional impairment; **OR**
  - Patient has pain as a result.

Diagnosis of **Sialorrhea Associated with Neurological Disorders**

- Patient is 18 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient has a history of troublesome sialorrhea for at least a 3 month period; **AND**
  - Patient has Parkinson's disease; **OR**
  - Patient has severe developmental delays **OR**
  - Patient has cerebral palsy; **OR**
  - Patient has amyotrophic lateral sclerosis

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Incontinence due to detrusor overactivity**

- Patient is 5 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient does not have a current, untreated urinary tract infection; **AND**
- Patient has detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) that is confirmed by urodynamic testing; **AND**
- Patient has failed a 1 month or longer trial of **two** medications from either the antimuscarinic (i.e., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) or beta-adrenergic (i.e., mirabegron) classes.
- **Documentation (e.g., clinical notes) is required to be submitted to demonstrate appropriate trials of required alternative medications and failures**

Diagnosis of **Overactive Bladder (OAB)**

- Patient is 18 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient does not have a current, untreated urinary tract infection; **AND**
- Patient has symptoms of urge urinary incontinence, urgency, and frequency; **AND**
- Patient has failed a 1 month or longer trial of **two** medications from either the antimuscarinic (i.e., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) and/or beta-adrenergic (i.e., mirabegron) classes.
- **Documentation (e.g., clinical notes) is required to be submitted to demonstrate appropriate trials of required alternative medications and failures**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Severe Palmar Hyperhidrosis**

- Patient is 18 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- **Documentation (e.g., clinical notes) is required to be submitted to demonstrate appropriate trials of required alternative medications and failures**
- Patient has tried and failed ≥ 1-month trial of a topical agent (e.g., aluminum chloride); **AND**
- Patient has failed with iontophoresis; **AND**
  - Patient has history of medical complications such as skin infections or significant functional impairments; **OR**
  - Patient has had a significant impact to activities of daily living due to the condition.

Diagnosis of **Chronic Anal Fissure**

- Patient is 18 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (i.e., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Other causes of disease have been ruled out (e.g., Crohn's Disease); **AND**
- Patient has failed on non-pharmacologic supportive measures (e.g., sitz baths, psyllium fiber, bulking agents); **AND**
- Patient has tried and failed a ≥ 1-month trial of conventional therapy (e.g., oral/topical nifedipine, diltiazem, and/or topical nitroglycerin, bethanechol, etc.).
- **Documentation (e.g., clinical notes) is required to be submitted to demonstrate appropriate trials of required alternative medications and failures**

Diagnosis of **Ventral Hernia**

- Patient is 18 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient has a large ventral hernia with loss of domain or contaminated ventral hernia; **AND**
- Used preoperatively in patients scheduled to receive abdominal wall reconstruction (AWR)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of a toxin spread effect (e.g., asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, swallowing/breathing difficulties, etc.), severe hypersensitivity reactions, severe pulmonary effects (e.g., reduced pulmonary function), corneal exposure/ulceration, retrobulbar hemorrhage, bronchitis/upper-respiratory tract infections, autonomic dysreflexia, urinary tract infection, and urinary retention, etc.; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (i.e., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Disease response as evidenced by the following **(Documentation/clinical notes must be submitted to demonstrate objective response)**:
- Blepharospasms
  - Improvement of severity and/or frequency of eyelid spasms
- Cervical dystonia
  - Improvement in the severity and frequency of pain; **AND**
  - Improvement of abnormal head positioning
- Strabismus
  - Improvement in alignment of prism diopters compared to pre-treatment baseline
- Focal Upper/Lower Limb Spasticity
  - Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (e.g., Ashworth Scale, Physician Global Assessment, Clinical Global Impression [CGI])
- Hemifacial Spasms
  - Decrease in frequency and/or severity of spasm, or a decrease in tone and/or improvement in asymmetry to the affected side of the face
- Severe primary axillary hyperhidrosis
  - Significant reduction in spontaneous axillary sweat production; **AND**
  - Patient has a significant improvement in activities of daily living.
- Prophylaxis for chronic migraines
  - Not used in combination with calcitonin gene-related peptide (CGRP) inhibitors (e.g., erenumab), *(NOTE: This does not include CGRP inhibitors used for acute treatment [i.e., ubrogepant])*; **AND**
  - Significant decrease in the number, frequency, and/or intensity of headaches; **AND**
  - Improvement in function; **AND**
  - Patient continues to utilize prophylactic intervention modalities (i.e., pharmacotherapy, behavioral therapy, physical therapy).

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

- Esophageal achalasia
  - Improvement and/or relief in symptoms (e.g., dysphagia, pain); **OR**
  - Improvement in esophageal emptying as evidenced by functional testing.
- Focal Dystonias
  - Focal upper limb dystonia
    - Improvement in pain and/or function
  - Laryngeal dystonia
    - Improvement in voice function or quality
  - Oromandibular dystonia
    - Improvement in pain and function
- Sialorrhea associated with neurological disorders
  - Significant decrease in saliva production
- Incontinence due to detrusor overactivity
  - Patient does not have a current, untreated urinary tract infection; **AND**
  - Significant improvements in weekly frequency of incontinence episodes; **AND**
  - Patient's post-void residual (PVR) periodically assessed as medically appropriate.
- Overactive bladder (OAB)
  - Patient does not have a current, untreated urinary tract infection; **AND**
  - Significant improvement in daily frequency of urinary incontinence or micturition episodes and/or volume voided per micturition; **AND**
  - Patient's post-void residual (PVR) periodically assessed as medically appropriate.
- Severe Palmar Hyperhidrosis
  - Significant reduction in spontaneous palmar sweat production; **AND**
  - Patient has a significant improvement in activities of daily living
- Chronic anal fissure
  - Complete healing of anal fissure; **OR**
  - Symptomatic improvement of persistent fissures
- Spastic Conditions, Other (Plegias, etc.)
  - Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (e.g., Ashworth Scale, Physician Global Assessment, Clinical Global Impression [CGI])
- Ventral Hernias
  - May not be renewed

DOSAGE AND ADMINISTRATION

- When initiating treatment, the lowest recommended dose should be used.
- In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 units, in a 3-month (12-week) interval.
- In treating pediatric patients, the total should not exceed the lower of 8 units/kg body weight or 300 units, in a 3-month (12-week) interval.
- Unless otherwise stated, re-treatment should occur no sooner than 12 weeks from the prior injection.

NOTE: For denials due to quantity requests over the FDA limit, please use the following initiative and reason code:

- SPC: Botulinum Toxin
- DCDD: Denial: Does not Meet FDA criteria for Diagnosis and Dose

Indication	Dose
Blepharospasm	1.25–2.5 units (0.05–0.1 mL per site) injected into each of 3 sites per affected eye every three months. There appears to be little benefit obtainable from injecting more than 5 units per site. The effect of treatment lasts an average of 12 weeks. Cumulative dose in 30 days should not exceed 200 units
Cervical Dystonia	198–300 units divided among the affected muscles. No more than 50 units per site. May re-treat in 12 weeks.
Strabismus	Based on muscle(s) affected, 1.25–2.5 units in any one muscle initially. Subsequent doses may be increased up to two-fold compared to previously administered dose. No more than 25 units in any one muscle for recurrent cases. The effect of treatment usually lasts about 12 weeks.
Esophageal Achalasia	100 units (20–25 units per quadrant) per administration. Dose may be repeated in 6 months (24 weeks).
Upper Limb Spasticity	Dosing in initial and sequential treatment sessions should be tailored to the individual based on the size, number and location of muscles involved, severity of spasticity, the presence of local muscle weakness, the patient's response to previous treatment, or adverse event history with Botox®. For pediatrics, localization of the involved muscles with techniques such as needle electromyographic guidance, nerve stimulation, or ultrasound is recommended. Adults • In clinical trials, doses ranging from 75–400 units were divided among selected muscles at a given treatment session no sooner than every 12 weeks. Pediatrics • The recommended dose for treating pediatric upper limb spasticity is 3–6 units/kg divided among the affected muscles. The total dose of Botox® administered per treatment session in the upper limb should not exceed 6 units/kg or 200 units, whichever is lower. The maximum cumulative dose should not exceed the lower of 8 units/kg body weight or 300 units, in a 3-month interval.

Indication	Dose
Lower Limb Spasticity	Adults • 300–400 units divided among 5 muscle groups (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus) no sooner than every 12 weeks. Pediatrics • The recommended dose for treating pediatric lower limb spasticity is 4–8 units/kg divided among the affected muscles. The total dose of Botox® administered per treatment session in the lower limb should not exceed 8 units/kg or 300 units, whichever is lower. The maximum cumulative dose should not exceed the lower of 10 units/kg body weight or 340 units in a 3-month interval.
Chronic Migraine	155 units administered intramuscularly (IM) as 0.1 mL (5 units) injections per each site. Injections should be divided across 7 specific head/neck muscle areas. The recommended re-treatment schedule is every 12 weeks.
Severe Primary Axillary Hyperhidrosis	50 units intradermally per axilla every 16 weeks.
Sialorrhea	15–40 units in the parotid gland injected in two places and 10–15 units in the submandibular glands (total dose from 50-100 units per patient/administration) repeated in 3 months (12 weeks) if needed.
Neurogenic Bladder/Detrusor Overactivity	200 units per treatment injected into the detrusor muscle using 30 injections (6.7 units each). Re-inject no sooner than 12 weeks from the prior bladder injection.
Overactive Bladder (OAB)	100 units per treatment injected into the detrusor muscle using 20 injections (5 units each). Re-inject no sooner than 12 weeks from the prior bladder injection.
Palmar Hyperhidrosis	50–100 units per hand repeated every 6 months (24 weeks) as needed
Hemifacial Spasms	Recommended dose of 20–40 units divided among affected muscles. Re-treatment within 12 weeks.
Oromandibular Dystonia	80 units per side (~40 units injected into both the masseter and submentalis complex muscles) every 12 weeks.
Laryngeal Dystonia	Starting dose of 1.25–5 units into thyroarytenoid muscle. Dose is titrated based on response and side effects after. Re-treat every 3 months (12 weeks).
Chronic Anal Fissures	Recommended doses of up to 25 units injected into the anal sphincter. Re-treat every 3 months (12 weeks).
Ventral Hernia	500 units divided among abdominal muscles injected 2–4 weeks prior to AWR surgery. *May not be renewed*.
All other indications (unless otherwise specified)	Not to exceed a cumulative dose of 400 units (for one or more indications) every 12 weeks.

- When initiating treatment, the lowest recommended dose should be used.
- In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 units in a 3-month (12-week) interval (unless used for ventral hernia).
- In treating pediatric patients, the total should not exceed the lower of 10 units/kg body weight or 340 units in a 3-month (12-week) interval.
- Unless otherwise stated, re-treatment should occur no sooner than 12 weeks from the prior injection.

DOSAGE AND ADMINISTRATION *(CONTINUED)*

Max Units (per dose and over time):

Indication	# vials to build in FirstTrax℠	Per # days*
Blepharospasm	1 (200 unit vial)	84
Cervical Dystonia	2 (200 unit vial)	84
Strabismus	1 (100 unit vial)	84
Esophageal Achalasia	1 (100 unit vial)	168
Adult Upper Limb Spasticity	2 (200 unit vial)	84
Adult Lower Limb Spasticity	2 (200 unit vial)	84
Chronic Migraine	1 (200 unit vial)	84
Severe Primary Axillary Hyperhidrosis	1 (100 unit vial)	112
Sialorrhea	1 (100 unit vial)	84
Neurogenic Bladder/Detrusor Overactivity	1 (200 unit vial)	84
Overactive Bladder	1 (100 unit vial)	84
Chronic Anal Fissures	1 (100 unit vial)	84
Palmar Hyperhidrosis	1 (200 unit vial)	168
Pediatric Upper limb spasticity	3 (100 unit vial)	84
Pediatric Lower Limb Spasticity	3 (100 unit vial)	84
Laryngeal Dystonia	1 (100 unit vial)	84
Hemifacial Spasms	1 (100 unit vial)	84
Oromandibular Dystonia	1 (200 unit vial)	84
Ventral Hernia	5 (100 unit vial)	N/A
All other indications	2 (200 unit vial)	84

Available in 100 unit and 200 unit single-use vials.

* The plan may only allow for a max of 30 days to be billed at a time; no days' supply override needs to be placed to allow these to pay. The pharmacy may process as 30 days. These limitations will not allow the member to fill more than the allotted vials.

BPH MEDICATIONS

Length of Authorization:	1 year
Initiative:	MNC: BPH Medications (IE 2462 / NCPDP 75) Gender Override: (IE SX/NCPCP 88) included.

STANDARD AND PRECISION FORMULARY

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

STEP CRITERIA FOR CARDURA XL (NO GRANDFATHERING)

- Trial and failure of one of the following generics: alfuzosin, doxazosin, dutasteride, finasteride, silodosin, tamsulosin, or terazosin

BRAFTOVI™ (ENCORAFENIB)

Length of Authorization:	6 months, eligible for renewal Coverage for the adjuvant treatment of melanoma is up to a maximum of 1 year of therapy.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cutaneous Melanoma**

- Patient is at least 18 years of age; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, dabrafenib, cobimetinib, trametinib) unless otherwise specified; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong or moderate CYP3A4 inhibitors (e.g., fluconazole, itraconazole, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.)
  - Drugs known to prolong the QT/QTc interval (e.g., amitriptyline, amiodarone, etc.); **AND**
- Patient has BRAF V600 mutation-positive disease as detected by an FDA approved or CLIA compliant test; **AND**
  - Patient has unresectable or metastatic** disease; **AND**
    - Used in combination with binimetinib or as a single-agent if BRAF/MEK inhibitor combination contraindications exist; **AND**
      - Used as initial therapy or subsequent therapy; **OR**
      - Used as re-induction therapy for patients who experience disease control (i.e., complete response, partial response, or stable disease) from prior BRAF inhibitor therapy but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**
  - Used as adjuvant therapy in combination with binimetinib in patients with unacceptable toxicities to dabrafenib/trametinib; **AND**
    - Patient has lymph node involvement following complete resection, complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; **OR**
    - Patient has clinical satellite/in-transit metastases or local satellite/in-transit recurrence with no evidence of disease (NED) after complete excision to clear margins; **OR**
- Patient has NTRK gene fusion positive disease, **AND**
  - Patient has unresectable or metastatic** disease; **AND**
  - Used as single agent therapy; **AND**
  - Used as subsequent therapy for disease progression or after maximum clinical benefit from BRAF targeted therapy

***Metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease*

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

Diagnosis of **Colorectal Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, dabrafenib, cobimetinib, trametinib) unless otherwise specified; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong or moderate CYP3A4 inhibitors (e.g., fluconazole, itraconazole, etc.), if therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.)
  - Drugs known to prolong the QT/QTc interval (e.g., amitriptyline, amiodarone, etc.); **AND**
- Patient has BRAF V600E or V600K mutation positive disease as detected by an FDA approved or CLIA compliant test
- Used in combination with cetuximab or panitumumab; **AND**
  - Used as primary treatment for unresectable metastatic disease after previous adjuvant FOLFOX or CapeOX within the past 12 months; **OR**
  - Used as subsequent therapy for advanced or metastatic disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., major hemorrhagic events, QTc prolongations (i.e., QTc > 500 ms), uveitis, new primary malignancies)
- **Adjuvant treatment of Melanoma**
  - Treatment has not exceeded 1 year of therapy
- **Cutaneous Melanoma (re-induction therapy)**
  - Refer to initial criteria (see Cutaneous Melanoma – used as re-induction therapy)

BRAND/GENERIC STEP THERAPY INITIATIVE

Length of Authorization:	1 year, may be renewed
Initiative:	MNC: MNC: Multisource Brand Step(IE 2462 / NCPDP 75) (for standard formulary) MNC: Non-formulary Product (50698) (For precision formulary)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

STANDARD FORMULARY

ENHANCED FORMULARY

- If there is no criteria elsewhere in the document for the brand medication, the patient must try the equivalent generic for at least 60 days.
- Members utilizing anticonvulsants and thyroid medications on this list may be grandfathered if they were previously established.

PRECISION FORMULARY

CORE FORMULARY

- For Precision/Plus exclusions follow the Precision/Plus and Core Exception process. **Please refer to this link for the precision exclusion list.**
- Members utilizing anticonvulsants and thyroid medications on this list may be grandfathered if they were previously established.

CLINICAL CRITERIA FOR RENEWAL

See initial criteria.

BREYANZI® (LISOCABTAGENE MARALEUCEL)

Length of Authorization:	• Coverage will be provided for one treatment course (1 dose of Breyanzi) and may not be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Submission of medical records related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation via direct upload through the PA web portal or by fax.

Diagnosis of **Large B-cell Lymphoma**

- Patient is 18 years or older; **AND**
- Patient does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy and will not receive live vaccines during lisocabtagene maraleucel treatment and until immune recovery following treatment; **AND**
- Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**
- Healthcare facility has enrolled in the BREYANZI REMS Program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
- Patient has not received prior CAR-T therapy; **AND**
- Patient has not received prior anti-CD19 therapy, (e.g., tafasitamab, etc.) OR patient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**
- Used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); **AND**
- Patient does not have primary central nervous system lymphoma; **AND**
- Patient has diffuse large B cell lymphoma (DLBCL), high-grade B-cell lymphoma, primary mediastinal B-cell lymphoma (PMBCL), follicular lymphoma grade 3B, AIDS-related B-cell lymphoma (e.g., diffuse large B-cell lymphoma, primary effusion lymphoma, and HHV8-positive diffuse large B-cell lymphoma, not otherwise specified), or monomorphic post-transplant lymphoproliferative disorder (B-cell type); **AND**
  - Used as additional therapy for patients with intention to proceed to transplant who have a partial response following second-line therapy for relapsed or refractory disease; **OR**
  - Used for treatment of disease that is in second or greater relapse; **OR**
- Patient has histologic transformation of follicular lymphoma, gastric or non-gastric MALT lymphoma, or nodal or splenic marginal zone lymphoma to DLBCL OR Richter's transformation of CLL to DLBCL; **AND**
  - Patient received at least two (2) prior lines of chemoimmunotherapy, which must have included an anthracycline or anthracenedione-based regimen, unless contraindicated

CLINICAL CRITERIA FOR RENEWAL

- Coverage cannot be renewed

BRINEURA™ (CERLIPONASE ALFA)

Length of Authorization:	6 months, eligible for renewal
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Late infantile neuronal ceroid lipofuscinosis type 2 (CLN2); tripeptidyl peptidase 1 (TPP1) deficiency**

- Patient is at 3 years of age or older; **AND**
- Patient must not have acute intraventricular access device-related complications (e.g., leakage, extravasation of fluid, or device-related infection); **AND**
- Patient must not have ventriculoperitoneal shunts; **AND**
- Patient has no sign or symptom of acute, unresolved localized infection on or around the device insertion site (e.g., cellulitis or abscess); or a suspected or confirmed CNS infection; **AND**
- Patient must have a definitive diagnosis of late infantile CLN2 confirmed by deficiency of the lysosomal enzyme tripeptidyl peptidase-1 (TPP1) and/or molecular analysis indicating dysfunctional mutation of the TPP1 gene on chromosome 11p15.4; **AND**
- Patient has mild to moderate disease documented by a two-domain score of 3 to 6 on the motor and language domains of the Hamburg CLN2 Clinical Rating Scale, with a score of at least 1 in each of these two domains; **AND**
- Patient is ambulatory; **AND**
- Patients with a history of bradycardia, conduction disorder, or with structural heart disease must have electrocardiogram (ECG) monitoring performed during the infusion

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug or complications from the device (e.g., meningitis and other intraventricular access device-related infections, intraventricular access device-related complications, severe hypersensitivity reaction, severe cardiovascular reactions, severe hypotension); **AND**
- Patient had a 12-lead ECG evaluation performed within the last 6 months (those with cardiac abnormalities require ECG during each infusion); **AND**
- Patient has responded to therapy compared to pretreatment baseline with stability/lack of decline in motor function/milestones on the **Motor** domain of the Hamburg CLN2 Clinical Rating Scale (decline is defined as having an unreversed [sustained] 2-category decline or an unreversed score of 0).

BRONCHITOL® (MANNITOL)

Length of Authorization:	12 months, may be renewed
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cystic Fibrosis**

- Patient is 18 years of age or older; **AND**
- Bronchitol will be used as add-on maintenance therapy to improve pulmonary function; **AND**
- Patient has passed the Bronchitol Tolerance Test (BTT); **AND**
- Patient does NOT have bronchospasm; **AND**
- Patient does NOT have significant hemoptysis; **AND**
- Patient does NOT have a hypersensitivity to mannitol or to any of the capsule components; **AND**
- Prescribed by or in consultation with a pulmonologist.

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet initial criteria above; **AND**
- Patient must have symptom improvement (pulmonary function [e.g., FEV_1 improvement]); **AND**
- Patient has NOT experienced any treatment-restricting adverse effects (e.g., cough, hemoptysis).

BRUKINSA (ZANUBRUTINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **B-Cell Lymphomas**

- Patient is at least 18 years of age; **AND**
- Used as single agent therapy; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with moderate or strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, phenobarbital, etc.); **AND**
  - Coadministration with moderate or strong CYP3A inhibitors (e.g., itraconazole, clarithromycin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Mantle Cell Lymphoma (MCL)
  - Patient has received at least one prior therapy
- Marginal Zone Lymphomas (Gastric or Nongastric MALT Lymphoma, Nodal MZL, or Splenic MZL)
  - Patient has relapsed or refractory disease; **AND**
  - Used as subsequent therapy after at least one prior anti-CD20 monoclonal antibody-based regimen (e.g., rituximab, obinutuzumab, ofatumumab, etc.)

Diagnosis of **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL)**

- Patient is at least 18 years of age; **AND**
- Used as single agent therapy; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with moderate or strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, phenobarbital, etc.); **AND**
  - Coadministration with moderate or strong CYP3A inhibitors (e.g., itraconazole, clarithromycin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented

Diagnosis of **Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL)**

- Patient is at least 18 years of age; **AND**
- Used as single agent therapy; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with moderate or strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, phenobarbital, etc.); **AND**
  - Coadministration with moderate or strong CYP3A inhibitors (e.g., itraconazole, clarithromycin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented
- Patient does NOT have ibrutinib-refractory disease with BTK C481S mutations; **AND**
- Patient has a contraindication to treatment with other BTK-inhibitors (e.g., ibrutinib, acalabrutinib, etc.); **AND**
  - Used as first-line therapy for disease with del(17p)/TP53 mutation; **OR**
- Patient has a contraindication or intolerance to treatment with other BTK-inhibitors (e.g., ibrutinib, acalabrutinib, etc.); **AND**
  - Used as subsequent therapy for disease with or without del(17p)/TP53 mutation

***NOTE:** Testing for BTK and PLCG2 mutations may be useful in patients with disease progression or no response while on BTK inhibitor therapy. BTK and PSCG2 mutation status alone is not an indication to change treatment.*

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hemorrhage, severe infections, myelosuppression (neutropenia, thrombocytopenia, anemia), atrial fibrillation/flutter, second primary malignancies, etc; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread.

BYLVAY™ (ODEVIXIBAT)

Length of Authorization:	6 months initial, 1 year on renewal
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **progressive familial intrahepatic cholestasis (PFIC) type 1 or type 2**:

- Patient is at least 3 months of age; **AND**
- The diagnosis has been confirmed by genetic test; AND
- Patient has elevated serum bile acid concentration; **AND**
- Patient experiences persistent moderate to severe pruritus; **AND**
- Patient does NOT have any of the following:
  - Positive test for the *ABCB11* gene variant that predicts complete absence of the bile salt export pump (BSEP) protein; **AND**
  - Prior hepatic decompensation event; **AND**
  - Another concomitant liver disease; **AND**
  - An international normalized ratio (INR) > 1.4; **AND**
  - Significant portal hypertension; **AND**
  - An alanine aminotransferase (ALT) or total bilirubin (TB) level more than 10 times the upper limit of normal (ULN); **AND**
  - Medical history or ongoing chronic diarrhea; **AND**
  - Decompensated cirrhosis; **AND**
  - Significant portal hypertension; **AND**
- Odevixibat is prescribed by or in consultation with a specialist (e.g., gastroenterologist, hepatologist, dermatologist); **AND**
- Patient has failed an adequate trial, or is intolerant to, or has a contraindication to at least 1 pruritus treatment (e.g., ursodeoxycholic acid [ursodiol], cholestyramine, rifampin, naloxone, naltrexone, antihistamine). ***Note: use of these agents are off-label***

CLINICAL CRITERIA FOR RENEWAL

- Patient has experienced a reduction in serum bile acids from baseline; **AND**
- Patient must continue to meet the above criteria, with the exception of the initial serum bile acid approval criteria; **AND**
- Patient must experience improvement in pruritus; **AND**
- Patient has NOT experienced any treatment-restricting adverse effects (e.g., persistent diarrhea; persistent fat-soluble vitamin deficiency despite vitamin A, D, E, K supplementation; elevated liver function tests [alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TB), direct bilirubin (DB)]); **AND**
- Patient has not developed decompensated cirrhosis; **AND**
- Patient has not developed significant portal hypertension

CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS

Length of Authorization:	Aimovig, Ajovy, Emgality: Three months for initial approval; twelve months for renewal Nurtec, Ubrelvy: Twelve months for initial and renewal
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

AIMOVIG, AJOVY, AND EMGALITY

Migraine

- Patient is 18 years of age or older; **AND**
- Diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria; **AND**
- Medication overuse headache has been ruled out by trial and failure of titrating off acute migraine treatments in the past; **AND**
- Patient has ≥ 4 migraine days per month for at least 3 months; **AND**
- Patient has tried and failed a ≥ 1-month trial of any two different classes of the following oral medications:
  - Antidepressants (e.g., amitriptyline, venlafaxine, etc.)
  - Beta blockers (e.g., propranolol, metoprolol, timolol, atenolol, etc.)
  - Anti-epileptics (e.g., valproate, topiramate, etc.)
  - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan, etc.); **AND**
- Not used in combination with botulinum agents (i.e., Botox, Dysport, Myobloc, Xeomin)

EMGALITY

Episodic cluster headache

- Patient is 18 years of age or older; **AND**
- Diagnosis of episodic cluster headache; **AND**
- Patient has experienced at least 2 cluster periods lasting 7 days to 365 days, separated by pain-free periods lasting at least three months; **AND**
- Requested by or in consultation with a specialist (including neurologist or pain specialist); **AND**
- Not used in combination with another CGRP inhibitor; **AND**
- Not used in combination with botulinum agents (e.g., Botox, Dysport, Myobloc, Xeomin)

AJOVY (NO GRANDFATHERING)

- In addition to the above clinical criteria:
  - Patient has a trial and failure of Aimovig AND Emgality.

CLINICAL CRITERIA FOR RENEWAL (MAY BE REQUESTED BY PCP)

- Not used in combination with botulinum agents (e.g., Botox, Dysport, Myobloc, Xeomin); **AND**
- Patient demonstrated significant decrease in the number, frequency, and/or intensity of headaches; **AND**
- Patient has an overall improvement in function with therapy; **AND**
- Absence of unacceptable toxicity (e.g., intolerable injection site pain or constipation).

CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS (CONTINUED)

NURTEC

For **acute treatment of migraine**:

- Patient is 18 years of age or older; **AND**
- Diagnosis of migraine, with or without aura; **AND**
- Patient must **not** have headache frequency ≥ 15 headache days per month during the prior 6 months [indication is for acute use only]; **AND**
- Patient must **not** be concurrently using strong CYP3A4 inhibitors, strong or moderate CYP3A inducers, or P-gp or BCRP inhibitors; **AND**
- Patient must have tried and failed at least one of the following: NSAID, non-opioid analgesic, acetaminophen OR caffeinated analgesic combination; **AND**
- Patient must have tried and failed, or has a contraindication or intolerance to 2 generic triptans.

For **preventive treatment of episodic migraine**:

- Patient is 18 years of age or older; **AND**
- Diagnosis of migraine, with or without aura; **AND**
- Patient must **not** be concurrently using strong CYP3A4 inhibitors, strong or moderate CYP3A inducers, or P-gp or BCRP inhibitors; **AND**
- Patient must **not** have headache frequency ≥ 15 headache days per month during the prior 6 months; **AND**
- Patient has tried and failed a ≥ 1-month trial of any two different classes of the following oral medications:
  - Antidepressants (e.g., amitriptyline, venlafaxine, etc.)
  - Beta blockers (e.g., propranolol, metoprolol, timolol, atenolol, etc.)
  - Anti-epileptics (e.g., valproate, topiramate, etc.)
  - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan, etc.)

For renewal:

- Patient must continue to meet initial criteria; **AND**
- Patient is experiencing symptom improvement; **AND**
- The patient is not experiencing any treatment-limiting adverse reactions of the medication

UBRELVY

- Patient is 18 years of age or older; **AND**
- Diagnosis of migraine, with or without aura; **AND**
- Patient must **not** have headache frequency ≥ 15 headache days per month during the prior 6 months [indication is for acute use only]; **AND**
- Patient must **not** be concurrently using a strong CYP3A4 inhibitor; **AND**
- Patient must have tried and failed at least one of the following: NSAID, non-opioid analgesic, acetaminophen OR caffeinated analgesic combination; **AND**
- Patient must have tried and failed, or has a contraindication or intolerance to 2 generic triptans.

For renewal:

- Patient must continue to meet initial criteria; **AND**
- Patient is experiencing symptom improvement; **AND**
- The patient is not experiencing any treatment-limiting adverse reactions of the medication

PRECISION FORMULARY CRITERIA

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

AIMOVIG AND EMGALITY

Migraine

- Patient is 18 years of age or older; **AND**
- Diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria; **AND**
- Medication overuse headache has been ruled out by trial and failure of titrating off acute migraine treatments in the past; **AND**
- Patient has ≥ 4 migraine days per month for at least 3 months; **AND**
- Patient has tried and failed a ≥ 1-month trial of any two different classes of the following oral medications:
  - Antidepressants (e.g., amitriptyline, venlafaxine, etc.)
  - Beta blockers (e.g., propranolol, metoprolol, timolol, atenolol, etc.)
  - Anti-epileptics (e.g., valproate, topiramate, etc.)
  - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan, etc.); **AND**
- Not used in combination with botulinum agents (e.g., Botox, Dysport, Myobloc, Xeomin)

EMGALITY

Episodic cluster headache

- Patient is 18 years of age or older; **AND**
- Diagnosis of episodic cluster headache; **AND**
- Patient has experienced at least 2 cluster periods lasting 7 days to 365 days, separated by pain-free periods lasting at least three months; **AND**
- Requested by or in consultation with a specialist (including neurologist or pain specialist); **AND**
- Not used in combination with another CGRP inhibitor; **AND**
- Not used in combination with botulinum agents (e.g., Botox, Dysport, Myobloc, Xeomin)

CLINICAL CRITERIA FOR RENEWAL (MAY BE REQUESTED BY PCP)

- Not used in combination with botulinum agents (e.g., Botox, Dysport, Myobloc, Xeomin); **AND**
- Patient demonstrated significant decrease in the number, frequency, and/or intensity of headaches; **AND**
- Patient has an overall improvement in function with therapy; **AND**
- Absence of unacceptable toxicity (e.g., intolerable injection site pain or constipation).

NURTEC

For **acute treatment of migraine**:

- Patient is 18 years of age or older; **AND**
- Diagnosis of migraine, with or without aura; **AND**
- Patient must **not** have headache frequency ≥ 15 headache days per month during the prior 6 months [indication is for acute use only]; **AND**
- Patient must **not** be concurrently using strong CYP3A4 inhibitors, strong or moderate CYP3A inducers, or P-gp or BCRP inhibitors; **AND**
- Patient must have tried and failed at least one of the following: NSAID, non-opioid analgesic, acetaminophen OR caffeinated analgesic combination; **AND**
- Patient must have tried and failed, or has a contraindication or intolerance to 2 generic triptans.

For **preventive treatment of episodic migraine**:

- Patient is 18 years of age or older; **AND**
- Diagnosis of migraine, with or without aura; **AND**
- Patient must **not** be concurrently using strong CYP3A4 inhibitors, strong or moderate CYP3A inducers, or P-gp or BCRP inhibitors; **AND**
- Patient must **not** have headache frequency ≥ 15 headache days per month during the prior 6 months; **AND**
- Patient has tried and failed a ≥ 1-month trial of any two different classes of the following oral medications:
  - Antidepressants (e.g., amitriptyline, venlafaxine, etc.)
  - Beta blockers (e.g., propranolol, metoprolol, timolol, atenolol, etc.)
  - Anti-epileptics (e.g., valproate, topiramate, etc.)
  - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan, etc.)

For renewal:

- Patient must continue to meet initial criteria; **AND**
- Patient is experiencing symptom improvement; **AND**
- The patient is not experiencing any treatment-limiting adverse reactions of the medication

UBRELVY

- Patient is 18 years of age or older; **AND**
- Diagnosis of migraine, with or without aura; **AND**
- Patient must **not** have headache frequency ≥ 15 headache days per month during the prior 6 months [indication is for acute use only]; **AND**
- Patient must **not** be concurrently using a strong CYP3A4 inhibitor; **AND**
- Patient must have tried and failed at least one of the following: NSAID, non-opioid analgesic, acetaminophen OR caffeinated analgesic combination; **AND**
- Patient must have tried and failed, or has a contraindication or intolerance to 2 preferred triptans.

For renewal:

- Patient must continue to meet initial criteria; **AND**
- Patient is experiencing symptom improvement; **AND**
- The patient is not experiencing any treatment-limiting adverse reactions of the medication

CALCIUM CHANNEL BLOCKERS

Length of Authorization:	1 year
Initiative:	MNC: Antihypertensive Medications (IE 2462 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

CONJUPRI

- Patient has had a trial of generic amlodipine

CLINICAL CRITERIA FOR INITIAL APPROVAL

PRESTALIA (NO GRANDFATHERING)

- Patient has had a trial and failure of the following:
  - Amlodipine OR Perindopril

KATERZIA (AMLODIPINE SUSPENSION)

Product will automatically be approved if patient is <18 years of age. If patient is 18 years of age or older, then:
Initial Criteria

- Patient age is 18 years or older; **AND**
- Patient has a diagnosis of one of the following; **AND**
  - Hypertension; **OR**
  - Chronic stable angina; **OR**
  - Vasospastic angina; **OR**
  - Angiographically documented CAD in patients without heart failure or an ejection fraction < 40%; **OR**
  - Pulmonary hypertension (off label)
- Patient has difficulty swallowing solid dosage forms or the dosage needed is not available in another formulation.

CLINICAL CRITERIA FOR RENEWAL

- Continue to meet above criteria; **AND**
- No contraindications to continuation of therapy; **AND**
- Documentation of positive clinical response to therapy

CALQUENCE® (ACALABRUTINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **B-Cell Lymphomas**

- Patient is at least 18 years of age; **AND**
- Patient does not have severe hepatic impairment (i.e., Child-Pugh class C); **AND**
- Patient will avoid concomitant use with the following drugs
  - Strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Strong CYP3A inhibitors (e.g., itraconazole, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Proton pump inhibitors (e.g., omeprazole, lansoprazole, pantoprazole, etc.); **AND**
- Used as single-agent therapy; **AND**
  - Used as alternate subsequent therapy; **AND**
    - Patient is intolerant to, or has contraindications to, ibrutinib; **AND**
    - Patient has one of the following:
      - Gastric MALT lymphoma that is relapsed or progressive
      - Non-gastric MALT lymphoma that is recurrent or progressive
      - Nodal marginal zone lymphoma that is refractory or progressive
      - Splenic marginal zone lymphoma that is recurrent; **OR**
  - Used as preferred subsequent therapy for mantle cell lymphoma; **AND**
    - Patient has NOT received any prior treatment with a BTK-inhibitor (e.g., ibrutinib, zanubrutinib)

Diagnosis of **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**

- Patient is at least 18 years of age; **AND**
- Patient does not have severe hepatic impairment (i.e., Child-Pugh class C); **AND**
- Patient will avoid concomitant use with the following drugs
  - Strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Strong CYP3A inhibitors (e.g., itraconazole, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Proton pump inhibitors (e.g., omeprazole, lansoprazole, pantoprazole, etc.); **AND**
- Used for previously untreated disease with or without del(17p)/TP53 mutation as single agent therapy or in combination with obinutuzumab; **OR**
- Used for relapsed or refractory disease with or without del(17p)/TP53 mutation as single agent therapy; **AND**
  - Patient does **not** have ibrutinib-refractory disease with BTK C481S mutations*, when BTK-mutation testing is available, and status has been assessed

Diagnosis of **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL)**

- Patient is at least 18 years of age; **AND**
- Patient does not have severe hepatic impairment (i.e., Child-Pugh class C); **AND**
- Patient will avoid concomitant use with the following drugs
  - Strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Strong CYP3A inhibitors (e.g., itraconazole, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Proton pump inhibitors (e.g., omeprazole, lansoprazole, pantoprazole, etc.); **AND**
- Used as a single agent; **AND**
  - Patient has received at least one prior therapy; **OR**
  - Used for progressive or relapsed disease

*__Note__: Testing for BTK and PLCG2 mutations may be useful in patients receiving acalabrutinib and suspected of having progression. BTK and PSCG2 mutation status alone is not an indication to change treatment.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treated as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hemorrhage, severe infections, myelosuppression [neutropenia, thrombocytopenia, anemia, lymphopenia], atrial fibrillation, second primary malignancies)

CAMPATH® (ALEMTUZUMAB)

Length of Authorization:	6 months
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

Diagnosis of chronic lymphocytic leukemia (CLL) B-Cell

- Patient does not have grade 3 or grade 4 lymphopenia

CAMPTOSAR® (IRINOTECAN)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Coverage is provided in the following conditions:

- Colorectal adenocarcinoma (CRC) (excluding neoadjuvant use)
- Esophageal/esophagogastric junction cancer (adenocarcinoma, squamous cell carcinoma)
- Gastric adenocarcinoma
- Neuroendocrine and adrenal tumors – poorly differentiated (high-grade)/large or small cell
- Ovarian cancer – Epithelial ovarian, fallopian tube, primary peritoneal (carcinosarcoma, clear cell, endometrioid, mucinous, serous)
- Small cell lung cancer (small cell carcinoma)
- Bone cancer – Ewing sarcoma
- Pancreatic adenocarcinoma
- Soft tissue sarcoma – Non-pleomorphic rhabdomyosarcoma
- Occult primary (adenocarcinoma or carcinoma not otherwise specified)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe diarrhea, cholinergic reactions [rhinitis, increased salivation, miosis, lacrimation, diaphoresis, flushing, and intestinal hyperperistalsis], severe myelosuppression, renal impairment/failure, severe hypersensitivity reactions, pulmonary toxicity/interstitial pulmonary disease-like events)

CAPRELSA® (VANDETANIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Thyroid Carcinoma**

- Patient is at least 18 years of age; **AND**
- Prescriber is enrolled in the Caprelsa® Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
- Patient does not have uncorrected electrolyte abnormalities (e.g., hypocalcemia, hypokalemia, hypomagnesemia); **AND**
- Patient does not have long QT syndrome (i.e., QTcF interval > 450 milliseconds); **AND**
- Patient does not have a history of Torsades de pointes, congenital long QT syndrome, bradyarrhythmias, or uncompensated heart failure; **AND**
- Patient must not have had a major surgical procedure within the preceding 14 days or have a surgical wound that has not fully healed; **AND**
- Used as single agent therapy; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort, etc.); **AND**
  - Coadministration with anti-arrhythmic drugs (e.g., amiodarone, disopyramide, procainamide, sotalol, dofetilide, etc.); **AND**
  - Coadministration with QTc prolonging drugs (e.g., chloroquine, clarithromycin, dolasetron, granisetron, haloperidol, methadone, moxifloxacin, pimozide, etc.); **AND**
- Patient has papillary, follicular, or Hürthle cell carcinoma; **AND**
  - Patient has unresectable recurrence, persistent disease, or distant metastases; **AND**
  - Patient has progressive and/or symptomatic disease that is not susceptible to radioactive iodine (RAI) therapy; **AND**
  - Treatment with clinical trials or other systemic therapies are not available or appropriate
- Patient has medullary carcinoma; **AND**
  - Patient has unresectable locally advanced, recurrent, or metastatic disease; **AND**
  - Patient has asymptomatic, symptomatic, or progressive disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include interstitial lung disease (ILD) or pneumonitis, severe skin reactions (i.e., toxic epidermal necrolysis and Stevens-Johnson syndrome), hypertension, QT prolongation, Torsades de Pointes, ventricular tachycardia, ischemic cerebrovascular events, hemorrhage, heart failure, reversible posterior leukoencephalopathy syndrome (RPLS), severe diarrhea (i.e., ≥ grade 3 severity), hypothyroidism, impaired wound healing, etc.

CARDIOVASCULAR AGENTS: MISCELLANEOUS

Length of Authorization:	1 Year
Initiative:	MNC: Cardiovascular Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

VECAMYL

Diagnosis of **Essential Hypertension or Malignant Hypertension**

- Patient has tried and failed (or had a contraindication or intolerance) to **ALL** the following:
  - ACE inhibitor or ARB plus a diuretic; **AND**
  - Beta blocker plus a diuretic, **AND**
  - Calcium Channel Blocker plus a diuretic; **AND**
  - Clonidine; **AND**
  - Hydralazine

CAROSPIR

- The patient has difficulty swallowing or cannot swallow tablets

DURLAZA

- Patient must have an FDA approved indication (i.e., acute ischemic stroke, stroke prophylaxis in patients with a history of ischemic stroke or TIA); **AND**
- Must have a documented history of ischemic stroke or transient ischemic attack; **OR**
  - Must have a documented history of coronary artery disease
    - History of MI
    - Unstable angina pectoris
    - Chronic stable angina
- Must have a history of failure, contraindication, or intolerance to **or** is not successfully managed with immediate-release aspirin

CLINICAL CRITERIA FOR RENEWAL

- The patient has benefited from therapy; **AND**
- The patient's condition has not progressed or worsened while on therapy; **AND**
- The patient has not developed any contraindications or other exclusions to its continued use.

CAYSTON® (AZTREONAM)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cystic Fibrosis (CF)**

- Patient is 7 years of age or older; **AND**
- Patient has a baseline percent predicted forced expiratory volume (FEV_1) (renewal will require reported measurement within previous 30 days); **AND**
- Confirmation that the patient is colonized with *Pseudomonas aeruginosa* per positive sputum culture; **AND**
- The patient is not colonized with *Burkholderia cepacia*; **AND**
- Confirmation the patient is not receiving treatment with other inhaled antibiotics and/or anti-infective agents, including alternating treatment schedules; **AND**
- Confirmation the patient has been colonized with pseudomonas aeruginosa per positive sputum culture; **AND**
- Patient has a documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum three-month trial on previous therapy with tobramycin inhalation (generic TOBI); **OR**
- Patient's sputum culture shows resistance to tobramycin

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

- Patient continues to meet initial criteria above; **AND**
- Disease response as indicated by one of the following:
  - Improvement in quality of life (e.g., Cystic Fibrosis Questionnaire-Revised [CFQ-R] score)
  - Improvement or stabilization of lung function (measured by percent predicted FEV_1 within previous 30 days) compared to baseline
  - Decrease in decline of lung function (measured by percent predicted FEV_1 within previous 30 days) compared to baseline
  - Decrease in respiratory-related hospitalizations
  - Decreased use of intravenous antipseudomonal antibiotics
  - Reduced sputum bacterial density (i.e., reduced number of *P. aeruginosa* colony forming units [CFUs]); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe allergic reactions and bronchospasms during nebulizer use.

CERDELGA® (ELIGLUSTAT)

Length of Authorization:	12 months and renewable
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Type I Gaucher Disease**

- Patient is 18 years of age or older; **AND**
- Must be used as a single agent; **AND**
- Patient's CYP2D6 phenotype has been determined by an FDA-cleared test as one of the following: extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM); **AND**
- Patient does not have any of the following contraindications based on their CYP2D6 phenotype:
  - EM do not have moderate or severe hepatic impairment; **OR**
  - EM and IM are not taking a strong-moderate CYP2D6-inhibtor concomitantly with a strong-moderate CYP3A-inhibitor; **OR**
  - EM are not taking a strong-moderate CYP2D6-inhibtor with mild hepatic impairment; **OR**
  - IM or PM do not have any degree of hepatic impairment OR are taking a strong CYP3A-inhibitor; **AND**
- Patient does not have pre-existing cardiac conditions (e.g., congestive heart failure, recent acute myocardial infarction, bradycardia, heart block, ventricular arrhythmia, or long QT syndrome); **AND**
- Patient is not being treated with Class 1A antiarrhythmic medications (e.g., quinidine, procainamide) or Class III antiarrhythmic medications (e.g., amiodarone, sotalol); **AND**
- Patient has a documented diagnosis of type 1 Gaucher disease as confirmed by a beta-glucosidase leukocyte (BGL) test with significantly reduced or absent glucocerebrosidase enzyme activity; **AND**
- Patient's disease results in one of the following conditions:
  - Anemia (i.e., hemoglobin less than or equal to 11 g/dL [women] or 12 g/dL [men]) not attributed to iron, folic acid or vitamin B12 deficiency; **OR**
  - Moderate to severe hepatomegaly (liver size 1.25 or more times normal) or splenomegaly (spleen size 5 or more times normal); **OR**
  - Skeletal disease (e.g., lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis); **OR**
  - Symptomatic disease (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life); **OR**
  - Thrombocytopenia (platelet count less than or equal to 120,000/mm^3); **AND**

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

- Disease response with treatment, as defined by one or more of the following (compared to pre-treatment baseline):
  - Improvement in symptoms (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life)
  - Reduction in size of liver or spleen
  - Improvement in hemoglobin/anemia
  - Improvement in skeletal disease (e.g. increase in lumbar spine and/or femoral neck BMD, no bone crises or bone fractures)
  - Improvement in platelet counts; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: ECG changes and cardiac arrhythmias, etc.

CEREZYME® (IMIGLUCERASE)

Length of Authorization:	12 months
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 78)

CLINICAL CRITERIA FOR INITIAL APPROVAL

For new starts only for patients 4 years and older, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Elelyso® OR Vpriv®

Diagnosis of **Type 1 Gaucher Disease**:

- Patient age at least 2 years or older; **AND**
- Patient has a documented diagnosis of type 1 Gaucher disease as confirmed by a beta-glucosidase leukocyte (BGL) test with significantly reduced or absent glucocerebrosidase enzyme; **AND**
- Adults only (i.e., patients at least 18 years or older):
  - Patient's disease results in one of the following conditions:
    - Anemia (i.e., hemoglobin less than or equal to 11 g/dL [women] or 12 g/dL [men]) not attributed to iron, folic acid or vitamin B12 deficiency; **OR**
    - Moderate to severe hepatomegaly (liver size 1.25 or more times normal volume) or splenomegaly (spleen size 5 or more times normal volume); **OR**
    - Skeletal disease (e.g., lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis); **OR**
    - Symptomatic disease (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life); **OR**
    - Thrombocytopenia (platelet count less than or equal to 120,000/mm^3); **AND**
- Must be used as a single agent

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment, as defined by one or more of the following (compared to pre-treatment baseline):
  - Improvement in symptoms (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life)
  - Reduction in size of liver or spleen
  - Improvement in hemoglobin/anemia
  - Improvement in skeletal disease (e.g., increase in lumbar spine and/or femoral neck BMD, no bone crises or bone fractures)
  - Improvement in platelet counts; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hypersensitivity reactions, etc.

CINQAIR® (RESLIZUMAB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75)

CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Severe Asthma**

- Patient is at least 18 years of age; **AND**
- Will not be used in combination with other anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody (e.g., omalizumab, mepolizumab, benralizumab, dupilumab, etc.); **AND**
- Must NOT be used for either of the following:
  - Treatment of other eosinophilic conditions (e.g., allergic bronchopulmonary aspergillosis/mycosis, Churg-Strauss syndrome, hypereosinophilic syndrome, etc.)
  - Relief of acute bronchospasm or status asthmaticus; **AND**
- Patient must have severe disease; **AND**
- Patient must have asthma with an eosinophilic phenotype indicated by blood eosinophils ≥ 400 cells/mL within 4 weeks of dosing; **AND**
- Must be use for add-on maintenance treatment in patients regularly receiving BOTH of the following:
  - Medium to high-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifier, etc); **AND**
- Patient must have two or more exacerbations in the previous year requiring daily oral corticosteroids for at least 3 days (in addition to the regular maintenance therapy defined above); **AND**
- Baseline measurement of at least one of the following for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV_1)

Note: For Core Formulary, Cinqair is non-formulary.

***Components of severity for classifying asthma as SEVERE may include any of the following (not all inclusive):**
• Symptoms throughout the day
• Nighttime awakenings, often 7 times per week
• SABA use for symptom control occurs several times per day
• Extremely limited normal activities
• Lung function (percent predicted FEV_1) <60%
• Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

CRITERIA FOR RENEWAL

- Must not be used in combination with another monoclonal antibody (e.g., benralizumab, mepolizumab, omalizumab); **AND**
- Absence of unacceptable toxicity from the drug (e.g., parasitic [helminth] infection, herpes zoster infection, severe hypersensitivity reactions); **AND**
- Treatment has resulted in clinical benefit:
  - Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
    - Use of systemic corticosteroids
    - Two- fold or greater decrease in inhaled corticosteroid use for at least 3 days
    - Hospitalizations
    - ER visits
    - Unscheduled visits to healthcare provider; **OR**
  - Improvement from baseline in forced expiratory volume in 1 second (FEV_1)

DOSAGE AND ADMINISTRATION

Indication	Dose
Severe Asthma with an eosinophilic phenotype	3 mg/kg via intravenous infusion every 4 weeks

Max vials (per dose and over time):

Indication	# vials to build in FirstTrax℠	Per # days*
Severe Asthma with an eosinophilic phenotype	Up to 4 vials (100 mg per vial)	28

Note: The number of vials is dependent on weight.

COMETRIQ®; CABOMETYX® (CABOZANTINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75 –, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Thyroid Carcinoma** (Cometriq®):

- Patient is 18 or older; **AND**
- Patient does not have a recent history of severe hemorrhage; **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Patient must not have had major surgery within the preceding 2 weeks or have a surgical wound that has not fully healed; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, St. John's Wort, rifampin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., nefazodone, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
- Patient has medullary disease; **AND**
  - Patient has progressive, unresectable, recurrent, persistent, or metastatic disease; **OR**
- Patient has follicular, Hürthle cell, or papillary carcinoma ; **AND**
  - Patient has unresectable recurrent, persistent, or metastatic disease; **AND**
  - Patient has progressive and/or symptomatic iodine-refractory disease; **AND**
  - Clinical trials or other therapies are not available or appropriate

Diagnosis of **Thyroid Carcinoma** (Cabometyx®):

- Patient is 12 years of age or older; **AND**
- Patient does not have a recent history of severe hemorrhage; **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Patient must not have had major surgery within the preceding 2 weeks or have a surgical wound that has not fully healed; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, St. John's Wort, rifampin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., nefazodone, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has locally advanced or metastatic differentiated thyroid cancer (DTC); **AND**
- Disease has progressed following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy (e.g., sorafenib, lenvatinib, etc.); **AND**
- Patient is radioactive iodine-refractory or ineligible; **AND**
- Used as a single agent; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Renal Cell Carcinoma** (Cabometyx®):

- Patient is 18 or older; **AND**
- Patient does not have a recent history of severe hemorrhage; **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Patient must not have had major surgery within the preceding 2 weeks or have a surgical wound that has not fully healed; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, St. John's Wort, rifampin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., nefazodone, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
  - Patient has advanced, relapsed, or metastatic disease; **AND**
    - Used as first-line therapy for clear cell histology in patients with intermediate/poor risk disease with at least one of the following; **AND**
      - Less than one year from time of diagnosis to systemic therapy
      - Performance status < 80% (Karnofsky)
      - Hemoglobin < lower limit of normal (Normal: 12 g/dL)
      - Calcium > upper limit of normal (Normal: 8.5–10.2 mg/dL)
      - Neutrophil > upper limit of normal (Normal: 2.0–7.0 x 10^9/L)
      - Platelets > upper limit of normal (Normal: 150,000–400,000); **OR**
    - Used as subsequent therapy for clear cell histology; **OR**
    - Patient has non-clear cell histology; **OR**
- Used in combination with nivolumab; **AND**
  - Used for locally advanced disease; **AND**
  - Used as first-line therapy for clear-cell histology

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Hepatocellular Carcinoma** (Cabometyx®):

- Patient is 18 or older; **AND**
- Patient does not have a recent history of severe hemorrhage; **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Patient must not have had major surgery within the preceding 2 weeks or have a surgical wound that has not fully healed; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, St. John's Wort, rifampin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., nefazodone, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
- Used as subsequent therapy in patients with Child-Pugh Class A hepatic impairment (i.e., excludes class B and C impairments); **AND**
  - Patient had disease progression on or after sorafenib therapy ; **OR**
  - Patient has metastatic disease or extensive liver tumor burden; **OR**
  - Patient has unresectable disease and is not a transplant candidate; **OR**
  - Patient has local disease, or local disease with minimal extrahepatic disease, and considered inoperable due to performance status or comorbidities

Diagnosis of **Non-Small Cell Lung Cancer (Cometriq & Cabometyx)**:

- Patient is 18 years or older; **AND**
- Patient does not have a recent history of severe hemorrhage; **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Patient must not have had major surgery within the preceding 2 weeks or have a surgical wound that has not fully healed; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, St. John's Wort, rifampin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., nefazodone, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Patient has confirmed RET gene rearrangements

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Bone Cancer (Cabometyx)**:

- Patient is 18 years or older; **AND**
- Patient does not have a recent history of severe hemorrhage; **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Patient must not have had major surgery within the preceding 2 weeks or have a surgical wound that has not fully healed; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, St. John's Wort, rifampin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., nefazodone, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
- Used as second-line therapy for Osteosarcoma or Ewing's Sarcoma; **AND**
- Used for relapsed, refractory, or metastatic disease

Diagnosis of **Gastrointestinal Stromal Tumors - GIST (Cabometyx)**:

- Patient is 18 years or older; **AND**
- Patient does not have a recent history of severe hemorrhage; **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Patient must not have had major surgery within the preceding 2 weeks or have a surgical wound that has not fully healed; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, St. John's Wort, rifampin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., nefazodone, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
- Used as subsequent therapy for unresectable, recurrent, or metastatic disease

IMPORTANT MEDICATION INFORMATION

Cometriq® (approved for thyroid cancer) is **not** interchangeable with Cabometyx® tablets

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: development of visceral perforation or fistula formation, severe hemorrhage, serious thrombotic events (e.g., myocardial infarction or arterial/venous thromboembolism), severe hypertension/hypertensive crisis, osteonecrosis of the jaw, severe diarrhea, palmar-plantar erythrodysesthesia syndrome (PPES), reversible posterior leukoencephalopathy syndrome, nephrotic syndrome, proteinuria, impaired wound healing, severe hepatotoxicity, severe adrenal insufficiency, severe thyroid dysfunction, severe hypocalcemia, etc.

COMPOUNDS

Length of Authorization:	Duration of therapy, 3-day DOS to allow one claim or up to 1 year
Initiative:	**MNC: Compound (IE 2462 and 50081 / NCPDP 75)** ADM: Compound: DOS 70 Error Override (NCPDP 70 / IE 2211 & 50076 – List) ADM: Compound: DOS Co-pay Override ADM: Compound: DOS Cost Override (NCPDP 78 / IE 3024, 15301 – List) ADM: Compound: DOS PA & Cost Override (NCPDP 75 & 78 / IE 2462 & 3024 – List) ADM: Compound: DOS Quantity Override (NCPDP 76 / IE 2641, 7001, 7032, 2637 – List) ADM: Compound: DOS Dup Claim Override (NCPDP 16 / IE 2120 – List)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Similar commercially available product is not available; **AND**
- Requested drug component is not an excluded medication; **AND**
- Must meet one of the following:
  - Requested Rx component is FDA-approved for the condition being treated
  - If requested for off-label indication, the off-label guidelines **MUST** be met; **AND**
- If a drug is included in the compound requires PA, all drug-specific prior authorization criteria **MUST** be met
- If a chemical entity is no longer available commercially, it must not have been withdrawn for safety reasons; **AND**
- Must meet one of the following:
  - A unique vehicle is required for topically administered compounds; **OR**
  - A unique dosage form not available commercially due to the patient's age, weight, or inability to take a solid dosage form; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Coverage for compounds and bulk powders will **not** be approved for any of the following:
  - Resveratrol is an excluded item and compounds containing it are not covered
  - If the compound contains any of the following over-the-counter (OTC) ingredients (unless OTC compounds are covered by client):
    - Cetyl Myristoleate
    - Coenzyme Q10
    - Methylcobalamin
    - Hyaluronic Acid
    - Nicotinamide
    - Methyltetrahydrofolate
    - Ibuprofen
    - Lipoic acid
    - Beta Glucan
    - Ubiquinol
    - Chrysin
    - Glutathiones
    - Ubiquinol
    - Lactobacillus
    - Vitamin E
    - Ascorbic Acid
    - Melatonin
    - Pyridoxal-5-Phosphate (Vitamin B6)
    - Loperamide; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- For topical compound preparations (e.g., creams, ointments, lotions or gels applied to skin for ANY topical route like transdermal, transcutaneous), requested drug MUST have an FDA-approved or has Off-label support for TOPICAL use, including but not limited to:
  - Ketamine
  - Gabapentin
  - Flurbiprofen (topical ophthalmic use not included)
  - Ketoprofen
  - Morphine
  - Nabumetone
  - Oxycodone
  - Cyclobenzaprine
  - Baclofen
  - Tramadol
  - Hydrocodone
  - Meloxicam
  - Amitriptyline
  - Pentoxifylline
  - Orphenadrine
  - Piroxicam
  - Levocetirizine
  - Amantadine
  - Oxytocin
  - Sumatriptan
  - Chorionic gonadotropin (human); **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Requested compound contains topical fluticasone. Topical fluticasone will **not** be approved unless it is treating a dermatological condition; **AND**
  - Patient has a contraindication to ALL commercially available topical fluticasone formulations; **OR**
- Requested compound contains any of the following ingredients which are for COSMETIC use: (do not approve unless client has an A category for cosmetic use and compound)
  - Hydroquinone
  - Acetyl hexapeptide-8
  - Tocopheryl Acid Succinate
  - PracaSil TM-Plus
  - Chrysaderm Day Cream
  - Chrysaderm Night Cream
  - PCCA Spira-Wash
  - Lipopen Ultra
  - Versapro**; OR**
    - Requested compounds have a high quantity of tablets or capsules.

- Requestor (Physician, pharmacist) must submit 2 relevant and compelling multi-source random controlled trial(s) to confirm medication is safe and effective in its current ***compounded*** formulation, and dosage. Current dosage strength must be an approved FDA strength for the FDA approved indication.
  - If the strength is higher than the FDA dose; **OR**
  - If the formulation is outside of an FDA formulation for the indication; **OR**
  - The product is available in a non-compounded FDA approved product; **OR**
  - There is a non-compounded product that is available for the indication.

Forward to the RPh for denial.

- Technicians: If the following products are listed on the compound, deny claim with documentation that the drug is on the excluded category list. If you are uncertain, escalate to the pharmacist queue for clinical review.

CONSENSI (AMLODIPINE/CELECOXIB)

Length of Authorization:	12 months, may be renewed
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient must be ≥ 18 years of age; **AND**
- Patient has hypertension and osteoarthritis; **AND**
- Treatment with amlodipine for hypertension and celecoxib for osteoarthritis are appropriate; **AND**
- Patient has had a trial and failure of generic amlodipine **AND** generic celecoxib when used in combination.

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet initial criteria; **AND**
- Patient is experiencing symptom improvement; **AND**
- The patient is not experiencing any treatment-limiting adverse reactions of the medication

COPD AGENTS

Length of Authorization:	1 Year
Initiative:	MNC: COPD Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

DALIRESP

Diagnosis of COPD associated with chronic bronchitis

- Patient has a history of exacerbations; **AND**
  - No liver impairments; **AND**
  - Must be used as adjunct therapy (i.e., must be used with first line therapy (inhaled corticosteroid plus long-acting beta2 agonist, long acting anticholinergic or long acting beta2 agonist).

CLINICAL CRITERIA FOR RENEWAL

The patient has had a disease response with the medication.

COPIKTRA® (DUVELISIB)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with strong CYP3A inhibitors (e.g. itraconazole, ketoconazole, clarithromycin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has not received previous therapy with a small-molecule inhibitor (phosphtidylinositol-3 kinase inhibitor [PI3-K]) therapy (e.g., idelalisib, umbralisib, copanlisib, alpelisib); **AND**
- Patient has not received previous therapy with a Bruton's tyrosine kinase (BTK) inhibitor (e.g., ibrutinib, acalabrutinib); **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will receive prophylactic therapy for *Pneumocystis jirovecii* (PJP) while on treatment with duvelisib; **AND**
- Used as single agent therapy; **AND**
- Patient has relapsed or refractory disease

Diagnosis of **B-Cell Lymphomas**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with strong CYP3A inhibitors (e.g. itraconazole, ketoconazole, clarithromycin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has not received previous therapy with a small-molecule inhibitor (phosphtidylinositol-3 kinase inhibitor [PI3-K]) therapy (e.g., idelalisib, umbralisib, copanlisib, alpelisib); **AND**
- Patient has not received previous therapy with a Bruton's tyrosine kinase (BTK) inhibitor (e.g., ibrutinib, acalabrutinib); **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will receive prophylactic therapy for *Pneumocystis jirovecii* (PJP) while on treatment with duvelisib; **AND**
- Used as single agent therapy; **AND**
- Patient has relapsed, refractory, or progressive (*only applies to Follicular Lymphoma*) disease; **AND**
- Used as subsequent therapy after at least two (2) prior therapies; **AND**
- Patient has one of the following:
  - Follicular lymphoma (grade 1-2)
  - Gastric MALT lymphoma
  - Non-gastric MALT lymphoma (noncutaneous)
  - Nodal marginal zone lymphoma
  - Splenic marginal zone lymphoma

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include serious infections, neutropenia, serious diarrhea or colitis, hepatotoxicity, pneumonitis, serious cutaneous reactions [drug reaction with eosinophilia and systemic symptoms (DRESS) and toxic epidermal necrolysis (TEN)], etc.

CORLANOR (IVABRADINE)

Length of Authorization:	1 year
Initiative:	MNC: Antihypertensive Medications (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is aged 6 months to 18 years old **AND** has a diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy; **OR**
- Patient is ≥ 18 years old **AND** has a diagnosis of stable, symptomatic chronic heart failure with:
  - Left ventricular ejection fraction ≤ 35%; **AND**
  - Patient is in sinus rhythm with resting heart rate ≥ 70 beats per minute; **AND**
  - Patient is on maximally tolerated doses of beta-blockers **OR** has a contraindication to beta-blocker use; **OR**
- Patient has a diagnosis of inappropriate sinus tachycardia (IST); **AND**
  - Diagnosis of IST confirmed by both:
    - Sinus heart rate > 100 beats per minute at rest; **AND**
    - Mean 24 hour heart rate greater than 90 beats per minute; **AND**
  - Attestation that other causes of sinus tachycardia have been ruled out (e.g., hyperthyroidism, anemia, illicit stimulant drug use, caffeine, etc.); **AND**
  - Attestation that symptoms of IST are causing significant functional impairment or distress (palpitations, light-headedness, syncope, chest pain, dyspnea, etc.); **AND**
  - Prescribed by or in consultation with cardiologist
- For the suspension, in addition to the above criteria:
  Patient has difficulty swallowing solid dosage forms, or the dosage needed is not available in another formulation

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient is free of unacceptable toxicity from the drug

COSELA™ (TRLACICLIB)

Length of Authorization:	4 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chemotherapy Induced Myelosuppression**

- Patient is at least 18 years of age; **AND**
- Will not be used concomitantly with colony stimulating factors (e.g., G-CSF, peg-G-CSF, GM-CSF, etc) for primary prophylaxis of febrile neutropenia prior to day 1 cycle 1 of chemotherapy; **AND**
- Patient has a diagnosis of extensive-stage small cell lung cancer (ES-SCLC); **AND**
- Patient is undergoing myelosuppressive chemotherapy with one of the following:
  - Platinum (carboplatin or cisplatin) and etoposide-containing regimen; **OR**
  - Topotecan-containing regimen

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe injection site reactions, acute drug hypersensitivity reactions, interstitial lung disease/pneumonitis, etc.; **AND**
- Patient continues to undergo myelosuppressive chemotherapy with one of the following:
  - Platinum (carboplatin or cisplatin) and etoposide-containing regimen; **OR**
  - Topotecan-containing regimen

COSMETIC AGENTS – BENEFIT BUILDER

Length of Authorization:	6 months
Initiative:	**MNC: Cosmetic Agents** (IE 2462 / NCPDP 75)

Cosmetic agents are an excluded/benefit builder category unless the client overrides the edit. Check CRM.

The following drugs have alternate diagnosis besides cosmetic:

- Botox®, Dysport, Xeomin®, Retin-A® (age limit)
  - What is indication?
    - If for cosmetic indication – approve if allowable by plan (check CRM)
  - If for FDA approved indication that is not cosmetic, please refer to clinical criteria in this document if available

COTELLIC® (COBIMETINIB)

Length of Authorization:	6 months; may be renewed Coverage for the adjuvant treatment of melanoma is up to a maximum of 1 year of therapy.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis **of Cutaneous Melanoma**

- Patient is at least 18 years of age; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib) unless otherwise noted; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole, etc.)
  - Moderate CYP3A4 inhibitors (e.g., erythromycin, clarithromycin, etc.), if short-term therapy (≤14 days) is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient has BRAF V600 mutation-positive disease as detected by an FDA approved or CLIA compliant test; **AND**
  - Patient has unresectable or metastatic** disease; **AND**
    - Used in combination with atezolizumab and vemurafenib as first-line therapy; **OR**
    - Used in combination with vemurafenib; **AND**
      - Used as initial therapy or subsequent therapy; **OR**
      - Used as re-induction therapy for patients who experience disease control (i.e., complete response, partial response, or stable disease) from prior MEK inhibitor therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**
  - Used as adjuvant therapy in combination with vemurafenib in patients with unacceptable toxicities to dabrafenib/trametinib; **AND**
    - Patient has lymph node involvement following complete resection, complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; **OR**
    - Patient has clinical satellite/in-transit metastases or local satellite/in-transit recurrence with no evidence of disease (NED) after complete excision to clear margins

**Metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Central Nervous System (CNS) Cancers**

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole, etc.)
  - Moderate CYP3A4 inhibitors (e.g., erythromycin, clarithromycin, etc.), if short-term therapy (≤14 days) is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib) unless otherwise noted; **AND**
- Patient has BRAF V600E mutation-positive disease; **AND**
- Used in combination with vemurafenib; **AND**
  - Used as adjuvant treatment in a patient with incomplete resection, biopsy, or surgically inaccessible location
    - Patient has pilocytic astrocytoma OR pleomorphic xanthoastrocytoma (PXA) OR ganglioglioma; **OR**
  - Used for treatment of recurrent or progressive low-grade glioma; **OR**
  - Used for treatment of recurrent anaplastic glioma or glioblastoma

Diagnosis of **Histiocytic Neoplasms**

- Patient is at least 18 years of age; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib) unless otherwise noted; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole, etc.)
  - Moderate CYP3A4 inhibitors (e.g., erythromycin, clarithromycin, etc.), if short-term therapy (≤ 14 days) is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Used as a single agent; **AND**
- Patient has a MAP kinase pathway mutation, or no detectable mutation, or testing not available; **AND**
- Patient has one of the following:
  - Patient relapsed/refractory or symptomatic Erdheim-Chester Disease; **OR**
  - Rosai-Dorfman Disease; **AND**
    - Patient has symptomatic unifocal unresectable (bulky/site of disease) or symptomatic multifocal disease; **OR**
    - Relapsed or refractory disease; **OR**
  - Langerhans Cell Histiocytosis (LCH) **AND**
    - Patient has multisystem disease with symptomatic or impending organ dysfunction; **OR**
    - Patient has pulmonary disease; **OR**
    - Patient has multifocal single system bone disease not responsive to treatment with a bisphosphonate and >2 lesions; **OR**
    - Patient has CNS lesions; **OR**
    - Patient has relapsed or refractory disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment defined as stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Left ventricular ejection fraction (LVEF) has not had an **absolute** decrease of > 10% from baseline and is not below the lower limit of normal (LLN) *(LVEF results must be within the previous 3 months)*; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: new malignancies, serous retinopathy and retinal vein occlusion, severe dermatologic reactions, severe photosensitivity reactions, severe hepatotoxicity, rhabdomyolysis, severe hemorrhagic events, cardiomyopathy, etc.

Adjuvant treatment of Melanoma

- Treatment has not exceeded 1 year of therapy

Cutaneous Melanoma (re-induction therapy)

- *Refer to initial criteria (see Cutaneous Melanoma – Used as re-induction therapy)*

CRYSVITA® (BUROSUMAB-TWZA)

Length of Authorization:	6 months; may be renewed every 12 months thereafter
Initiative:	SPC: Miscellaneous PA Required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **X-Linked Hypophosphatemia (XLH)**

- Patient is at least 6 months of age; **AND**
- Patient has not received oral phosphate and/or active vitamin D analogs (e.g., calcitriol, paricalcitol, doxercalciferol, calcifediol) within 1 week prior to the start of therapy; **AND**
- Baseline fasting serum phosphorus* level with current hypophosphatemia, defined as a phosphate level below the lower limit of the laboratory normal reference range (**Note**: serum phosphorus levels should be monitored periodically throughout therapy, required on renewal); **AND**
- Other causes of hypophosphatemia (e.g., autosomal dominant or recessive hypophosphatemic rickets) have been ruled out; **AND**
- Must be prescribed by, or in consultation with, a nephrologist or endocrinologist; **AND**
- Will not be used concomitantly with oral phosphate and/or active vitamin D analogs (e.g., calcitriol, paricalcitol, doxercalciferol, calcifediol); **AND**
- Patient has a reduced tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR); **AND**
- Patient does not have severe renal impairment, defined as a glomerular filtration rate (GFR) of < 30 mL/min; **AND**
- Patient 25-hydroxy vitamin D levels will be monitored at baseline and intermittently and patient will be supplemented with cholecalciferol or ergocalciferol to maintain levels in the normal range for age; **AND**
- Diagnosis is confirmed by identifying at least one of the following:
  - Serum fibroblast growth factor-23 (FGF23) level > 30 pg/mL (> 230 RU/mL in children 3 months-17 years; > 180 RU/mL in adults using EDTA plasma); **OR**
  - Phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX-gene) mutations in the patient; **AND**
- Adult patients must have had an inadequate response from oral phosphate and active vitamin D analogs

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

Diagnosis of **Tumor-Induced Osteomalacia (TIO)**

- Patient is at least 2 years of age; **AND**
- Patient has not received oral phosphate and/or active vitamin D analogs (e.g., calcitriol, paricalcitol, doxercalciferol, calcifediol) within 1 week prior to the start of therapy; **AND**
- Baseline fasting serum phosphorus* level with current hypophosphatemia, defined as a phosphate level below the lower limit of the laboratory normal reference range (**Note**: serum phosphorus levels should be monitored periodically throughout therapy, required on renewal); **AND**
- Other causes of hypophosphatemia (e.g., autosomal dominant or recessive hypophosphatemic rickets) have been ruled out; **AND**
- Must be prescribed by, or in consultation with, a nephrologist or endocrinologist; **AND**
- Will not be used concomitantly with oral phosphate and/or active vitamin D analogs (e.g., calcitriol, paricalcitol, doxercalciferol, calcifediol); **AND**
- Patient has a reduced tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR); **AND**
- Patient does not have severe renal impairment, defined as a glomerular filtration rate (GFR) of < 30 mL/min; **AND**
- Patient 25-hydroxy vitamin D levels will be monitored at baseline and intermittently and patient will be supplemented with cholecalciferol or ergocalciferol to maintain levels in the normal range for age; **AND**
- Must have a diagnosis of tumor-induced osteomalacia associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized; **AND**
- Diagnosis is confirmed by identifying excessive FGF23 (i.e., level ≥ 100 pg/mL) that is not amenable to cure by surgical excision of the offending tumor/lesion

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, hyperphosphatemia and/or nephrocalcinosis, severe injection site reactions); **AND**
- Current serum phosphorus level is not above the upper limit of the laboratory normal reference range; **AND**
- Disease response as indicated by increased serum phosphorus levels, a reduction in serum total alkaline phosphatase activity, improvement in symptoms (e.g., skeletal pain, linear growth), and/or improvement in radiographic imaging of Rickets/osteomalacia; **AND**
- Pediatric patients must be re-evaluated at adulthood or upon closure of bony epiphyses (whichever occurs first) in order to determine if continued therapy is necessary (i.e., discontinuation of burosumab in order to reassess whether treatment with oral phosphate and active vitamin D analogs provide an adequate response)
- **(Tumor-Induced Osteomalacia only)***:* If a patient undergoes treatment of the underlying tumor (i.e., surgical excision or radiation therapy) treatment should be interrupted and serum phosphorus reassessed after treatment has been completed

CYCLOSET® (BROMOCRIPTINE)

Length of Authorization:	6 months
Initiative:	MNC: Hypoglycemics (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Diabetes Mellitus Type 2**

- Patient is 18 years of age or older; **AND**
- Must **not** have fainting (syncopal) migraine headaches or **not** taking dihydroergotamine products (i.e., Migranal), **OR** ergotamine products (Migergot, Cafergot, Ergomar); **AND**
- Must **not** be breast feeding (females); **AND**
- Patient must have failed a trial of metformin; **AND**
- Patient must have had a trial and failure or contraindication to at least **THREE** of the following: sulfonylurea, TZD, DPP-4, or meglitinide (Prandin or Starlix), GLP-1 agonists (i.e., Byetta, Bydureon, Bydureon BCise Trulicity, Victoza), Insulin

CLINICAL CRITERIA FOR RENEWAL

- The patient has had a disease response with the medication; **AND**
- Patient is free of unacceptable toxicity from the medication

CYRAMZA® (RAMUCIRUMAB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Gastric, Esophageal and Gastro-Esophageal Junction Adenocarcinoma**

- Patient is at least 18 years of age; **AND**
- Patient does not have uncontrolled severe hypertension; **AND**
- Patient must not have had a surgical procedure within the preceding 2 weeks or have a surgical wound that has not fully healed; **AND**
- Used as or subsequent therapy; **AND**
- Used as a single agent OR in combination with paclitaxel OR in combination with an irinotecan based regimen; **AND**
  - Patient has unresectable locally advanced, recurrent, or metastatic disease; **OR**
  - Used as palliative therapy for locoregional disease in patients who are not surgical candidates

Diagnosis of **Non-Small Cell Lung Cancer**

- Patient is at least 18 years of age; **AND**
- Patient does not have uncontrolled severe hypertension; **AND**
- Patient must not have had a surgical procedure within the preceding 2 weeks or have a surgical wound that has not fully healed; **AND**
- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as subsequent therapy for first progression after initial systemic therapy; **AND**
    - Used in combination with docetaxel; **AND**
    - Patient has not previously been treated with docetaxel or ramucirumab; **OR**
  - Used in combination with erlotinib for EGFR mutation-positive disease with exon 19 deletions or exon 21 (L858R) substitution mutations; **AND**
    - Used as first-line therapy; **OR**
    - Used for continuation of therapy following disease progression on combination erlotinib and ramucirumab therapy for asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited metastases

Diagnosis of **Colorectal Cancer (CRC)**

- Patient is at least 18 years of age; **AND**
- Patient does not have uncontrolled severe hypertension; **AND**
- Patient must not have had a surgical procedure within the preceding 2 weeks or have a surgical wound that has not fully healed; **AND**
- Used in combination with FOLFIRI (irinotecan, folinic acid/leucovorin, and 5-fluorouracil) for metastatic disease that progressed on or after therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine; **OR**
- Used in combination with irinotecan or FOLFIRI; **AND**
  - Used as primary treatment for metastatic disease after adjuvant therapy with FOLFOX (fluorouracil, folinic acid/leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the previous 12 months; **OR**
  - Used as subsequent therapy for advanced or metastatic disease; **AND**
    - Patient has not previously been treated with irinotecan-based therapy

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Hepatocellular Carcinoma (HCC)**

- Patient is at least 18 years of age; **AND**
- Patient does not have uncontrolled severe hypertension; **AND**
- Patient must not have had a surgical procedure within the preceding 2 weeks or have a surgical wound that has not fully healed; **AND**
- Used as single agent therapy; **AND**
- Used as subsequent therapy for progressive disease **AND**
- Patient has an alfa-fetoprotein (AFP) level of ≥ 400 ng/mL; **AND**
  - Patient was previously treated with sorafenib; **OR**
  - Patient has unresectable disease and is not a transplant candidate; **OR**
  - Patient has liver confined disease inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; **OR**
  - Patient has metastatic disease or extensive liver tumor burden

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hemorrhage, arterial thromboembolic events, uncontrolled hypertension, infusion-related reactions, severe proteinuria (> 3 g/24 h)/nephrotic syndrome, gastrointestinal perforations, impaired wound healing, posterior reversible encephalopathy syndrome (PRES), thyroid dysfunction, worsening of pre-existing hepatic impairment, etc; **AND**

Non-Small Cell Lung Cancer (continuation of therapy in combination with erlotinib following disease progression):

- Refer to initial criteria

CYSTEAMINE (CYSTAGON, PROCYSBI, CYSTARAN, CYSTADROPS)

Length of Authorization:	6 months, may be renewed annually thereafter
Initiative:	SPC: miscellaneous PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient must have a diagnosis of cystinosis confirmed by one of the following:
  - genetic analysis of the cystinosin (CTNS) gene
  - elevated cystine concentrations in polymorphonuclear (PMN) leukocytes
  - increased cystine content in cultured fibroblasts from amniotic fluid or in the placenta at the time of birth
  - cystine crystals in the cornea on slit lamp examination; **AND**
- For Cystagon and Procysbi:
  - Diagnosis of Nephropathic cystinosis; **AND**
  - Patient does not have a hypersensitivity to penicillamine; **AND**
  - Baseline values obtained for one or more of the following: growth/height, proximal renal tubular dysfunction (i.e., loss of electrolytes, amino acids, glucose), serum creatinine and creatinine clearance, etc.; **AND**
  - For Procysbi **only**:
    - Patient is age 1 year old or older; **AND**
    - Patient must try and have an inadequate response, contraindication, or intolerance to Cystagon (or patient is continuing treatment with Procysbi); **OR**
- For Cystaran and Cystadrops:
  - Corneal cystine crystals are observed on slit lamp examination

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug; examples of unacceptable toxicity include:
  - Orals: severe skin rash, severe CNS symptoms (e.g., seizures, encephalopathy), gastrointestinal ulceration/bleeding, leukopenia, pseudotumor cerebri, skin or bone lesions, etc.
  - Ophthalmic: pseudotumor cerebri, sensitivity to light, severe eye pain/irritation, visual field defects, etc.; **AND**
- Patient has received a beneficial response to therapy including, but not limited to, the following:
  - Orals: decrease in WBC cystine concentrations, improvement in renal manifestations of disease (e.g., serum creatinine, calculated creatinine clearance, and/or loss of electrolytes, amino acids, glucose, etc.), and/or non-renal improvement (e.g., growth/height) compared to pretreatment baseline
  - Ophthalmic: stability or reduction in the photo-rated corneal cystine crystal score (CCCS), reduction of crystals upon slit lamp examination, and/or improvement in symptoms (i.e., photophobia) compared to pretreatment baseline

CYTOXAN® (CYCLOPHOSPHAMIDE)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient has a diagnosis of leukemia, breast cancer, Burkitt's lymphoma, Hodgkin's disease, Myeloma, mycosis fungoides, nephrotic syndrome, neuroblastoma, non-Hodgkin's lymphoma, ovarian cancer, and retinoblastoma; **AND**
- Dosing is within FDA parameters for diagnosis.
- Off-label use:
  - If patient has a diagnosis of aplastic anemia, Behcet's Syndrome, Churg-Strauss Syndrome, dermatomyositis, heart transplant rejection, heart transplant rejection prophylaxis, idiopathic thrombocytopenic purpura (ITP), juvenile rheumatoid arthritis, juvenile idiopathic arthritis, kidney transplant rejection, kidney transplant rejection prophylaxis, lupus nephritis, osteogenic sarcoma, peripheral blood stem cell mobilization (PBSC), pneumonitis, polyarteritis nodosa, polymyositis, polymyositis, pulmonary fibrosis, rheumatoid arthritis, scleroderma(systemic sclerosis), small cell lung cancer, stem cell transplant preparation, system lupus (SLE), thymoma, trophoblastic disease, uveitis, Wegener's granulomatosis
  - Escalate to Pharmacist for review.

CLINICAL CRITERIA FOR RENEWAL

- The patient has had a disease response with the medication; **AND**
- The patient is free of toxicity.

DACOGEN® (DECITABINE) IV

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is 18 years of age or older; **AND**
- Diagnosis of one of the following**:**
  - **Myelodysplastic syndrome (MDS)**
  - **Acute Myeloid Leukemia (AML)**
  - **Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)**
  - **Myelofibrosis (MF)**
  - **Myelodysplastic/Myeloproliferative (MDS/MPN) Overlap Syndrome** (includes use for chronic myelomonocytic leukemia type 1 or 2 [CMML-1 or 2], atypical chronic myeloid leukemia [aCML] BCR-ABL negative, MDS/MPN unclassified and MDS/MPN with ring sideroblasts and thrombocytosis [MDS/MPN-RS-T])

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: serious myelosuppression (e.g., anemia, neutropenia, and thrombocytopenia), etc.; **AND**
- Adequate documentation of disease stability and/or improvement as indicated by at least one of the following: decrease in bone marrow blasts percentage, increase in platelets, increase in hemoglobin, or increase in WBC/ANC over pretreatment values

DANYELZA® (NAXITAMAB-GQGK)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **High-Risk Neuroblastoma**

- Patient is at least 1 year of age or older; **AND**
- Will not be used in combination with other GD2-binding monoclonal antibodies (e.g., dinutuximab, etc.); **AND**
- Patient does not have uncontrolled hypertension**; AND**
- Used in combination with granulocyte-macrophage colony-stimulating factor [GM-CSF] (e.g., sargramostim); **AND**
- Patient has relapsed or refractory disease in the bone or bone marrow; **AND**
- Patient had at least a partial or minor response or stable disease to at least one prior systemic therapy

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet indication-specific relevant criteria, such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in initial criteria; **AND**
- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe neurotoxicity (peripheral neuropathy, transverse myelitis, reversible posterior leukoencephalopathy syndrome, neurological disorders of the eye, and severe urinary retention), severe hypertension, etc.

DARAPRIM® (PYRIMETHAMINE)

Length of Authorization:	8 weeks, may be renewed for immunocompromised patients
Initiative:	MNC: Drug exclusion (IE 2211 / NCPDP 75)

- Daraprim is excluded from the formulary and members **must** get the formulary alternative from one of our compounding pharmacies in network.
- In situations in which the patient is unable to take the alternative
  - Provider must provide a letter of medical necessity
  - The below criteria must be met for approval
    - Treatment for toxoplasmosis
    - Patient must test positive for toxoplasmosis (detection of *Toxoplasma*-specific antibodies); **AND**
    - Must be used in combination with a sulfonamide and folinic acid (unless patient has a hypersensitivity to sulfa drugs, can use clindamycin); **AND**
    - Complete blood and platelet counts will be monitored twice a week; **AND**
    - No megaloblastic anemia due to folate deficiency; **AND**
    - Patient must have a diagnosis of one of the following:
      - Acute symptomatic toxoplasmosis; **OR**
      - Congenital toxoplasmosis; **OR**
      - Persons with compromised immune systems

OFF-LABEL USE

- **Prevention of toxoplasmosis and Isosporiasis**: Coverage of pyrimethamine will only be covered if provider has documentation that patient is not able to take or tolerate TMP-SMX which is the preferred therapy in HIV patients with CD4 counts <100 cells/µL
- **PCP prevention:** Coverage of pyrimethamine will only be covered if provider has documentation that patient is not able to take or tolerate the preferred first line therapy of TMP-SMX. Patient must have tried and failed or intolerant to TMP-SMX.

Note: The use of Daraprim for the treatment or prophylaxis of malaria is no longer recommended in the CDC Guidelines for the Treatment of Malaria in the United States due to resistance, therefore will not be covered for this indication.

DARZALEX FASPRO® (DARATUMUMAB AND HYALURONIDASE-FIHJ)

Length of Authorization:	• 6 months and may be renewed, unless otherwise specified • Use for newly diagnosed multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone may not be renewed • Use for newly diagnosed disease in combination with bortezomib • Use for newly diagnosed or relapsed disease in combination with cyclophosphamide, bortezomib and dexamethasone may be renewed for up to a maximum of 80 weeks *(32 weeks of induction therapy and 48 weeks of maintenance therapy)*. • Use for newly diagnosed systemic light chain amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone may be renewed for up to a maximum of 2 years
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma**

- Patient is at least 18 years of age; **AND**
- Therapy will not be used in combination with other anti-CD38 therapies (e.g., daratumumab, isatuximab); **AND**
- Used in the treatment of newly diagnosed disease in patients who are ineligible for autologous stem cell transplant (ASCT) in combination with **one** of the following regimens:
  - Lenalidomide and dexamethasone; **OR**
  - Bortezomib, melphalan, and prednisone; **OR**
  - Cyclophosphamide, bortezomib, and dexamethasone; **OR**
- Used in the treatment of newly diagnosed disease in patients who are eligible for autologous stem cell transplant (ASCT) in combination with **one** of the following regimens
  - Bortezomib, lenalidomide, and dexamethasone; **OR**
  - Bortezomib, thalidomide, and dexamethasone (VTd); **OR**
  - Cyclophosphamide, bortezomib, and dexamethasone; **OR**
- Used for disease relapse after 6 months following primary induction therapy with the same regimen in combination with ONE of the following regimens:
  - Lenalidomide and dexamethasone for non-transplant candidates; **OR**
  - Cyclophosphamide, bortezomib, and dexamethasone; **OR**
- Used as subsequent therapy in combination with dexamethasone and ONE of the following:
  - Lenalidomide; **OR**
  - Bortezomib; **OR**
  - Carfilzomib; **OR**
  - Cyclophosphamide and bortezomib; **OR**
  - Selinexor; **OR**
- Used in combination with pomalidomide and dexamethasone; **AND**
  - Used after at least **one** prior line of therapy including lenalidomide and a proteasome inhibitor (e.g., bortezomib, carfilzomib); **OR**
  - Used after at least **two** prior therapies including an immunomodulatory agent (e.g., pomalidomide) and a proteasome inhibitor (e.g., bortezomib, carfilzomib); **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Multiple Myeloma** *(CONTINUED)*

- Used as single agent therapy; **AND**
  - Patient received at least three previous lines of therapy, including a proteasome inhibitor (e.g., bortezomib, carfilzomib) and an immunomodulatory agent (e.g., lenalidomide, pomalidomide); **OR**
  - Patient must be double refractory to a proteasome inhibitor and an immunomodulatory agent

Diagnosis of **Systemic Light Chain Amyloidosis**

- Patient is at least 18 years of age; **AND**
- Therapy will not be used in combination with other anti-CD38 therapies (e.g., daratumumab, isatuximab); **AND**
- Patient must NOT have NYHA Class IIIB or Class IV, or Mayo Stage IIIB cardiac disease; **AND**
  - Used in the treatment of newly diagnosed disease in combination with bortezomib, cyclophosphamide and dexamethasone (D-VCd); **OR**
  - Used as single agent therapy for the treatment of relapsed/refractory disease

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hypersensitivity and other administration reactions (e.g., systemic administration-related reactions, local injection-site reactions), neutropenia, thrombocytopenia, cardiac toxicity, etc.; **AND**
- Disease response with treatment defined by stabilization of disease and decrease in size of tumor or tumor spread; **AND**

Multiple Myeloma

- Use for newly diagnosed multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone after 24 weeks of induction/consolidation therapy may not be renewed.
- Use for newly diagnosed disease in combination with bortezomib, lenalidomide and dexamethasone may be renewed for up to a maximum of 2 years of maintenance therapy.
- Use for newly diagnosed or relapsed disease in combination with cyclophosphamide, bortezomib and dexamethasone may be renewed for up to a maximum of 80 weeks (32 weeks of induction therapy and 48 weeks of maintenance therapy).

Systemic Light Chain Amyloidosis (newly diagnosed disease)

- Use for newly diagnosed disease in combination with bortezomib, cyclophosphamide and dexamethasone (D-VCd) may be renewed for a maximum of 2 years of therapy

DARZALEX® (DARATUMUMAB)

Length of Authorization:	• Coverage will be provided for six months and may be renewed • Use for newly diagnosed multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone may not be renewed • Use for newly diagnosed disease in combination with bortezomib, lenalidomide, and dexamethasone may be renewed for up to a maximum of 2 years of maintenance therapy • Use for newly diagnosed or relapsed disease in combination with cyclophosphamide, bortezomib, and dexamethasone may be renewed for up to a maximum of 80 weeks *(32 weeks of induction therapy and 48 weeks of maintenance therapy)*.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma**

- Patient is at least 18 years of age; **AND**
- Therapy will not be used in combination with other anti-CD38 therapies (e.g., daratumumab, isatuximab, etc.); **AND**
- Used in the treatment of newly diagnosed disease in patients who are ineligible for autologous stem cell transplant (ASCT) in combination with **one** of the following regimens:
  - Lenalidomide and dexamethasone; **OR**
  - Bortezomib, melphalan, and prednisone; **OR**
  - Cyclophosphamide, bortezomib, and dexamethasone; **OR**
- Used in the treatment of newly diagnosed disease in patients who are eligible for autologous stem cell transplant (ASCT) in combination with **one** of the following regimens:
  - Bortezomib, lenalidomide, and dexamethasone; **OR**
  - Bortezomib, thalidomide, and dexamethasone ; **OR**
  - Cyclophosphamide, bortezomib, and dexamethasone; **OR**
- Used for disease relapse after 6 months following primary induction therapy with the same regimen in combination with **one** of the following regimens:
  - Lenalidomide and dexamethasone for non-transplant candidates; **OR**
  - Cyclophosphamide, bortezomib, and dexamethasone; **OR**
- Used as subsequent therapy for relapsed or progressive disease in combination with dexamethasone and **one** of the following:
  - Lenalidomide; **OR**
  - Bortezomib; **OR**
  - Carfilzomib; **OR**
  - Cyclophosphamide and bortezomib; **OR**
  - Selinexor; **OR**
- Used in combination with pomalidomide and dexamethasone after at least two prior therapies including an immunomodulatory agent (e.g., lenalidomide pomalidomide) and a proteasome inhibitor (bortezomib, carfilzomib); **OR**
- Used as single agent; **AND**
  - Patient received at least three prior lines of therapy including a proteasome inhibitor (e.g., bortezomib, carfilzomib) and an immunomodulatory agent (e.g., lenalidomide, pomalidomide); **OR**
  - Patient must be double refractory to a proteasome inhibitor and an immunomodulatory agent

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Systemic Light Chain Amyloidosis (IV only)**

- Patient is at least 18 years of age; **AND**
- Therapy will not be used in combination with other anti-CD38 therapies (e.g., daratumumab, isatuximab, etc.); **AND**
- Used as single agent therapy; **AND**
- Used for the treatment of relapsed/refractory disease

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe infusion reactions including anaphylactic reactions, neutropenia, thrombocytopenia); **AND**
- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
  - Use for newly diagnosed disease in combination with bortezomib, thalidomide, and dexamethasone after 24 weeks of induction/consolidation therapy **may not be renewed.**
  - Use for newly diagnosed disease in combination with bortezomib, lenalidomide, and dexamethasone may be renewed for up to a maximum of 2 years of maintenance therapy.
  - Use for newly diagnosed or relapsed disease in combination with cyclophosphamide, bortezomib, and dexamethasone may be renewed for up to a maximum of 80 weeks *(32 weeks of induction therapy and 48 weeks of maintenance therapy)*.

DAURISMO® (GLASDEGIB)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Acute Myeloid Leukemia**

- Patient is 18 years of age or older; **AND**
- Patient has a baseline QTc interval of ≤ 470 ms **and** patient does not have a history of long QT syndrome; **AND**
- Women of child-bearing age must have a negative pregnancy test prior to initiating therapy **(females of reproductive potential and males should use effective contraception during and for at least 30 days after treatment)**; **AND**
- Patient does not have active, uncontrolled central nervous system (CNS) leukemia; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **OR**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort); **OR**
  - Coadministration with moderate CYP3A4 inducers (e.g., bosentan, modafinil), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **OR**
  - Coadministration with QTc prolonging drugs (e.g., ciprofloxacin, amitriptyline, quetiapine, sumatriptan), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have a t(9:22) cytogenetic translocation or acute promyelocytic leukemia; **AND**
  - Patient is 75 years or older OR patient is unable to receive intensive induction chemotherapy due to significant comorbidities (e.g., severe cardiac disease [i.e., LVEF < 50% or a cumulative anthracycline dose equivalent to 400-550 mg/m^2 of daunorubicin or 150 mg/m^2 of idarubicin], performance status score of ≥ 2, serum creatinine > 1.3 mg/dL); **AND**
    - Used in combination with low-dose cytarabine; **AND**
    - Patient has newly diagnosed acute myeloid leukemia; **AND**
      - Used for treatment induction without actionable mutations when not a candidate for or decline intensive therapy; **OR**
      - Used as post-induction therapy following a response to previous lower intensity therapy with the same regimen; **OR**
- Used for relapsed, refractory disease; **AND**
  - Used as a component of re-induction therapy of the initial successful induction regimen if the relapse occurred ≥ 12 months since induction

CLINICAL CRITERIA FOR RENEWAL

- Disease stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH; **AND**
- Absence of unacceptable toxicity from the drug (e.g., QTc-interval prolongation [i.e., interval ≥ 500 ms and/or interval prolongation with signs and symptoms of severe arrhythmia])

DEPO-SUBQ PROVERA 104

Length of Authorization:	1 year
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of endometriosis OR patient is using the medication for contraception

- Confirmation that patient does not have any of the following contraindications:
  - Known or suspected pregnancy; **OR**
  - Undiagnosed vaginal bleeding; **OR**
  - Known or suspected malignancy of the breast; **OR**
  - Active thrombophlebitis, current or past history of thromboembolic disorders, or cerebral vascular disease; **OR**
  - Significant liver disease.

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet above criteria; **AND**
- Patient is considered to have clinically meaningful response to treatment; **AND**
- Patient is free of unacceptable toxicity from the drug.

DERMATOLOGICS: ISOTRETINOIN

Length of Authorization:	20 weeks (initial and renewal)
Initiative:	MNC: Retinoids (IE 2462 / NCPDP 75 –and 50081/ 75 and 2194)

STANDARD FORMULARY CRITERIA FOR INITIAL APPROVAL

INITIAL CRITERIA

AMNESTEEM®, CLARAVIS®, ACCUTANE®, ABSORICA®/ABSORICA® LD, MYORISAN®, ZENATANE®

- Must have diagnosis of severe cystic acne, unresponsive to other treatment **OR**
- Congenital ichthyosis (orphan drug designation); **OR**
  - For other off label uses, must be prescribed by a dermatologist or oncologist for approval; **AND**
  - Forward to pharmacist for consideration of off-label use

FYI only – iPLEDGE™ Patients must be enrolled to get drug; AND

- iPLEDGE™ enrollment required. Access the iPLEDGE™ system via the internet (www.ipledgeprogram.com) or telephone (866-495-0654) to obtain an authorization

RENEWAL CRITERIA

- Patient continues to meet the above criteria; **AND**
- At least 8 weeks has passed since completion of the first course; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use

PRECISION FORMULARY CRITERIA FOR INITIAL APPROVAL

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

INITIAL CRITERIA

AMNESTEEM®, CLARAVIS®, ACCUTANE®, MYORISAN®, ZENATANE®

- Must have diagnosis of severe cystic acne, unresponsive to other treatment **OR**
- Congenital ichthyosis (orphan drug designation); **OR**
- For other off label uses, must be prescribed by a dermatologist or oncologist for approval; **AND**
  - Forward to pharmacist for consideration of off-label use

FYI only – iPLEDGE™ Patients must be enrolled to get drug; AND

- iPLEDGE™ enrollment required. Access the iPLEDGE™ system via the internet (www.ipledgeprogram.com) or telephone (1-866495-0654) to obtain an authorization

RENEWAL CRITERIA

- Patient continues to meet the above criteria; **AND**
- At least 8 weeks has passed since completion of the first course; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use

DERMATOLOGICS: STEROIDS

Length of Authorization:	1 Year
Initiative:	MNC: Dermatological Agents (IE 2462 / NCPDP 75 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

BRYHALI®, LEXETTE AND GENERIC HALOBETASOL 0.05% FOAM, TOPICORT® SPRAY

- Patient is 12 years of age or older (Lexette and generic halobetasol 0.05% foam) OR 18 years of age or older (Bryhali, Topicort spray); **AND**
- Has a diagnosis of moderate to severe plaque psoriasis.
- For Lexette® and Topicort® spray: Patient has tried **two** topical generic steroids

  Note: Treatment beyond 2 weeks for Lexette®, 4 weeks for Topicort® spray, and 8 weeks for Bryhali® is not recommended per package labeling. However, patient may have reoccurrence as it is a chronic disease state.

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to be carefully monitored for adverse effects by a healthcare provider throughout the duration of treatment; **AND**
- Patient has demonstrated clinical improvement in response to treatment.

DUOBRII®

Criteria:

- Patient is 18 years of age or older; **AND**
- Has a diagnosis of plaque psoriasis; **AND**
- Female patients of reproductive potential have had a negative pregnancy test within 2 weeks prior to initiating therapy; **AND**
- Female patients of reproductive potential have been counseled to use effective contraception; **AND**
- Patient has tried **two** topical generic steroids ***AND Enstilar***.

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet the above criteria; **AND**
- Patient continues to be carefully monitored for adverse effects by a healthcare provider throughout the duration of treatment; **AND**
- Patient has demonstrated clinical improvement in response to treatment.

HALOG®

- Patient has tried **two** topical generic steroids (e.g., Very high potency – Betamethasone dipropionate (augmented), clobetasol, halobetasol; High potency – amcinonide ointment, betamethasone dipropionate, desoximetasone gel or ointment, or cream ≥ 0.25%, fluocinolone cream ≥ 0.025%, fluocinonide, triamcinolone 0.5%)

CLOBETEX (CLOBETASOL PROPIONATE CREAM/DESLORATADINE)

Criteria:

- Patient is 12 years of age or older; **AND**
- Patient has a diagnosis of corticosteroid-responsive dermatoses; **AND**
- Patient has a diagnosis of either seasonal allergic rhinitis or perennial allergic rhinitis; **AND**
- Patient has had a trial and failure of generic clobetasol propionate cream 0.05% AND generic desloratadine 5 mg when used in combination**.**

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet the above criteria; **AND**
- Patient is considered to have clinically meaningful response to treatment; **AND**
- Patient is not experiencing any treatment-limiting adverse reactions of the medication.

DERMATOLOGICS: TOPICAL (MISCELLANEOUS)

Length of Authorization:	8 days
Initiative:	MNC: Dermatological Agents (IE 2462 / NCPDP 75 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

DOXEPIN 5% CREAM, ZONALON 5% CREAM, PRUDOXIN 5% CREAM

- The patient must have moderate pruritus associated with the diagnosis of atopic dermatitis or lichen simplex chronicus; **AND**
- Must be at least 18 years of age; **AND**
- Must have tried and failed nonpharmacologic interventions of proper skin care (i.e., gentle skin cleansers and daily skin moisturization (i.e., emollients, calamine lotions, cooling of skin, avoidance of skin irritants)

CLINICAL CRITERIA FOR RENEWAL

- The patient has benefited from therapy; **AND**
- The patient's condition has not progressed or worsened while on therapy; **AND**
- The patient has not developed any contraindications or other exclusions to its continued use

DERMATOLOGICS: TOPICAL ANTIBIOTIC AGENTS FOR ACNE/ROSACEA

STANDARD FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Dermatological Agents (IE 2462 / NCPDP 75 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

ACANYA®, AKTIPAK®, BENZACLIN®, BENZAMYCIN®, DUAC®, EVOCLIN®, VELTIN®, ZIANA® [BRANDS]

Diagnosis of **acne**

- The patient has tried one of the following: adapalene gel, adapalene/benzoyl peroxide, clindamycin gel/lotion/solution, clindamycin/benzoyl peroxide, erythromycin/benzoyl peroxide, tretinoin cream, Epiduo® Forte, or Onexton®

BRAND ACZONE® 5%

Patient has tried two generics in class (e.g., adapalene gel, adapalene-benzoyl peroxide, clindamycin gel/lotion/solution, clindamycin/benzoyl peroxide, dapsone, erythromycin/benzoyl peroxide, tretinoin cream)

FINACEA® GEL

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of mild to moderate rosacea; **AND**
- The patient has failed a trial of ONE of the following: azelaic acid gel, Soolantra, or Finacea foam

AZELAIC ACID

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of mild to moderate rosacea

CLINDAGEL® (AND GENERIC CLINDAGEL)

- The patient has a diagnosis of acne vulgaris; **AND**
- Patient is 12 years of age or older; **AND**
- Patient must have a history of failure, contraindication, or intolerance to **two** generic clindamycin topical products

METROGEL

- The patient has failed a trial of ONE of the following: metronidazole gel, Soolantra or Finacea foam

NORITATE

- The patient has failed a trial of ONE of the following: Soolantra or Finacea foam or azelaic acid

PRECISION/PLUS FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Dermatological Agents (IE 2462 / NCPDP 75 and 2193)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

BRAND ACZONE® 5% AND 7.5%

- **Step Criteria (No Grandfathering):** Patient has tried two generics in class (e.g., adapalene gel, adapalene-benzoyl peroxide, clindamycin gel/lotion/solution, clindamycin/benzoyl peroxide, dapsone, erythromycin/benzoyl peroxide, tretinoin cream)

FINACEA® GEL

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of mild to moderate rosacea; **AND**
- The patient has failed a trial of ONE of the following: azelaic acid gel, Soolantra, or Finacea foam

AZELAIC ACID

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of mild to moderate rosacea

CORE FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Dermatological Agents (IE 2462 / NCPDP 75 – HICL and 2193)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

BRAND ACZONE 7.5%

- Patient has tried two generics in class (e.g., adapalene gel, adapalene-benzoyl peroxide, clindamycin gel/lotion/solution, clindamycin/benzoyl peroxide, dapsone, erythromycin/benzoyl peroxide, tretinoin cream)

FINACEA® GEL

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of mild to moderate rosacea; **AND**
- The patient has failed a trial of ONE of the following: ivermectin cream, azelaic acid gel, or Finacea foam

AZELAIC ACID

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of mild to moderate rosacea

DERMATOLOGICS: TOPICAL ANTIBIOTICS

Length of Authorization:	1-time fill
Initiative:	MNC: Dermatological Agents (IE 2462 / NCPDP 75 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

CENTANY®

Diagnosis of **Impetigo**

- Must be positive for S. Aureus methicillin-susceptible isolates only or S. pyogenes; **AND**
- Must be at least 2 months of age; **AND**
- Must have a history of failure, contraindication, intolerance to, or medical reason that generic Bactroban (mupirocin) cannot be used

ALTABAX®

Diagnosis of **Impetigo**

- Must be positive for S. Aureus methicillin-susceptible isolates only or S. pyogenes; **AND**
- Must be at least 9 months of age; **AND**
- Must have a history of failure, contraindication, intolerance to, or medical reason which generic Bactroban (mupirocin) cannot be used

BACTROBAN NASAL

- Must be 12 years of age or older; **AND**
- Must be at high risk of MRSA infection (e.g., institutional outbreaks, healthcare workers, etc.)

XEPI®

- The patient has a diagnosis of impetigo due to *S. aure*us or *S. pyogenes*; **AND**
- Must be at least 2 months of age; **AND**
- Must have a history of failure, contraindication, intolerance to, or medical reason that generic Bactroban (mupirocin) cannot be used.

DERMATOLOGICS: TOPICAL ANTINEOPLASTICS

Length of Authorization:	Klisyri: 5 days, All others: 1 Year
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193) – for Targretin MNC: Antineoplastics (IE 2462 / NCPDP 75, 50081 and 2193) for all others

STEP CRITERIA (NO GRANDFATHERING)

PICATO®

Diagnosis of **Actinic Keratosis**

- If there has been a therapeutic failure of fluorouracil or imiquimod.

CLINICAL CRITERIA FOR INITIAL APPROVAL

CARAC®

Diagnosis of **Actinic or Solar Keratosis**

- Patient has tried and failed generic fluorouracil 0.5% cream.

CLINICAL CRITERIA FOR RENEWAL

- Patient has demonstrated clinical improvement in response to treatment; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use.

KLISYRI

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of actinic keratosis on the face or the scalp; **AND**
- Patient has contraindication to, failure of, or intolerance to ≥ 2 preferred topical products approved for actinic keratosis.

  Note: Many patients will have full clearance of the treated lesion with Klisyri. Recurrence rates for AK are high, therefore, all new occurrences should be treated as a new request.

TARGRETIN® TOPICAL

Diagnosis of **Cutaneous T-Cell Lymphoma (CTCL)**

- Patient is 18 years of age or older; **AND**
- Females of reproductive potential must have a negative pregnancy test and use effective contraception one month prior to initiating treatment and monthly while on therapy; **AND**
- Patient has a diagnosis of cutaneous manifestations of cutaneous T-cell lymphoma (e.g., mycosis fungoides/Sezary syndrome); **AND**
- Patient has limited/localized skin involvement; **AND**
- Used as initial treatment for stage IA/IB–IIA/IIB disease; **OR**
- Patient has relapsed, refractory, or persistent disease following other therapies

Diagnosis of **Primary Cutaneous B-Cell Lymphoma**

- Patient is 18 years of age or older; **AND**
- Females of reproductive potential must have a negative pregnancy test and use effective contraception one month prior to initiating treatment and monthly while on therapy; **AND**
- Topical therapy for primary cutaneous marginal zone or follicle center lymphoma

CLINICAL CRITERIA FOR INITIAL APPROVAL (CONTINUED)

TARGRETIN® TOPICAL (CONTINUED)

Diagnosis of **Adult T-Cell Leukemia/Lymphoma**

- Patient is 18 years of age or older; **AND**
- Females of reproductive potential must have a negative pregnancy test and use effective contraception one month prior to initiating treatment and monthly while on therapy; **AND**
- Used as first line topical therapy; **AND**
- Patient has chronic/smoldering disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hyperlipidemia, pancreatitis, hepatotoxicity (greater than three times the upper limit of normal values for SGOT/AST, SGPT/ALT, or bilirubin), cholestasis, hepatic failure, hematologic toxicities (leukopenia, neutropenia), hypothyroidism, hypoglycemia, cataracts, photosensitivity, etc.

DERMATOLOGICS: TOPICAL ANTIVIRALS

Length of Authorization:	1 Year
Initiative:	MNC: Antivirals (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of Herpes labialis

- History of cold sores/fever blisters on the face or lips; **AND**
- Trial of a preferred oral antiviral (i.e., valacyclovir, acyclovir, famciclovir)

Coverage is **not** provided in the following conditions:

- History of Genital herpes
- If patient has a history of genital herpes, must try preferred oral antivirals
- Acyclovir, famciclovir, valacyclovir (standard of care for genital herpes)

SITAVIG (BUCCAL ACYCLOVIR)

- Patient must meet the criteria above; **AND**
- Patient is 18 years of age or older; **AND**
- Documentation of patient being immunocompetent

XERESE (ACYCLOVIR/HYDROCORTISONE)

- Patient must meet the criteria above; **AND**
- Patient is 6 years of age or older; **AND**
- If patient is 12 years of age or older, must try and fail preferred agent (i.e., acyclovir, famciclovir, valacyclovir) or documentation of why it cannot be used

ZOVIRAX CREAM AND DENAVIR CREAM

- Patient must meet the criteria above; **AND**
- Patient is 12 years of age or older; **AND**
- Documentation of patient being immunocompetent

DERMATOLOGICS: TOPICAL IMMUNOMODULATORS

Length of Authorization:	1 Year
Initiative:	MNC: Immunomodulators: Topical (IE 2462 / NCPDP 75 and 75/50081 and 2193)

STEP CRITERIA (NO GRANDFATHERING)

ELIDEL®, PIMECROLIMUS, PROTOPIC®, TACROLIMUS

- Patient is ≥ 2 years old for Protopic® 0.03% or Elidel®; **OR**
- Patient is ≥ 16 years for Protopic 0.1%; **AND**
- If there has been a therapeutic trial and failure of **one** topical corticosteroid

Override criteria: May have a situation in which a topical steroid would be medically inappropriate (i.e., large BSA)

DERMATOLOGICS: TOPICAL PHOSPHODIESTERASE-4 INHIBITORS (PDE-4)

Length of Authorization:	1 Year
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

STEP CRITERIA – EUCRISA

Must have a history of failure, contraindication or intolerance to **or** is not successfully managed with a preferred topical steroid **or** may have a situation in which a topical steroid would be inappropriate (i.e., large BSA)

DERMATOLOGICS: TOPICAL RETINOIDS

Length of Authorization:	1 year
Initiative:	MNC: Immunomodulators: Topical (IE 2462/ NCPCP 75, 50081 /75 and 2193)

CLINICAL CRITERIA FOR PLANS THAT REQUIRE PA

Diagnosis of acne vulgaris or keratosis follicularis (also known as Darier's or Darier-White disease)

CLINICAL CRITERIA FOR ADAPALENE LOTION/SWAB/SOLUTION, DIFFERIN, AKLIEF®, ALTRENO®, ARAZLO®, ATRALIN®, RETIN-A®, RETIN-A® MICRO 0.04% AND 0.1%, TRETIN-X®

Diagnosis of **Acne Vulgari**s

- Patient must have a trial and failure of generic adapalene cream/gel **or** generic tretinoin

CLINICAL CRITERIA FOR RETIN-A® MICRO 0.06% AND 0.08% PUMP

For ages 26 years or older, diagnosis of **acne vulgari**s

CLINICAL CRITERIA FOR TAZORAC

Diagnosis of **Acne Vulgari**s

- ***Patient must have a trial and failure of generic tazarotene cream*; OR**

Diagnosis of **Psoriasis**

- For brand Tazorac 0.05% cream or gel, approve
- ***For brand Tazorac 0.1% cream or gel, patient must have a trial and failure of generic tazarotene cream***

CLINICAL CRITERIA FOR TRETINOIN MICRO GEL

INITIAL CRITERIA

Diagnosis of **Acne Vulgaris**

- Patient is 12 years of age or older; **AND**
- Must not be used for cosmetic purposes; **AND**
- Patient must have a history of failure, contraindication to **or** is not successfully managed with preferred generic tretinoin (i.e., cream) for acne vulgaris

CLINICAL CRITERIA FOR RENEWAL

- The patient has benefited from therapy; **AND**
- The condition has not progressed or worsened while on therapy; **AND**
- The patient has not developed any contraindications or other exclusions to its continued use

CLINICAL CRITERIA FOR FABIOR (TAZAROTENE 0.1% FOAM)

INITIAL CRITERIA

Diagnosis of **Acne Vulgaris**

- Patient is 12 years of age or older; **AND**
- Patient is not pregnant (contraindicated in pregnancy); **AND**
- Must not be used for cosmetic purposes; **AND**
- ***Patient must have a history of failure or contraindication to a trial of both a preferred generic tretinoin (e.g., cream) for acne vulgaris AND generic tazarotene***

CLINICAL CRITERIA FOR RENEWAL

- The patient has benefited from therapy; **AND**
- The condition has not progressed or worsened while on therapy; **AND**
- The patient has not developed any contraindications or other exclusions to its continued use

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

- All cosmetic-only products in HIC3 L9I, such as Renova® (*tretinoin emollient*), are not covered. Only clients with A category in Cosmetic agents are covered.
- Eligible products in HIC3 L9B are **not** covered without a medical (vs. cosmetic) indication.
- Examples of non-approvable, cosmetic diagnoses include photo damage, wrinkles, and lentigo

DERMATOLOGICS: VITAMIN D ANALOGS

Length of Authorization:	1 Year
Initiative:	MNC: Dermatological Agents (IE 2462 / NCPDP 75 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

DOVONEX®, SORILUX®, VECTICAL®

Diagnosis of plaque psoriasis

- Patient is 2 years of age or older (Vectical®), patient is 4 years of age or older (Sorilux®), or patient is 18 years of age or older (Dovonex®).
- For brand Dovonex®: Patient has tried and failed generic calcipotriene 0.005% cream.
- For brand Vectical®: Patient has tried and failed of generic calcitriol ointment (this step only if the plan covers the generic; generic is MVG).

Note: Treatment beyond 8 weeks for Dovonex® is not recommended per package labeling. However, patient may have reoccurrence as it is a chronic disease state.

CLINICAL CRITERIA FOR RENEWAL

- Patient has demonstrated clinical improvement in response to treatment; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use

DERMATOLOGICS: VITAMIN D ANALOG/ANTI-INFLAMMATORY STEROIDS

Length of Authorization:	1 Year
Initiative:	MNC: Dermatological Agents (IE 2462 / NCPDP 75 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

TACLONEX® OINTMENT, CALCIPOTRIENE-BETAMETHASONE OINTMENT

Diagnosis of plaque psoriasis

- Patient is 12 years of age or older; **AND**
- Patient is unable to use the individual components of the drug separately

CLINICAL CRITERIA FOR RENEWAL

- Patient has benefited from therapy; **AND**
- The patient's condition has not progressed or worsened while on therapy; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use

DIABETIC SUPPLIES

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Category A: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

Trial and failure of a 90-day supply of **BOTH** of the following in the last **180** days:

- Contour/Contour Next
- One Touch

Exceptions:

- Patient is using an insulin pump that does not adequately communicate with a preferred meter
  - Documentation (medical records) must be provided to validate that the insulin pump does not interface with the preferred product(s).
- Patient requires a specialized meter for vision impairment
- Pharmacist may use judgement for other reasons patient may need to use non-preferred
  - Documentation must be provided stating the preferred product has not been effective, **AND**
  - Documented justification must be provided for why the non-preferred product is expected to provide benefit when the preferred product has not been shown to be effective

NOTE FOR RENEWAL

- If the patient has previously tried **both** Contour/Contour Next **AND** One Touch, they will not be required to try them again. You may approve if the patient had a previous approval showing a trial of **both** Contour/Contour Next **AND** One Touch.

Note: This is only a partial product listing of nonpreferred products. Refer to PDL for products not otherwise listed here.

PRECISION/PLUS FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Category A: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

Only preferred products: (all others are excluded)

- Contour
- Contour Next

Exceptions:

- Patient is using an insulin pump that does not adequately communicate with a preferred meter
  - Documentation (medical records) must be provided to validate that the insulin pump does not interface with the preferred product(s).
- Patient requires a specialized meter for vision impairment
- Pharmacist may use judgment for other reasons patient may need to use non-preferred
  - Documentation must be provided stating the preferred product has not been effective, **AND**
  - Documented justification must be provided for why the non-preferred product is expected to provide benefit when the preferred product has not been shown to be effective

  Note: This is only a partial product listing of nonpreferred products. Refer to PDL for products not otherwise listed here.

Quantity limit = 10 strips per day

ENHANCED FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Category A: PA required (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

Trial and failure of a 90-day supply of **both** of the following in the last **365** days:

- Accu-Chek®
- One Touch®

Exceptions:

- Patient is using an insulin pump that does not adequately communicate with a preferred meter
  - Documentation (medical records) must be provided to validate that the insulin pump does not interface with the preferred product(s).
- Patient requires a specialized meter for vision impairment
- Pharmacist may use judgement for other reasons patient may need to use non-preferred
  - Documentation must be provided stating the preferred product has not been effective, **AND**
  - Documented justification must be provided for why the non-preferred product is expected to provide benefit when the preferred product has not been shown to be effective

NOTE FOR RENEWAL

- If the patient has previously tried **both** Accu-Chek® and One Touch®, they will not be required to try them again. You may approve if the patient had a previous approval showing a trial of both Accu-Chek® and One Touch®.

  Note: This is only a partial product listing of nonpreferred products. Refer to PDL for products not otherwise listed here.

CORE FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Category A: PA required (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

Only preferred product: (all others are excluded)

- One Touch®

Exceptions:

- Patient is using an insulin pump that does not adequately communicate with a preferred meter
  - Documentation (medical records) must be provided to validate that the insulin pump does not interface with the preferred product(s).
- Patient requires a specialized meter for vision impairment
- Pharmacist may use judgement for other reasons patient may need to use non-preferred
  - Documentation must be provided stating the preferred product has not been effective, **AND**
  - Documented justification must be provided for why the non-preferred product is expected to provide benefit when the preferred product has not been shown to be effective

DIURETICS

Length of Authorization:	1 year
Initiative:	MNC: Antihypertensive Medications (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

DYRENIUM AND GENERIC TRIAMTERENE

- Patient is at least 18 years or older; **AND**
- Patient must have a diagnosis of one of the following, **AND**:
  - edema associated with congestive heart failure, cirrhosis of the liver and the nephrotic syndrome
  - steroid-induced edema
  - idiopathic edema
  - edema due to secondary hyperaldosteronism
- Have had an adequate trial and failure, contraindication, or intolerance to another generic potassium sparing diuretic (e.g., spironolactone, amiloride)

DMARDS

Length of Authorization:	1 year
Initiative:	Rasuvo, RediTrex, Otrexup, and Xatmep: MNC: Immunomodulators: Systemic (IE 2462 / NCPDP 75)

RASUVO

- Diagnosis of **psoriasis**; **AND**
- Patient requires symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy; **AND**
- Patient has failed a trial of topical agents (e.g., emollients, corticosteroids, retinoids, vitamin D analogs, tacrolimus, pimecrolimus); **AND**
- Patient has had an adverse reaction, intolerance, or inadequate response to oral methotrexate; **OR**
- Patient is continuing treatment with Rasuvo.

OR

- Adult patient has severe, active rheumatoid arthritis (RA); **AND**
- Patient has had a trial and failure of NSAIDs or corticosteroids; **AND**
- Patient has had an adverse reaction, intolerance, or inadequate response to oral methotrexate; **OR**
- Patient is continuing treatment with Rasuvo.

OR

- Patient is a child with active polyarticular juvenile idiopathic arthritis; **AND**
- Had an inadequate response or trial with NSAIDs or corticosteroids; **AND**
- Patient has had an adverse reaction, intolerance, or inadequate response to oral methotrexate; **OR**
- Patient is continuing treatment with Rasuvo.

CLINICAL CRITERIA FOR RENEWAL

- Patient is free of any unacceptable toxicity
- Patient has had a disease response with the medication

OTREXUP, REDITREX

Diagnosis of Juvenile Idiopathic arthritis OR RA:

- Patient has had a trial and failure of NSAIDs or corticosteroids; **AND**
- Patient has had an adverse reaction, intolerance, or inadequate response to oral methotrexate; **OR**
- Patient is continuing with therapy.

Diagnosis of **Psoriasis**

- Patient has failed a trial of topical agents (e.g., emollients, corticosteroids, retinoids, vitamin D analogs, tacrolimus, pimecrolimus); **AND**
- Patient has had an adverse reaction, intolerance, or inadequate response to oral methotrexate; **OR**
- Patient is continuing with therapy.

CLINICAL CRITERIA FOR RENEWAL

- Patient is free of any unacceptable toxicity
- Patient has had a disease response with the medication

CLINICAL CRITERIA FOR RENEWAL

XATMEP (METHOTREXATE ORAL SOLUTION)

Diagnosis of active polyarticular juvenile idiopathic arthritis:

- Patient is a child with active disease; **AND**
- Patient has had an inadequate response or trial with NSAIDs or corticosteroids; **AND**
- Patient has had an adverse reaction, intolerance, or inadequate response to oral methotrexate; **OR**
- Patient is continuing treatment with Xatmep oral solution; **OR**
- Patient has difficulty swallowing

Diagnosis of **acute lymphoblastic leukemia (ALL):**

- Approve

CLINICAL CRITERIA FOR RENEWAL

- The patient has had an improvement with therapy; **AND**
- The patient's condition has not progressed or worsened while on therapy; **AND**
- The patient has not developed any contraindications or other exclusions to its continued use

DOJOLVI® (TRIHEPTANOIN)

Length of Authorization:	1 year, may be renewed
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Long-Chain Fatty Acid Oxidation Disorder (LC-FAOD)**

- Patient must have a diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) confirmed by 2 of the following:
  - Low enzyme activity in cultured fibroblasts
  - 1 or more pathogenic mutations in the CPT2, ACADVL, HADHA, or HADHB genes
  - Disease specific elevations of acylcarnitines on a newborn blood spot or in plasma
- Patient is being followed by a clinical specialist knowledgeable in appropriate disease-related dietary management; **AND**
- Patient is practicing appropriate dietary measures for their age and specific disorder (high carbohydrate, low long-chain fatty acids, avoidance of fasting); **AND**
- Patient is NOT taking a pancreatic lipase inhibitor (e.g., orlistat); **AND**
- Patient will NOT receive an additional medium chain triglyceride while taking triheptanoin

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet initial criteria; **AND**
- Patient must demonstrate disease improvement and/or stabilization (e.g., cardiac function, exercise tolerance, reduction in major clinical events, including hospitalization); **AND**
- Patient does not experience serious treatment-related adverse effects (e.g., gastrointestinal effects)

DOPTELET® (AVATROMBOPAG)

Length of Authorization:	Thrombocytopenia due to CLD • Coverage is provided for one 5-day course of therapy and may not be renewed. Chronic ITP • Coverage is provided for three months and may be renewed.
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Thrombocytopenia due to Chronic Liver Disease (CLD)**

- Patient is 18 years of age or older; **AND**
- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., romiplostim, eltrombopag, lusutrombopag, etc.) or fostamatinib; **AND**
- Avatrombopag is not being used to attempt to normalize platelet count; **AND**
- Laboratory values are current (i.e., drawn within the previous 28 days); **AND**
- Patient will avoid concomitant therapy with strong or moderate dual inhibitors of CYP2C9 and CYP3A4 (e.g., fluconazole, fluvoxamine, voriconazole, etc.), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant therapy with strong or moderate dual inducers of CYP2C9 and CYP3A4 (e.g., carbamazepine, rifampin, etc.), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient is scheduled to undergo a procedure with a risk of bleeding which would necessitate a platelet transfusion; **AND**
- Patient will not be undergoing any of the following procedures:
  - Neurosurgical intervention;
  - Thoracotomy;
  - Laparotomy;
  - Organ resection; **AND**
- The patient is at increased risk for bleeding as indicated by platelet count of less than $< 50 \times 10^9$/L

Diagnosis of **Chronic Immune Thrombocytopenia (ITP)**

- Patient is 18 years of age or older; **AND**
- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., romiplostim, eltrombopag, lusutrombopag) or fostamatinib; **AND**
- Patient has had chronic ITP for at least 6 months (or meets the corticosteroid requirement below); **AND**
- Avatrombopag is not being used to attempt to normalize platelet count; **AND**
- Laboratory values are current (i.e., drawn within the previous 28 days); **AND**
- Patient will avoid concomitant therapy with strong or moderate dual inhibitors of CYP2C9 and CYP3A4 (e.g., fluconazole, fluvoxamine, voriconazole, etc.), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant therapy with strong or moderate dual inducers of CYP2C9 and CYP3A4 (e.g., carbamazepine, rifampin, etc.), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL (CONTINUED)

- Patient has previously failed any of the following treatments for ITP:
  - Patient has failed previous therapy with corticosteroids (i.e., patient had no response to at least a 3-month trial or is corticosteroid-dependent); **OR**
  - Patient has failed previous therapy with immunoglobulins; **OR**
  - Patient has had splenectomy; **AND**
- The patient is at increased risk for bleeding as indicated by platelet count of less than 30×10^9/L (30,000/mm³)

CLINICAL CRITERIA FOR RENEWAL

Chronic ITP

- Patient continues to meet criteria identified in initial criteria; **AND**
- Absence of unacceptable toxicity from the drug (e.g., thrombotic/thromboembolic complications [blood clots]); **AND**
- Platelet count (within the preceding 28 days) does not exceed 400 x 10^9/L; **AND**
- Disease response indicated by the achievement and maintenance of a platelet count of at least 50×10^9/L as necessary to reduce the risk for bleeding

Thrombocytopenia due to CLD

Coverage **cannot** be renewed.

DOXIL®, LIPODOX (DOXORUBICIN)

Length of Authorization:	6 months, may be renewed Use in the treatment of Mycosis Fungoides/Sezary Syndrome and T-Cell Lymphoproliferative Disorders will be limited to 8 cycles. Use in the treatment of Hodgkin lymphoma will be limited to 6 cycles. Use in the treatment of multiple myeloma and Non-Hodgkin lymphoma is limited to 8 cycles.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of one of the following:

- AIDS-related Kaposi sarcoma (KS)
- Multiple myeloma
- Ovarian cancer (including fallopian tube, primary peritoneal, and epithelial ovarian cancers)
- Breast cancer
- Classic Hodgkin lymphoma
- Non-Hodgkin lymphoma
  - B-cell lymphomas
    - Follicular lymphoma (grade 1-2)
    - Diffuse large B-cell lymphoma (including histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma)
    - Multicentric Castleman's disease
    - Mycosis fungoides/Sézary syndrome
  - T-cell lymphomas
    - Peripheral T-cell lymphoma
    - Adult T-cell leukemia/lymphoma
    - Hepatosplenic T-cell lymphoma
- Soft tissue sarcoma
  - Extremity/body wall, head/neck
  - Retroperitoneal/intra-abdominal
  - Angiosarcoma
  - Pleomorphic rhabdomyosarcoma
  - Desmoid tumors (aggressive fibromatosis)
  - Solitary fibrous tumor
- Uterine sarcoma (including stromal, undifferentiated and leiomyosarcoma)
- Uterine endometrial carcinoma (including adenocarcinoma, carcinosarcoma, clear cell carcinoma, serous carcinoma, undifferentiated/dedifferentiated carcinoma)
- Primary cutaneous lymphomas
  - Primary cutaneous CD30+ T-cell lymphoproliferative disorders
  - Mycosis fungoides/Sézary syndrome

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hand-foot syndrome, cardiomyopathy, secondary oral neoplasms, severe infusion related reactions)

DUPIXENT® (DUPILUMAB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Atopic Dermatitis**:

- Patient is at least 6 years of age; **AND**
- Patient will not receive live vaccines during therapy; **AND**
- Will not be used in combination with other anti-immunoglobulin E (IgE), anti-IL4, or anti-IL5 monoclonal antibody (e.g., omalizumab, mepolizumab, reslizumab, benralizumab); **AND**
- Patient has moderate to severe atopic dermatitis (AD); **AND**
- Patient did not respond adequately (or is not a candidate) to a trial of a topical corticosteroid or topical calcineurin inhibitor (i.e., tacrolimus or pimecrolimus) OR a topical PDE4 inhibitor (e.g., Eucrisa).

Diagnosis of **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):**

- Patient is at least 18 years of age; **AND**
- Patient will not receive live vaccines during therapy; **AND**
- Will not be used in combination with other anti-immunoglobulin E (IgE), anti-IL4, or anti-IL5 monoclonal antibody (e.g., omalizumab, mepolizumab, reslizumab, benralizumab); **AND**
- Patient has bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks; **AND**
- Other causes of nasal congestion/obstruction have been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Therapy will be used in combination with intranasal corticosteroids unless not able to tolerate or is contraindicated

Diagnosis of **Asthma**

- Patient is at least 6 years of age; **AND**
- Patient will not receive live vaccines during therapy; **AND**
- Will not be used in combination with other anti-immunoglobulin E (IgE), anti-IL4, or anti-IL5 monoclonal antibody (e.g., omalizumab, mepolizumab, reslizumab, benralizumab); **AND**
- Patient has moderate to severe* (see table below) disease; **AND**
  - Patient must have asthma with an eosinophilic phenotype and a baseline blood eosinophil count of ≥ 150 cells/mcL; **OR**
  - Patient has oral corticosteroid dependent asthma; **AND**
- Must be used for add-on maintenance treatment in patients **REGULARLY** receiving BOTH of the following**:**
  - Medium to high-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g., long-acting beta agonist).
- Baseline measurement of at least one of the following for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV_1); **AND**
- Will not be used for treatment of acute bronchospasm or status asthmaticus

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

***Components of severity for classifying asthma as MODERATE may include any of the following (not all inclusive):**
• Daily symptoms • Nighttime awakenings > 1x/week but not nightly • SABA use for symptom control occurs daily • Some limitation to normal activities • Lung function (percent predicted FEV_1) > 60%, but < 80% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to mild asthma
***Components of severity for classifying asthma as SEVERE may include any of the following (not all inclusive):**
• Symptoms throughout the day • Nighttime awakenings, as often as 7x/week • SABA use for symptom control occurs several times daily • Extremely limited in normal activities • Lung function (percent predicted FEV_1) < 60% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

CLINICAL CRITERIA FOR RENEWAL

Diagnosis of **Atopic Dermatitis**

- Will not be used in combination with other anti-immunoglobulin E (IgE), anti-IL4, or anti-IL5 monoclonal antibody (e.g., omalizumab, mepolizumab, reslizumab, benralizumab, etc.); **AND**
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity, conjunctivitis, keratitis, immunogenicity); **AND**
- Disease response as indicated by improvement in signs and symptoms compared to baseline .

Diagnosis of **Chronic Rhinosinusitis w/ Nasal Polyps**

- Will not be used in combination with other anti-immunoglobulin E (IgE), anti-IL4, or anti-IL5 monoclonal antibody (e.g., omalizumab, mepolizumab, reslizumab, benralizumab, etc.); **AND**
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity, conjunctivitis, keratitis, immunogenicity); **AND**
- Disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool [e.g., nasal polyposis score (NPS), nasal congestion (NC) symptom severity score, sino-nasal outcome test-22 (SNOT-22), etc.]; **OR**
  - Patient had an improvement in at least one of the following response criteria:
    - Reduction in nasal polyp size
    - Reduction in need for systemic corticosteroids
    - Improvement in quality of life
    - Improvement in sense of smell
    - Reduction of impact of comorbidities

CLINICAL CRITERIA FOR RENEWAL (*CONTINUED*)

Diagnosis of **Asthma**

- Will not be used in combination with other anti-immunoglobulin E (IgE), anti-IL4, or anti-IL5 monoclonal antibody (e.g., omalizumab, mepolizumab, reslizumab, benralizumab, etc.); **AND**
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity, conjunctivitis, keratitis, immunogenicity); **AND**
- Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in **one or more** of the following:
  - Use of systemic corticosteroids
  - Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
  - Hospitalizations
  - ER visits
  - Unscheduled visits to healthcare provider; **OR**
- Improvement from baseline in forced expiratory volume in 1 second (FEV1)

DOSAGE AND ADMINISTRATION

Indication	Dose
Atopic Dermatitis	**Dosing in Pediatric Patients** (patients 6 to 17 years of age) • Body weight 15 to < 30 kg: – 600 mg (two 300 mg injections) subcutaneously initially, followed by 300 mg subcutaneously every 4 weeks • Body weight 30 to < 60 kg : – 400 mg (two 200 mg injections) subcutaneously initially, followed by 200 mg subcutaneously every other week • Body weight ≥ 60 kg: – 600 mg (two 300 mg injections in different sites) subcutaneously initially, followed by 300 mg subcutaneously every other week **Dosing in Adults** • Inject 600 mg (two 300 mg injections in different sites) subcutaneously initially, followed by 300 mg subcutaneously every other week
Asthma (eosinophilic)	• Inject 400 mg (two 200 mg injections in different sites) subcutaneously initially, followed by 200 mg subcutaneously every other week; OR • Inject 600 mg (two 300 mg injections in different sites) subcutaneously initially, followed by 300 mg subcutaneously every other week
Asthma (oral corticosteroid-dependent) **OR** asthma with co-morbid atopic dermatitis	• Inject 600 mg (two 300 mg injections in different sites) subcutaneously initially, followed by 300 mg subcutaneously every other week
Chronic Rhino- sinusitis with Nasal Polyps	• The recommended dose is 300 mg subcutaneously every other week

Max mL (per dose and over time):

Indication	# mL to build in FirstTrax℠	Per # days
Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)	4 mL (300 mg/2 mL)	28
Atopic Dermatitis	**Loading Dose** (one month only): • Adolescents : – 15 to < 30 kg–6 mL (300 mg/2 mL) – 30 to < 60 kg–4.56 mL (200 mg/1.14 mL) – > 60 kg–8 mL (300 mg/2 mL) • Adults: – 8 mL (300 mg/2 mL)	28 (one month only)
	Maintenance Dose: Adolescents: – 15 to < 30 kg– 2 mL – 30 to < 60 kg– 2.28 mL Adults: 4 mL (300 mg/2 mL)	28
Asthma (eosinophilic)	**Loading Dose** (one month only): • 4.56 mL (200 mg/1.14 mL); **OR** • 8 mL (300 mg/2 mL)	28 (one month only)
	Maintenance Dose: • 2.28 mL (200 mg/ 1.14 mL); **OR** 4 mL (300 mg/2 mL)	28
Asthma (oral corticosteroid dependent) OR with co-morbid atopic dermatitis	**Loading dose** (one month only): 8 mL (300 mg/2 mL)	28 (one month only)
	Maintenance dose: 4 mL (300 mg/2 mL)	28

Note: For diagnoses that have a loading dose and maintenance dose, a PA will be entered for each.

DYSPORT® (ABOTULINUM TOXIN A)

Length of Authorization:	6 months, may be renewed Preoperative use in Ventral Hernia may NOT be renewed
Initiative:	SPC: Botulinum Toxin (IE 2641 / NCPDP 76)

CLINICAL CRITERIA FOR INITIAL APPROVAL

NOTE: FOR ANY COSMETIC PURPOSE, REFER TO THE MAIN CRITERIA DOCUMENT "COSMETIC AGENTS – BENEFIT BUILDER"

NOTE: For denials due to quantity requests over the FDA limit, please use the following initiative and reason code:

- SPC: Botulinum Toxin

DCDD: Denial: Does not Meet FDA criteria for Diagnosis and Dose

Note: For Core Formulary, all botulinum toxin products are non-formulary.

Diagnosis of **Cervical Dystonia**

- Patient is 18 years or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have a hypersensitivity to cow's milk protein; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient has a history of recurrent involuntary contraction of one or more muscles in the neck; **AND**
  - Patient has sustained head tilt; **OR**
  - Abnormal posturing with limited range of motion in neck

Diagnosis of **Spastic Conditions**

- Patient is 18 years or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty**; AND**
- Patient is not on concurrent treatment with another botulinum toxin (i.e., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have a hypersensitivity to cow's milk protein; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient has one of the following:
  - Upper/Lower Limb Spasticity in adults (i.e., spasticity post-stroke, traumatic brain or spinal cord injuries)
  - Upper/Lower Limb Spasticity in pediatric patients at least 2 years of age
  - Spasticity of the lower limbs due to multiple sclerosis or Schilder's disease

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

Diagnosis of **Blepharospasms**

- Patient age 18 or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient does not have a hypersensitivity to cow's milk protein

Diagnosis of **Prophylaxis for Chronic Migraines**

- Patient age 18 or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have a hypersensitivity to cow's milk protein; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Not used in combination with prophylactic calcitonin gene-related peptide (CGRP) inhibitors (e.g. eptinezumab, erenumab, galcanezumab, fremanezumab) *[NOTE: This does not include CGRP inhibitors used for acute treatment (e.g., ubrogepant)]*; **AND**
- Patient is utilizing prophylactic intervention modalities (e.g., pharmacotherapy, behavioral therapy, or physical therapy); **AND**;
- Patient has 15 or more headache (tension-type-like and/or migraine-like) days per month for at least 3 months (**supported through clinical documentation/clinical notes**); **AND**
  - Patient has had at least five attacks with features consistent with migraine (with and/or without aura); **AND**
  - On at least 8 days per month for at least 3 months:
    - Headaches have characteristics and symptoms consistent with migraine; **OR**
    - Patient suspected migraines are relieved by a triptan or ergot derivative medication; **AND**
- Patient has failed at least an 8-week trial of any two oral medications (total of 16 weeks) for the prevention of migraines, such as (not all inclusive): **Documentation (e.g., clinical notes) is required to be submitted to demonstrate appropriate trials of required alternative medications and failures**
  - Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline)
  - Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol)
  - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan)
  - Anti-epileptics (e.g., divalproex, valproate, topiramate)
  - Calcium channels blockers (e.g., verapamil)

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

Migraine Features
Migraine without aura: • At least five attacks have the following: – Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated) – Headache has at least two of the following characteristics: • Unilateral location • Pulsating quality • Moderate or severe pain intensity • Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs); **AND** – During headache, at least one of the following: • Nausea and/or vomiting • Photophobia and phonophobia
Migraine with aura: • At least two attacks have the following: – One or more of the following fully reversible aura symptoms: • Visual • Sensory • Speech and/or language • Motor • Brainstem • Retinal; **AND** – At least three of the following characteristics: • At least one aura symptom spreads gradually over ≥5 minutes • Two or more symptoms occur in succession • Each individual aura symptom lasts 5 to 60 minutes • At least one aura symptom is unilateral • At least one aura symptom is positive (e.g., scintillations and pins and needles) • The aura is accompanied, or followed within 60 minutes, by headache

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

Diagnosis of **Sialorrhea Associated with Neurological Disorders:**

- Patient is 18 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have a hypersensitivity to cow's milk protein; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient has a history of troublesome sialorrhea for at least a 3-month period; **AND**
  - Patient has Parkinson's disease; **OR**
  - Patient has severe developmental delays**; OR**
  - Patient has cerebral palsy

Diagnosis of **Chronic Anal Fissure**

- Patient is 18 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have a hypersensitivity to cow's milk protein; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Other causes of disease have been ruled out (e.g., Crohn's Disease); **AND**
- Patient has failed on non-pharmacologic supportive measures (e.g., sitz baths, psyllium fiber, bulking agents); **AND**
- Patient has tried and failed a ≥ 1-month trial of conventional pharmacologic therapy (e.g., oral/topical nifedipine, diltiazem, and/or topical nitroglycerin, bethanechol). **Documentation (e.g., clinical notes) is required to be submitted to demonstrate appropriate trials of required alternative medications and failures**

Diagnosis of **Incontinence due to neurogenic detrusor overactivity**

- Patient is 18 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have a hypersensitivity to cow's milk protein; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient has detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) that is confirmed by urodynamic testing; **AND**
- Patient has failed a 1 month or longer trial of **two** medications from either antimuscarinic (i.e., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) or beta-adrenergic (i.e., mirabegron) classes. **Documentation (e.g., clinical notes) is required to be submitted to demonstrate appropriate trials of required alternative medications and failures**

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

Diagnosis of **Overactive Bladder (OAB)**

- Patient is 18 years of age or older; **AND**
- Patient has symptoms of urge urinary incontinence, urgency, and frequency; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have a hypersensitivity to cow's milk protein; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient has failed a 1 month or longer trial of **two** medications from either antimuscarinic (i.e., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) or beta-adrenergic (i.e., mirabegron) classes. **Documentation (e.g., clinical notes) is required to be submitted to demonstrate appropriate trials of required alternative medications and failures**

Diagnosis of **Severe Primary Axillary Hyperhidrosis**

- Patient is 18 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have a hypersensitivity to cow's milk protein; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- **Documentation (e.g., clinical notes) is required to be submitted to demonstrate appropriate trials of required alternative medications and failures**
- Patient has tried and failed ≥ 1-month trial of a topical agent (e.g., aluminum chloride, glycopyrronium); **AND**
  - Patient has history of medical complications such as skin infections or significant functional impairments; **OR**
  - Patient has had a significant burden of disease or impact to activities of daily living due to condition (e.g., impairment in work performance/productivity, frequent change of clothing, difficulty in relationships and/or social gatherings)

Diagnosis of **Hemifacial Spasms**

- Patient is 18 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty**; AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient does not have a hypersensitivity to cow's milk protein

Diagnosis of **Ventral Hernia**

- Patient is 18 years of age or older; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty**; AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have a hypersensitivity to cow's milk protein; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient has a large ventral hernia with loss of domain or contaminated ventral hernia; **AND**
- Used preoperatively in patients scheduled to receive abdominal wall reconstruction (AWR)

RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., symptoms of a toxin spread effect [e.g., asthenia, diplopia, ptosis, dysphagia, dysphonia, dysarthria, breathing difficulties]); **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Disease response as evidenced by the following **(Documentation/clinical notes must be submitted to demonstrate objective response):**
  - Blepharospasms
    - Improvement of severity and/or frequency of eyelid spasms
  - Cervical dystonia
    - Improvement in the severity and frequency of pain; **AND**
    - Improvement of abnormal head positioning
    - Upper/lower limb spasticity
    - Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (e.g., Ashworth Scale, Physician Global Assessment, Clinical Global Impression [CGI])
  - Severe primary axillary hyperhidrosis
    - Significant reduction in spontaneous axillary sweat production; **AND**
    - Patient has a significant improvement in activities of daily living
  - Prophylaxis for chronic migraines
    - Not used in combination with calcitonin gene-related peptide (CGRP) inhibitors (e.g., erenumab) (*NOTE: This does not include CGRP inhibitors used for acute treatment [e.g., ubrogepant]*); **AND**
    - Significant decrease in the number, frequency, and/or intensity of headaches; **AND**
    - Improvement in function; **AND**
    - Patient continues to utilize prophylactic intervention modalities (e.g., pharmacotherapy, behavioral therapy, physical therapy)

- Sialorrhea associated with neurological disorders
  - Significant decrease in saliva production
- Incontinence due to detrusor overactivity
  - Significant improvements in weekly frequency of incontinence episodes; **AND**
  - Patient's post-void residual (PVR) periodically assessed as medically appropriate.
- Overactive bladder (OAB)
  - Significant improvement in daily frequency of urinary incontinence or micturition episodes and/or volume voided per micturition; **AND**
  - Patient's post-void residual (PVR) periodically assessed as medically appropriate.
- Hemifacial spasms
  - Decrease in frequency and/or severity of spasm, or a decrease in tone and/or improvement in asymmetry to the affected side of the face.
- Chronic anal fissure
  - Complete healing of anal fissure; **OR**
  - Symptomatic improvement of persistent fissures.
- Ventral hernia
  - May not be renewed

DOSAGE AND ADMINISTRATION

- When initiating treatment, the lowest recommended dose should be used.
- Unless otherwise stated, re-treatment should occur no sooner than 12 weeks from the prior injection.

NOTE: For denials due to quantity requests over the FDA limit, please use the following initiative and reason code:

- SPC: Botulinum Toxin
- DCDD: Denial: Does not Meet FDA criteria for Diagnosis and Dose

Indication	Dose
Cervical Dystonia	**Initial dose:** 500 units divided among the affected muscles. **Re-treatment:** 250–1000 units every 12–16 weeks or longer as necessary.
Upper Limb Spasticity	**Adults**: 500-1000 units divided among the affected muscles every 12-16 weeks or longer, as necessary *Maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1500 units.* **Pediatrics:** Up to 8-16 units/kg per limb every 12 weeks. Maximum dose per treatment session for upper limb spasticity is 16 units/kg or 640 units, whichever is lower. *Maximum recommended total dose per treatment session for spasticity in pediatric patients is 30 units/kg or 1000 units, whichever is lower*
Chronic Migraine Prophylaxis	Up to 240 units divided among the affected muscles every 12 weeks.
Sialorrhea	Up to 450 units divided among the affected muscles every 12 weeks.
Chronic Anal Fissure	Up to 150 units divided among the affected muscles every 12 weeks.

Indication	Dose
Lower Limb Spasticity	**Adults**: Up to 1500 units divided among the affected muscles every 12 weeks *Maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1500 units* **Pediatrics:** Up to 10-15 units/kg divided among gastrocnemius-soleus complex muscles, per limb, every 12 weeks. Maximum dose per treatment session for lower limb spasticity is 15 units/kg for unilateral lower limb injections, 30 units/kg for bilateral lower limb injections, or 1000 units, whichever is lower. *Maximum recommended total dose per treatment session for spasticity in pediatric patients is 30 units/kg or 1000 units, whichever is lower.*
Blepharospasms	Up to 120 units per affected eye every 12 weeks.
Neurogenic detrusor overactivity; OAB	Up to 750 units divided among the affected muscles every 12 weeks.
Severe Primary Axillary Hyperhidrosis	Up to 200 units per axilla not more often than every 12 weeks.
Hemifacial Spasms	Up to 220 units per treatment session based on sites and severity of the spasm. Subsequent injections administered upon recurrence of spasm, every 12 weeks, if needed.
Ventral Hernia	500 units divided among abdominal muscles, injected 2–4 weeks prior to AWR surgery. ***May not be renewed.***

Max Units (per dose and over time):

Indication	# vials to build in FirstTrax℠	Per # days*
Cervical Dystonia	2 (500-unit vial)	84
Chronic Migraine Prophylaxis	1 (300-unit vial)	84
Sialorrhea	1 (500-unit vial)	84
Chronic Anal Fissure	1 (300-unit vial)	84
Blepharospasms	1 (500-unit vial)	84
Upper Limb Spasticity	2 (500-unit vial)	84
Upper Limb Spasticity (Pediatric)	2 (500-unit vial)	84
Lower Limb Spasticity	3 (500-unit vial)	84
Lower Limb Spasticity (Pediatric)	2 (500-unit vial)	84
Neurogenic Detrusor Overactivity/OAB	2 (500-unit vial)	84
Severe Primary Axillary Hyperhidrosis	1 (500-unit vial)	84
Hemifacial Spasms	1 (300-unit vial)	84
Ventral Hernia	1 (500-unit vial)	N/A

Available in 300 unit and 500 unit single-use vials.

* The plan may only allow for a max of 30 days to be billed at a time; no days' supply override needs to be placed to allow these to pay. The pharmacy may process as 30 days. These limitations will not allow the member to fill more than the allotted vials per max days' supply (e.g., 84, 112, or 168).

EGRIFTA® (TESAMORELIN)

Length of Authorization:	6 months, eligible for renewal
Initiative:	SPC: Growth Hormone (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Lipodystrophy**

- Patient has diagnosis of HIV/AIDS; **AND**
- Patient age is between 18 and 65 years of age; **AND**
- Patient is on a stabilized regimen of anti-retroviral therapy for at least 8 weeks prior to start of therapy; **AND**
- **MALE**: Patient has a waist circumference of ≥ 95 cm (37.4 inches) AND a waist-to-hip ratio of ≥ 0.94; **AND**
- **FEMALE**: Patient has a waist circumference of ≥ 94 cm (37.0 inches) AND a waist-to-hip ratio of ≥ 0.88 **AND**
- Body mass index (BMI) is greater than 20 kg/m^2; **AND**
- Fasting blood glucose (FBG) is less than 150 mg/dL; **AND**
- Patient does not have a history of hypophysectomy, hypopituitarism, pituitary tumor or surgery, head irradiation or head trauma; **AND**
- Patient does not have an active malignancy; **AND**
- FEMALE: Patient is currently not pregnant, planning to become pregnant, or breastfeeding

CLINICAL CRITERIA FOR RENEWAL

- Patient has been adherent to anti-retroviral therapy; **AND**
- Disease response indicated by a reduction in visceral adipose tissue measured by waist circumference or computed tomography (CT) scan; **AND**
- Absence of unacceptable toxicity from the drug. Examples include Severe injection site reactions, severe glucose intolerance, severe fluid retention, severe hypersensitivity reactions, persistent elevated IGF-1 levels, recurrent malignancies, etc.

ELAPRASE® (IDURSULFASE)

Length of Authorization:	1 year, eligible for renewal
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Hunter Syndrome (Mucopolysaccharidosis II; MPS II)**

- Patient is at least 16 months old; **AND**
- Patient has absence of severe cognitive impairment; **AND**
- Diagnosis has been confirmed by one of the following:
  - Deficient or absent iduronate 2-sulfatase (I2S) enzyme activity in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase; **OR**
  - Detection of pathogenic mutations in the *IDS* gene by molecular genetic testing; **AND**
- Documented baseline value for urinary glycosaminoglycan (uGAG) has been obtained; **AND**
- Documented baseline values for one or more of the following have been obtained:
  - **Patients 5 years or older**: 6-minute walk test (6-MWT), percent predicted forced vital capacity (FVC), joint range of motion, left ventricular hypertrophy, quality of life (CHAQ/HAQ/MPS HAQ); **OR**
  - **Patients < 5 years**: spleen volume, liver volume, FVC, and/or 6-minute walk test

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions including anaphylaxis, antibody development and serious adverse reactions in Hunter syndrome patients with severe genetic mutations, acute respiratory complications, acute cardiorespiratory failure); **AND**
- Patient does not have progressive/irreversible severe cognitive impairment; **AND**
- Patient has a documented reduction in uGAG levels; **AND**
- Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following:
  - **Patients 5 years or older**: percent predicted FVC and/or 6-minute walk test, increased joint range of motion, decreased left ventricular hypertrophy, improved growth, improved quality of life (clinically meaningful change in the CHAQ/HAQ/MPS HAQ disability index); **OR**
  - **Patients < 5 years**: reductions in spleen volume, and/or liver volume or stabilization/improvement in FVC and/or 6-MWT

ELELYSO® (TALIGLUCERASE ALFA)

Length of Authorization:	1 year, eligible for renewal
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Type 1 Gaucher Disease**

- Patient is at least 4 years of age; **AND**
- Must be used as a single agent; **AND**
- Patient has a documented diagnosis of type 1 Gaucher disease as confirmed by a beta-glucosidase leukocyte (BGL) test with significantly reduced or absent glucocerebrosidase enzyme activity; **AND**
- Adults only (i.e., patients at least 18 years or older):
  - Patient's disease results in one or more of the following:
    - Anemia (i.e., hemoglobin less than or equal to 11 g/dL [women] or 12 g/dL [men]) not attributed to an iron, folic acid, or vitamin B12 deficiency; **OR**
    - Moderate to severe hepatomegaly (liver size 1.25 or more times normal) or splenomegaly (spleen size 5 or more times normal); **OR**
    - Skeletal disease (e.g., lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis); **OR**
    - Symptomatic disease (e.g., bone pain, fatigue dyspnea, angina, abdominal distension, diminished quality of life); **OR**
    - Thrombocytopenia (platelet count less than or equal to 120,000/mm^3)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by one or more of the following (compared to pre-treatment baseline):
  - Improvement in symptoms (i.e., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life)
  - Reduction in size of liver or spleen
  - Improvement in hemoglobin/anemia
  - Improvement in skeletal disease (e.g., increase in lumbar spine and/or femoral neck BMD, no bone crises or bone fractures)
  - Improvement in platelet counts; **AND**
- Absence of unacceptable toxicity from the drug Examples of unacceptable toxicity include the following: severe hypersensitivity reactions, etc.

ELITEK® (RASBURICASE)

Length of Authorization:	Coverage will be provided for a single course of treatment, consisting of 5 days of therapy, and may not be renewed
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Hyperuricemia Due to Tumor Lysis**

- Patient is 1 month or older; **AND**
- Patient must not have a deficiency in glucose-6-phosphate dehydrogenase (G6PD); **AND**
- Patient must be receiving chemotherapy for leukemia, lymphoma, or solid tumors; **AND**
  - Used as prophylactic therapy in patients whose chemotherapy is expected to result in tumor lysis and subsequent elevation of plasma uric acid; **AND**
    - Patient must be at high-risk* for developing hyperuricemia; **OR**
  - Used for treatment in patients who develop hyperuricemia despite standard prophylactic therapies (i.e., hydration, allopurinol, febuxostat)

***Risk factors for development of tumor lysis syndrome and subsequent hyperuricemia**
• High Risk Tumor Type (i.e., Burkitt lymphoma; lymphoblastic lymphomas; ALL; DLBCL; solid tumors with high proliferative rate or rapid response to therapy) • Patient with bulky disease or large tumor burden (i.e., bulky disease > 10cm; elevated LDH > 2x ULN; elevated WBC > 25,000/mcL); organ infiltration; or bone marrow involvement) • Dehydration or situations where adequate hydration may be difficult or impossible • Renal Insufficiency or Failure (pre-existing renal failure or oliguria) • Pre-existing hyperuricemia (baseline serum/plasma uric acid > 7.5mg/dl) or hyperphosphatemia

CLINICAL CRITERIA FOR RENEWAL

- May not be renewed

ELMIRON® (PENTOSAN POLYSULFATE SODIUM)

Length of Authorization:	6 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **interstitial cystitis**

- Patient has bladder pain or discomfort; **AND**
- Patient is 16 years of age or older; **AND**
- Must have tried and failed nonpharmacological interventions: Examples include:
  - Application of heat or cold over the bladder or perineum
  - Avoidance of food or beverages that may exacerbate symptoms
    - Caffeine, alcohol, artificial sweeteners, hot peppers
  - Bladder training

CLINICAL CRITERIA FOR RENEWAL

- The patient has benefited from therapy (e.g., decreased bladder pain, decreased frequency or urgency of urination); **AND**
- The patient's condition has not progressed or worsened while on therapy; **AND**
- The patient has not developed any contraindications or other exclusions to continued use of the medication.

ELOXATIN® (OXALIPLATIN)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of **colorectal cancer**
- Diagnosis of **bladder cancer** (non-urothelial and urothelial adenocarcinoma)
- Diagnosis of **chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)**
- Diagnosis of **esophageal and esophagogastric junction center (adenocarcinoma, squamous cell carcinoma)**
- Diagnosis of **gastric adenocarcinoma**
- Diagnosis of **classical Hodgkin lymphoma (cHL)**
- Diagnosis of **non-Hodgkin lymphoma**
  - B-cell lymphomas
    - AIDS-related diffuse large B-cell (DLBCL), primary effusion lymphoma, and HHV8-positive DLBCL not otherwise specified
    - Diffuse large B-cell (including histological transformation of marginal zone lymphoma to DLBCL)
    - Follicular lymphoma (grade 1-2)
    - Mantle cell lymphoma
    - Post-transplant lymphoproliferative disorders (monomorphic)
    - High-grade B-cell lymphoma
  - T-cell lymphomas
    - Adult T-cell leukemia/lymphoma
    - Extranodal NK/T-cell lymphoma, nasal type
    - Peripheral T-cell lymphoma (includes all of the following: anaplastic large cell lymphoma, peripheral T-cell lymphoma not otherwise specified, angioimmunoblastic T-cell lymphoma, enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma with TFH phenotype, or follicular T-cell lymphoma)
    - Hepatosplenic gamma-delta T-cell lymphoma
    - Breast Implant- Associated ALCL
- Diagnosis of **ovarian cancer**
  - Fallopian tube, primary peritoneal, epithelial cancer
  - Mucinous carcinoma
- Diagnosis of **occult primary**
- Diagnosis of **pancreatic adenocarcinoma**
- Diagnosis of **testicular cancer**
- Diagnosis of **hepatobiliary cancer**
  - Intrahepatic cholangiocarcinoma (adenocarcinoma)
  - Extrahepatic cholangiocarcinoma (adenocarcinoma)
  - Gallbladder cancer (adenocarcinoma)
- Diagnosis of **neuroendocrine tumors and adrenal tumors**
  - Neuroendocrine tumors of the pancreas
  - Poorly differentiated (high grade)/large or small cell
  - Gastrointestinal tract-carcinoid syndrome
- Diagnosis of **anal squamous cell carcinoma**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Diagnosis of **primary cutaneous lymphoma**
  - Mycosis fungoides/Sézary syndrome
  - Primary cutaneous CD30+ T-cell lymphoproliferative disorder
- Diagnosis of **small bowel adenocarcinoma**

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity [including anaphylactic/anaphylactoid reactions], severe neutropenia, sensory neuropathy, reversible posterior leukoencephalopathy syndrome [RPLS], pulmonary toxicity, hepatotoxicity, cardiovascular toxicity [QT prolongation and ventricular arrhythmias], rhabdomyolysis)

ELZONRIS® (TAGRAXOFUSP-ERZS)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)**

- Patient is at least 2 years of age or older; **AND**
- Patient has CD-123 positive/expressing disease; **AND**
- Patient has a baseline serum albumin level of at least 3.2 g/dL; **AND**
- Patient does not have significant cardiovascular disease (e.g., uncontrolled or any NYHA Class 3 or 4 congestive heart failure, uncontrolled angina, history of myocardial infarction or stroke within 6 months of study entry, uncontrolled hypertension or clinically significant arrhythmias not controlled by medication, baseline left ventricular ejection fraction < 40%); **AND**
- Patient does not have active or suspected CNS leukemia; **AND**
- Must be used as a single agent; **AND**
- Patient must have a definitive diagnosis of BPDCN in the peripheral blood, bone marrow, spleen, lymph nodes, skin, and/or other sites; **AND**
  - Used as induction therapy in treatment-naïve patients who are candidates for intensive remission therapy; **OR**
  - Used as treatment until progression if a complete response (CR) was achieved after induction; **OR**
  - Used as treatment for relapsed/refractory disease if not already used

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., capillary leak syndrome, severe hypersensitivity reactions, severe hepatotoxicity); **AND**
- Disease stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular complete response) or clinical complete response [CRc] (i.e., complete response with residual skin abnormality not indicative of active disease)

EMFLAZA® (DEFLAZACORT)

Length of Authorization:	6 months
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient must have documentation of a confirmed diagnosis of Duchenne muscular dystrophy (DMD); **AND**
- Age ≥ 5 years; **AND**
- Patient retains meaningful voluntary motor function (e.g., patient is able to speak, manipulate objects using upper extremities, ambulate, etc.); **AND**
- Patient should be receiving physical therapy; **AND**
- Patient has experienced one of the following unacceptable adverse reactions directly attributable to previous therapy with prednisone:
  - Patient has manifested significant behavioral changes negatively impacting function at school, home, day care, etc.; **OR**
  - Patient has experienced significant weight gain (i.e., crossing two percentiles and/or reaching 98th percentile for age and sex).

CLINICAL CRITERIA FOR RENEWAL

- Patient retains meaningful voluntary motor function (e.g., patient is able to speak, manipulate objects using upper extremities, ambulate, etc.); **AND**
- Patient continues to receive physical therapy; **AND**
- Patient has received benefit from therapy, which may include one or more of the following:
  - Stability or slowing of decline in motor function
  - Stability or slowing of decline in respiratory function
  - Stability or slowing of decline in sequelae related to diminished strength of stabilizing musculature (e.g., scoliosis, etc.)
  - Quality of life

EMPAVELI™ (PEGCETACOPLAN)

Length of Authorization:	1 year, may be renewed
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Paroxysmal Nocturnal Hemoglobinuria (PNH)**

- Patient is at least 18 years of age; **AND**
- Patients must be vaccinated against encapsulated bacteria (e.g., *Streptococcus pneumoniae, Neisseria meningitidis, Haemophilus influenzae type B*, etc.) at least two weeks prior to initiation of therapy and revaccinated according to current medical guidelines for vaccine use *(If urgent Empaveli therapy is indicated in an unvaccinated patient, administer vaccine(s) as soon as possible and provide patients with two weeks of antibacterial drug prophylaxis)*; **AND**
- Prescriber is enrolled in the Empaveli Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
- Patient does not have an unresolved, serious systemic infection from encapsulated bacteria (e.g., *Streptococcus pneumoniae, Neisseria meningitidis, Haemophilus influenzae type B*, etc.); **AND**
- Will not be used in combination with another complement-inhibitor therapy (e.g., eculizumab, ravulizumab) [**Note**: a 4-week run-in period is allowed when transitioning from eculizumab to pegcetacoplan]; **AND**
- Used as switch therapy; **AND**
  - Patient is currently receiving treatment with Soliris or Ultomiris and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy; **OR**
- Patient is complement inhibitor treatment-naïve; **AND**
  - Diagnosis must be accompanied by detection of PNH clones of at least 10% by flow cytometry diagnostic testing; **AND**
    - Demonstrates the presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) within at least 2 different cell lines (e.g., granulocytes, monocytes, erythrocytes); **AND**
  - Patient has laboratory evidence of significant intravascular hemolysis (i.e., LDH ≥ 1.5 x ULN) and at least one other indication for therapy from the following:
    - Presence of a thrombotic event
    - Presence of organ damage secondary to chronic hemolysis (i.e., renal insufficiency, pulmonary insufficiency, or hypertension)
    - Patient is pregnant and potential benefit outweighs potential fetal risk
    - Patient has symptomatic anemia (regardless of transfusion dependence)
    - Patient has disabling fatigue
    - Patient has abdominal pain requiring admission or opioid analgesia; **AND**
  - Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH), hemoglobin level, packed RBC transfusion requirement, history of thrombotic events

Note: All patients must initiate therapy at the lowest starting dosing/frequency (e.g., twice weekly infusions), for dose escalation requests (e.g., every 3 days)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: serious encapsulated bacterial infections, severe infusion reactions, etc.; **AND**
  - Patient has shown a beneficial disease response compared to pre-PNH treatment baseline as indicated by one or more of the following:
    - Decrease in serum LDH
    - Stabilization/increase in hemoglobin level
    - Decrease in packed RBC transfusion requirement
    - Reduction in thromboembolic events; **OR**
- Dose escalation (up to the maximum dose and frequency specified below) may occur upon clinical review on a case by case basis provided that the patient has:
  - Shown an initial response to therapy; **AND**
  - Received initial dose **and** interval for at least 4 weeks; **AND**
  - Patient lactate dehydrogenase (LDH) levels are greater than 2x the upper limit of normal (ULN) despite initial treatment

Switch therapy from Soliris or Ultomiris to Empaveli

Refer to initial criteria

EMPLICITI® (ELOTUZUMAB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma:**

- Patient is at least 18 years of age; **AND**
- Used in combination with lenalidomide and dexamethasone after failure of one to three prior therapies; **OR**
  - Used in combination with pomalidomide and dexamethasone after failure of at least two prior therapies, including immunomodulatory agent (e.g., lenalidomide, pomalidomide, etc.) and a proteasome inhibitor (e.g., bortezomib, carfilzomib, etc.); **OR**
  - Used in combination with bortezomib and dexamethasone for the treatment of relapsed or progressive disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe infusion reactions, infections, second primary malignancies, hepatotoxicity)

EMVERM® (MEBENDAZOLE)

Length of Authorization:	1 or 3 days
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

Must be used for:

- Treatment of pinworm (*Enterobius vermicularis*), whipworm (*Trichuris trichiura*), common roundworm (*Ascaris lumbricoides*), common hookworm (*Ancylostoma duodenale*), and American hookworm (*Necator americanus*), as single or mixed infections

QUANTITY LIMIT AND APPROVAL LENGTH

- Common roundworm, Hookworm, and Whipworm: 1 tablet morning and evening for 3 consecutive days; approve x 3 days [6 tabs, 3 days]
- Pinworm: 1 tablet, single dose; approve x 1 day [1 tab, 1 day]

ENDARI® (L-GLUTAMINE)

Length of Authorization:	1 year
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of sickle cell disease; **AND**
- Patient is over ≥ 5; **AND**
- Patient is not pregnant or lactating

CLINICAL CRITERIA FOR RENEWAL

- The patient continued to meet initial criteria; **AND**
- The patient has had disease improvement with the medication

ENHERTU® (FAM-TRASTUZUMAB DERUXTECAN-NXKI)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**

- Patient at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2) positive disease; **AND**
- Used as single agent therapy; **AND**
- Therapy will not be substituted with or for any trastuzumab-based formulation (e.g., trastuzumab [or trastuzumab biosimilar product], ado-trastuzumab emtansine, trastuzumab-hyaluronidase, pertuzumab/trastuzumab and hyaluronidase-zzxf, etc.); **AND**
- Patient has recurrent, unresectable or metastatic disease; **AND**
- Patient has previously been treated with at least 2 prior HER2-targeted therapies for metastatic disease

Diagnosis of **Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma**

- Patient at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2) positive disease; **AND**
- Used as single agent therapy; **AND**
- Therapy will not be substituted with or for any trastuzumab-based formulation (e.g., trastuzumab [or trastuzumab biosimilar product], ado-trastuzumab emtansine, trastuzumab-hyaluronidase, pertuzumab/trastuzumab and hyaluronidase-zzxf, etc.); **AND**
- Patient has locally advanced or metastatic disease; **AND**
- Patient has previously been treated with a trastuzumab-based regimen

Diagnosis of **Colorectal Adenocarcinoma**

- Patient at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2) positive disease; **AND**
- Used as single agent therapy; **AND**
- Therapy will not be substituted with or for any trastuzumab-based formulation (e.g., trastuzumab [or trastuzumab biosimilar product], ado-trastuzumab emtansine, trastuzumab-hyaluronidase, pertuzumab/trastuzumab and hyaluronidase-zzxf, etc.); **AND**
- Patient has RAS and BRAF wild-type (WT) disease; **AND**
  - Used as subsequent therapy for progression of advanced or metastatic disease after at least one prior line of treatment in the advanced or metastatic disease setting; **OR**
  - Patient is not appropriate for intensive therapy; **AND**
    - Used as initial systemic therapy for locally unresectable (or medically inoperable) or metastatic disease; **OR**
    - Used for unresectable or metastatic disease that remains unresectable after primary treatment; **OR**
    - Used for metastatic disease in patients who have received adjuvant FOLFOX or CapeOX more than 12 months ago OR who have received previous fluorouracil/leucovorin (5-FU/LV) or capecitabine therapy

CLINICAL CRITERIA FOR INITIAL APPROVAL (CONTINUED)

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2) positive disease; **AND**
- Used as single agent therapy; **AND**
- Therapy will not be substituted with or for any trastuzumab-based formulation (e.g., trastuzumab [or trastuzumab biosimilar product], ado-trastuzumab emtansine, trastuzumab-hyaluronidase, pertuzumab/trastuzumab and hyaluronidase-zzxf, etc.); **AND**
- Patient has metastatic disease with activity against HER2 mutations

***HER2-positive overexpression criteria:**
• Immunohistochemistry (IHC) assay 3+; **OR** • Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number ≥ 4.0 signals/cell; **OR** • Dual-probe in situ hybridization (ISH) assay **and** concurrent IHC indicating one of the following: – HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number < 4.0 signals/cell **and** concurrent IHC 3+; **OR** – HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 6.0 signals/cell **and** concurrent IHC 2+ or 3+; **OR** – HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 4.0 and < 6.0 signals/cell **and** concurrent IHC 3+

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., left ventricular dysfunction/symptomatic congestive heart failure, pulmonary toxicity [i.e., interstitial lung disease/pneumonitis], neutropenia/febrile neutropenia); **AND**
  - LVEF is > 45% and **absolute** decrease is ≤ 20% from baseline (LVEF results must be within the previous 3 months); **OR**
  - LVEF is 40% to 45% and **absolute** decrease is < 10% from baseline (LVEF results must be within the previous 3 months)

ENSPRYNG (SATRALIZUMAB-MWGE)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Neuromyelitis Optica Spectrum Disorder (NMOSD)**

- Patient must be 18 years of age or older; **AND**
- Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment and confirmed negative for active HBV; **AND**
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Live or live-attenuated vaccinations will not be administered within the 4-weeks prior to the start of therapy and will not be administered concurrently while on treatment; **AND**
- Patient is not on concomitant therapy with and does not have hypersensitivity to other interleukin-6 (IL-6) receptor antagonists (e.g., tocilizumab, sarilumab, etc.); **AND**
- Patient has not previously received, and will not concomitantly receive, therapy with any of the following:
  - Other drugs which can result in prolonged additive immunosuppression (e.g., alemtuzumab, cladribine, cyclophosphamide, or mitoxantrone) *[Note: concomitant therapy with corticosteroids and/or immunosuppressants such as azathioprine or mycophenolate are allowed];* **AND**
  - Other immunosuppressant procedures (i.e., total body irradiation, bone marrow transplant); **AND**
- Patient has not received therapy within the prior 6 months with any of the following:
  - Anti-BLyS monoclonal antibody (e.g., belimumab); **AND**
  - Therapies for prevention of multiple sclerosis (MS) relapse (e.g., interferon, natalizumab, glatiramer acetate, fingolimod, teriflunomide or dimethyl fumarate); **AND**
- Patient will not concomitantly receive therapy with any of the following:
  - Complement-inhibitors (e.g., eculizumab, ravulizumab); **AND**
  - Anti-CD20-directed antibody (e.g., rituximab); **AND**
  - Anti-CD19-directed antibody (e.g., inebilizumab); **AND**
- Patient has a confirmed diagnosis based on the following:
  - Patient was found to be seropositive for aquaporin-4 (AQP4) IgG antibodies; **AND**
  - Patient has at least one core clinical characteristic §; **AND**
  - Alternative diagnoses have been excluded (e.g., multiple sclerosis, sarcoidosis, cancer, chronic infection, etc.); **AND**
- Patient has a history of one or more relapses that required rescue therapy within the prior year or two or more relapses that required rescue therapy within the prior 2 years; **AND**
- Patient has an Expanded Disability Status Score (EDSS) of ≤ 6.5 (i.e., requires two walking aids—pair of canes, crutches, etc.—to walk about 20 m without resting); **AND**
- Patient is at risk of having a disabling relapse of NMOSD for which oral agents (e.g., corticosteroids and immunosuppressants such as azathioprine and mycophenolate) alone are inadequate and biologic therapy is necessary

§ Core Clinical Characteristics of NMOSD
• Optic neuritis • Acute myelitis • Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting • Acute brainstem syndrome • Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions • Symptomatic cerebral syndrome with NMOSD-typical brain lesions

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions, serious infections, elevated liver enzymes, severe neutropenia, etc.; **AND**
- Disease response as indicated by stabilization/improvement in one or more of the following:
  - Neurologic symptoms as evidenced by a decrease in acute relapses, stability, or improvement in EDSS
  - Reduced hospitalizations
  - Reduction/discontinuation in plasma exchange treatments
  - Reduction/discontinuation of corticosteroids without relapse

ENTEREG (ALVIMOPAN)

Length of Authorization:	7 days
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient must be 18 years of age or older; **AND**
- Patient must be hospitalized; **AND**
- Patient must have undergone a partial bowel resection surgery with primary anastomosis; **AND**
- Hospital must be registered in and meet all of the requirements for the Entereg Access Support and Education (E.A.S.E.) REMS program

Contraindications: Patients who have taken therapeutic doses of opioids for more than 7 consecutive days immediately prior to taking Entereg

CLINICAL CRITERIA FOR RENEWAL

N/A

ENTYVIO® (VEDOLIZUMAB)

Length of Authorization:	14 weeks initially and then may be renewed every 6 months thereafter Immune Checkpoint Inhibitor related diarrhea/colitis: 3 doses and may not be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Crohn's Disease**

- Patient is 18 years or older; **AND**
- Patient is up to date with all vaccinations, in accordance with current immunization guidelines, prior to initiating therapy; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Must be prescribed by or in consultation with a specialist in gastroenterology; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier, or other non-biologic agent (e.g., apremilast, tofacitinib, baricitinib, upadacitinib); **AND**
- Documented moderate to severe active disease; **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate); **AND**
- Trial and failure, contraindication, or intolerance to **two** of the following preferred products, or attestation demonstrating that a trial may be inappropriate*:
  - Cimzia® (certolizumab pegol)
  - Humira® (adalimumab)
  - Stelara® (ustekinumab); **OR**
- For continuation of prior Entyvio therapy

Notes: *Includes attestation that the patient has failed to respond to the TNF inhibitor mechanism of action in the past and should not be made to try a second TNF inhibitor. In this case, only a single step through a preferred agent is required.

CLINICAL CRITERIA FOR INITIAL APPROVAL (CONTINUED)

Diagnosis of **Ulcerative Colitis**

- Patient is 18 years or older; **AND**
- Patient is up to date with all vaccinations, in accordance with current immunization guidelines, prior to initiating therapy; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Must be prescribed by, or in consultation with a specialist in gastroenterology; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier, or other non-biologic agent (e.g., apremilast, tofacitinib, baricitinib, upadacitinib); **AND**
- Documented moderate to severe active disease; **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial on previous therapy with corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate); **AND**
- Trial and failure, contraindication, or intolerance to **two** of the following, or attestation demonstrating that a trial may be inappropriate*:
  - Humira® (adalimumab)
  - Simponi® (golimumab)
  - Stelara® (ustekinumab); **OR**
- For continuation of prior Entyvio® therapy

Notes: *Includes attestation that the patient has failed to respond to the TNF inhibitor mechanism of action in the past and should not be made to try a second TNF inhibitor. In this case, only a single step through a preferred agent is required.

Diagnosis of **Management of Immune Checkpoint Inhibitor-Related Diarrhea/Colitis**

- Patient is 18 years or older; **AND**
- Patient is up to date with all vaccinations, in accordance with current immunization guidelines, prior to initiating therapy; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Must be prescribed by, or in consultation with a specialist in gastroenterology; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier, or other non-biologic agent (e.g., apremilast, tofacitinib, baricitinib, upadacitinib); **AND**
- Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab); **AND**
- Patient has moderate (grade 2) to severe (grade 3-4) diarrhea or colitis related to their immunotherapy;

CLINICAL CRITERIA FOR RENEWAL

- Patient is receiving ongoing monitoring for presence of TB or other active infections; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: anaphylaxis or other serious allergic, severe infusion-related or hypersensitivity reactions, severe infections, progressive multifocal leukoencephalopathy (PML), jaundice or other evidence of significant liver injury, etc.; **AND**
- For Crohn's Disease:
  - Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extraintestinal complications, use of anti-diarrheal drugs, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score].
- For Ulcerative colitis:
  - Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, normalization of C-reactive protein (CRP) or fecal calprotectin (FC), and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score or the Mayo Score.
- Management of immune checkpoint inhibitor related diarrhea/colitis
  - May not be renewed

ENVARSUS XR® (TACROLIMUS)

Length of Authorization:	1 year
Initiative:	SPC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

Patient must have a trial and failure of tacrolimus

ERBITUX® (CETUXIMAB)

Length of Authorization:	6 months, may be renewed unless otherwise specified **SCCHN in combination with radiation therapy**: Coverage will be provided for the duration of radiation therapy (6-7 weeks)
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Colorectal Cancer (CRC):**

- Patient is at least 18 years of age; **AND**
- Patient is both KRAS/NRAS mutation negative (wild-type) as determined by any FDA or CLIA-compliant test FDA-approved tests; **AND**
- Will not be used as part of an adjuvant treatment regimen; **AND**
- Patient has not been previously treated with cetuximab or panitumumab; **AND**
  - Patient has metastatic, unresectable (or medically inoperable), or advanced disease that is BRAF mutation negative (wild-type); **AND**
    - Used as primary treatment; **AND**
      - Used in combination with FOLFIRI; **OR**
      - Used in combination with FOLFOX *(Note: Colon cancer patients must have left sided tumors*); **OR**
      - Used in combination with irinotecan after previous adjuvant FOLFOX or CapeOX within the past 12 months; **OR**
    - Used as subsequent therapy; **AND**
      - Used in combination with irinotecan for oxaliplatin- and/or irinotecan-refractory disease; **OR**
      - Used in combination with FOLFIRI for oxaliplatin-refractory disease; **OR**
      - Used in combination with FOLFOX for irinotecan-refractory disease; **OR**
      - Used as a single agent for oxaliplatin- and irinotecan-refractory disease OR irinotecan-intolerant disease; **OR**
  - Patient has BRAF V600E mutation positive disease; **AND**
    - Used in combination with encorafenib; **AND**
      - Used as subsequent therapy for disease progression after at least one prior line of treatment in the advanced or metastatic disease setting; **OR**
      - Used as primary treatment for unresectable metastatic disease after previous adjuvant FOLFOX or CapeOX within the past 12 months

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Squamous Cell Carcinoma of the Head and Neck (SCCHN):**

- Patient is at least 18 years of age; **AND**
- Used in one of the following regimens:
  - In combination with radiation therapy for first-line treatment of regionally or locally advanced disease; **OR**
  - As a single agent for recurrent or metastatic disease after failure on platinum-based therapy; **OR**
  - In combination with platinum-based therapy for first-line treatment of recurrent, loco-regional, or metastatic disease; **AND**
- Patient has one of the following sub-types of SCCHN:
  - Cancer of the glottic larynx
  - Cancer of the hypopharynx
    - Cetuximab may also be used as a single agent as sequential systemic therapy/radiation after induction chemotherapy for T4a, N0-3 disease
  - Cancer of the lip (mucosa)
  - Cancer of the nasopharynx
  - Cancer of the oral cavity
  - Cancer of the oropharynx
    - Cetuximab may also be used as a single agent as sequential systemic therapy/radiation after induction chemotherapy
  - Cancer of the supraglottic larynx
  - Ethmoid sinus tumors
    - Cetuximab may also be used as a single agent as sequential systemic therapy/radiation after a complete response to primary systemic therapy
  - Maxillary sinus tumors
  - Very advanced head and neck cancer (i.e., newly diagnosed locally advanced T4b [M0] disease, newly diagnosed unresectable nodal disease, metastatic disease at initial presentation [M1], recurrent or persistent disease, or patients unfit for surgery)
    - Cetuximab may also be used as one of the following:
      - First-line therapy or subsequent therapy as a single agent for non-nasopharyngeal cancer
      - Subsequent therapy in combination with platinum-based therapy for non-nasopharyngeal cancer *(except for locoregional recurrence without prior radiation therapy*)
      - Sequential systemic therapy/radiation in patients with non-nasopharyngeal cancer as a single agent following induction therapy or combination systemic therapy for recurrent disease
      - Subsequent therapy in combination with carboplatin for nasopharyngeal cancer

Diagnosis of **Occult Primary Head and Neck Cancers**

- Patient is at least 18 years of age; **AND**
- Used as initial treatment as a single agent as sequential systemic therapy/radiation following induction chemotherapy

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Squamous Cell Skin Cancer**

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
  - Patient is ineligible for or progressed on immune checkpoint inhibitor therapy and clinical trials; **AND**
    - Patient has locally advanced, high-risk, or very high-risk disease; **AND**
      - Curative surgery and curative radiation therapy are not feasible; **AND**
        - Used as primary systemic therapy for non-surgical candidates; **OR**
        - Used as post-operative systemic therapy if residual disease is present and further surgery is not feasible; **OR**
    - Patient has inoperable or not fully resectable new regional disease and curative radiation therapy is not feasible; **OR**
    - Used for regional recurrence or distant metastases; **OR**
- Used as a single agent in combination with radiation therapy; **AND**
  - Patient has locally advanced, high-risk, or very high-risk disease; **AND**
    - Used as primary systemic therapy for non-surgical candidates; **OR**
    - Used as post-operative systemic therapy if residual disease is present and further surgery is not feasible; **OR**
  - Patient has new regional disease; **AND**
    - Patient has high-risk regional disease with pathologic extracapsular extension (ECE) or incompletely excised nodal disease; **OR**
    - Patient has inoperable or not fully resectable disease; **OR**
  - Used for regional recurrence or distant metastases

Diagnosis of **Penile Cancer**

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Used as subsequent therapy for metastatic disease

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years of age; **AND**
- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Used in combination with afatinib (Gilotrif); **AND**
- Used as subsequent therapy for EGFR mutation-positive tumors (e.g., exon 19 deletion or L858R); **AND**
- Patient has progressed on EGFR tyrosine kinase inhibitor therapy (e.g., erlotinib, afatinib, gefitinib, dacomitinib, osimertinib); **AND**
  - Patient has asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited metastases; **OR**
  - Patient has multiple symptomatic systemic lesions; **AND**
    - Patient is T790M negative; **OR**
    - Patient is T790M positive and has progressed on osimertinib therapy

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., anaphylactic reactions, severe infusion reactions, cardiopulmonary arrest, pulmonary toxicity/interstitial lung disease, dermatologic toxicity, hypomagnesemia/electrolyte abnormalities)

ERECTILE DYSFUNCTION AGENTS

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Category A Drugs: PA required (IE 2462 / NCPDP 75)

CIALIS AND TADALAFIL

Verify CRM sexual dysfunction category and drug coverage comments for information on coverage

- Diagnosis of erectile dysfunction (**ED**)
  - If the plan excludes coverage of sexual dysfunction, admin deny for a diagnosis of ED
  - If the plan includes coverage of sexual dysfunction, approve for a diagnosis of ED
- Diagnosis of benign prostatic hyperplasia (**BPH**) or **ED/BPH**
  - If Cialis/tadalafil 2.5 mg or 5 mg is being prescribed for daily use for symptomatic BPH, approve even if the plan has sexual dysfunction as an exclusion

SILDENAFIL ORAL TABLETS 20 MG

- Not approvable for erectile dysfunction, only for pulmonary hypertension, please see Pulmonary Hypertension section

NON-ORAL ED DRUGS: ALPROSTADIL (MUSE, CAVERJECT, EDEX)

- Trial and failure or intolerant to oral PDE-5 inhibitors; **AND**
- Must not have conditions that might predispose them to priapism (i.e., sickle cell anemia or trait, multiple myeloma, or leukemia); **OR**
- Not to be used in patients with anatomical deformation of the penis (i.e., angulation, cavernosal fibrosis, or Peyronie's disease; **OR**
- Not to be used in patients with penile implants

PRECISION FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Category A Drugs: PA required (IE 2462 / NCPDP 75 – HICL)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

TADALAFIL

Verify CRM sexual dysfunction category and drug coverage comments for information on coverage

- Diagnosis of erectile dysfunction (**ED**)
  - If the plan excludes coverage of sexual dysfunction, admin deny for a diagnosis of ED
  - If the plan includes coverage of sexual dysfunction, approve for a diagnosis of ED
- Diagnosis of benign prostatic hyperplasia (**BPH**) or **ED/BPH**
  - If Cialis/tadalafil 2.5 mg or 5 mg is being prescribed for daily use for symptomatic BPH, approve even if the plan has sexual dysfunction as an exclusion

PRECISION FORMULARY CRITERIA (CONTINUED)

SILDENAFIL ORAL TABLETS 20 MG

- Diagnosis of pulmonary hypertension; only for pulmonary hypertension, please see Pulmonary Hypertension section

NON-ORAL ED DRUGS: ALPROSTADIL (MUSE, CAVERJECT, EDEX)

- Trial and failure or intolerant to oral PDE-5 inhibitors; **AND**
- Must not have conditions that might predispose them to priapism (i.e., sickle cell anemia or trait, multiple myeloma, or leukemia); **OR**
- Not to be used in patients with anatomical deformation of the penis (i.e., angulation, cavernosal fibrosis, or Peyronie's disease; **OR**
- Not to be used in patients with penile implants

ERIVEDGE® (VISMODEGIB)

Length of Authorization:	6 months, eligible for renewal
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Basal Cell Carcinoma**

- Patient is at least 18 years or older; **AND**
- Negative pregnancy test for women of child-bearing potential within the preceding 7 days *(Note: Females of reproductive potential should use effective contraception during and for at least 24 months after the last dose and males of reproductive potential should also do so during and for at least 3 months after the last dose)*; **AND**
- Used as a single agent; **AND**
- Patient has nodal or metastatic disease; **OR**
- Patient has locally advanced disease; **AND**
  - Disease has recurred following surgery or radiation therapy; **OR**
  - Patient is not a candidate for surgery and radiation therapy; **OR**
- Patient has diffuse basal cell carcinoma (BCC) formation (e.g., Gorlin syndrome, other genetic forms of multiple BCC)

Diagnosis of **CNS Cancer – Medulloblastoma**

- Patient is at least 18 years or older; **AND**
- Negative pregnancy test for women of child-bearing potential within the preceding 7 days *(Note: Females of reproductive potential should use effective contraception during and for at least 24 months after the last dose and males of reproductive potential should also do so during and for at least 3 months after the last dose)*; **AND**
- Used as a single agent; **AND**
- Patient has recurrent disease; **AND**
- Patient has received prior chemotherapy; **AND**
- Patient has mutations in the sonic hedgehog pathway

CLINICAL CRITERIA FOR RENEWAL

- Disease response as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe cutaneous adverse reactions (SCARs) (including Stevens-Johnson syndrome [SJS], toxic epidermal necrolysis [TEN), drug reaction with eosinophilia and systemic symptoms [DRESS]), premature fusion of the epiphyses, etc.

ERLEADA® (APALUTAMIDE)

Length of Authorization:	6 months, eligible for renewal
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Prostate Cancer**

- Patient is at least 18 years old; **AND**
- Patient will receive a GnRH-analog or has had a bilateral orchiectomy; **AND**
- Will not be used in combination with other androgen receptor inhibitors (e.g., enzalutamide, darolutamide); **AND**
  - Patient has **non-metastatic** castration-resistant prostate cancer (NM-CRPC); **OR**
  - Patient has metastatic castration-sensitive prostate cancer (M-CSPC)

For Standard, Precision, Enhanced, and Core Formularies (NO GRANDFATHERING):

For patients with non-metastatic castration-resistant prostate cancer (NM-CRPC), in addition to the above criteria:

- Patient has a documented failure (minimum three-month trial), contraindication or intolerance to Nubeqa

For patients with metastatic castration-sensitive prostate cancer (M-CSPC), in addition to the above criteria:

- Patient has a documented failure (minimum three-month trial), contraindication or intolerance to abiraterone

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include seizures, excessive falls and/or fractures, signs and symptoms of ischemic heart disease or cerebrovascular disorders, etc.

ERWINAZE (ASPARAGINASE ERWINIA CHRYSANTHEMI)

Length of Authorization:	6 months, eligible for renewal
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Acute lymphoblastic leukemia (ALL)**

- Patient is 1 year or older; **AND**
- Patient must not have a history of serious pancreatitis, thrombosis, or hemorrhagic events with prior L-asparaginase therapy; **AND**
- Used as a component of multi-agent chemotherapy; **AND**
- Used as a substitute for pegaspargase or E. coli-derived asparaginase in cases of systemic allergic reaction or anaphylaxis; **OR**
- Used as induction therapy in patients ≥ 65 years of age OR who have substantial comorbidities; **AND**
  - Patient has Philadelphia chromosome (Ph)-negative ALL; **OR**
  - Patient has Philadelphia chromosome (Ph)-positive B-ALL; **AND**
    - Treatment regimen includes a tyrosine kinase inhibitor (i.e., bosutinib, dasatinib, imatinib, nilotinib, or ponatinib)

CLINICAL CRITERIA FOR RENEWAL

- Disease stabilization or improvement as evidenced by a complete response (CR) (i.e., morphologic, cytogenetic or molecular CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions (including anaphylaxis), glucose intolerance/hyperglycemia, pancreatitis, serious thrombotic or hemorrhagic events, etc.

ESTROGEN AGENTS

Length of Authorization:	1 year
Initiative:	MNC: Miscellaneous: PA required (IE 2462 / NCPDP 75, 50081 and 2193)

STEP CRITERIA (NO GRANDFATHERING)

FEMRING

The patient has failed a trial of TWO of the following: Osphena, Premarin Vaginal Cream, or Imvexxy

ALORA, MENOSTAR, MINIVELLE, VIVELLE-DOT

The patient has failed a trial of a generic estradiol patch or Dotti

EVENITY® (ROMOSOZUMAB-AQQA)

Length of Authorization:	1 year, may not be renewed
Initiative:	SPC: Osteoporosis Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Osteoporosis in Women**

- Patient is at least 18 years of age; **AND**
- Confirmation patient is receiving calcium and vitamin D supplementation if dietary intake is inadequate; **AND**
- Patient must not have hypocalcemia; **AND**
- Patient has not had a myocardial infarction or stroke within the preceding year (**Note:** in patients with other cardiovascular disease and/or risk factors, consider whether benefits of therapy outweigh the risks.); **AND**
- Patient must be at a high risk for fracture[1]; **AND**
- Patient must be post-menopausal; **AND**
- Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
  - Hip/femur DXA (femoral neck or total hip) or lumbar spine T-score ≤ -2.5 and/or forearm DXA 33% (one-third) of the radius; **OR**
  - T-score ≤ -1 or low bone mass **and** a history of fragility fracture to the hip or spine; **OR**
  - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; **AND**
- **§** Documented treatment failure or ineffective response[2] to a minimum 12-month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; **OR**
  - Patient has a documented contraindication or intolerance to **both** oral bisphosphonates[3] **and** intravenous (IV) bisphosphonates[4] such as alendronate, risedronate, ibandronate, or zoledronic acid; **AND**
- **§** Documented treatment failure or ineffective response[2] to a minimum 12-month trial on previous therapy with *RANKL*-blocking agents such as denosumab, etc.; **OR**
  - Patient has a documented contraindication[5] or intolerance to *RANKL*-blocking agents such as denosumab, etc.; **AND**
  - **§** Patients with extremely low BMD (T < -3.5) or a T < -2.5 with a history of fragility fractures are not subject to prior trial and failure requirements with bisphosphonates and/or denosumab

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

[1] High risk for fractures include, but are not limited to, one or more of the following:
• History of an osteoporotic fracture as an adult • Parental history of hip fracture • Low BMI • Rheumatoid arthritis • Alcohol intake (3 or more drinks per day) • Current smoking • History of oral glucocorticoids ≥ 5 mg per day of prednisone (or equivalent) for > 3 months (ever)
[2] Ineffective response is defined as one or more of the following:
• Decrease in T-score in comparison with baseline T-score from DXA scan • Patient has a new fracture while on bisphosphonate therapy
[3] Examples of contraindications to oral bisphosphonate therapy include the following:
• Documented inability to sit or stand upright for at least 30 minutes • Documented pre-existing gastrointestinal disorder such as inability to swallow, Barrett's esophagus, esophageal stricture, dysmotility, or achalasia
[4] Examples of contraindications to injectable bisphosphonate therapy include the following:
• Documented pre-existing hypocalcemia and disturbances of mineral metabolism • Documented pre-existing renal insufficiency defined as creatinine clearance < 35 mL/min
[5] Examples of contraindications to *RANKL*-blocking therapy include the following:
• Documented pre-existing hypocalcemia and disturbances of mineral metabolism • Documented hypersensitivity to the active ingredient or its excipients

CLINICAL CRITERIA FOR RENEWAL

May not be renewed

EVKEEZA™ (EVINACUMAB-DGNB)

Length of Authorization:	3 Months initial, 12 months on renewal
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Homozygous familial hypercholesterolemia (HoFH)**

- Patient at least 12 years old; **AND**
- Baseline low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment (required for renewal); **AND**
- Patient does not have heterozygous familial hypercholesterolemia (HeFH); **AND**
- Must be prescribed by, or in consultation with, a specialist in cardiology, lipidology, or endocrinology; **AND**
- Patient has a confirmed diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) by any of the following:
  - Documented DNA test for functional mutation(s) in LDL receptor alleles or alleles known to affect LDL receptor functionality; **OR**
  - Untreated LDL-C > 500 mg/dL or treated LDL-C ≥ 300 mg/dL; **AND**
    - Cutaneous or tendon xanthoma before age 10 years; **OR**
    - Untreated LDL-C levels in both parents consistent with HeFH; **AND**
- Must be used as an adjunct to a low-fat or heart-healthy diet; **AND**
- Patient has been receiving stable background lipid lowering therapy for at least 4 weeks; **AND**
- Therapy will be used in conjunction with diet and other LDL-lowering therapies (e.g., statins, ezetimibe, PCSK9 inhibitors, lomitapide, LDL apheresis); **AND**
- Patient has tried and failed at least a 3-month trial of adherent therapy with ezetimibe used in combination with the highest available (or maximally tolerated*) dose of atorvastatin OR rosuvastatin, unless contraindicated; **AND**
- Patient has tried and failed at least a 3 month trial of adherent therapy with combination therapy consisting of the highest available (or maximally tolerated*) dose of atorvastatin OR rosuvastatin, ezetimibe, AND a PSCK9 inhibitor indicated for HoFH (e.g., evolocumab), unless contraindicated; **AND**
- Despite pharmacological treatment with a PCSK9 inhibitor, statin, and ezetimibe, the patient's LDL cholesterol ≥ 100 mg/dL (or ≥ 70 mg/dL for patients with clinical atherosclerotic cardiovascular disease [ASCVD])

***** If the patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms.

- Documentation must demonstrate that the patient experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following:
  - Muscle symptoms resolve after discontinuation of statin; **AND**
  - Muscle symptoms occurred when re-challenged at a lower dose of the same statin; **AND**
  - Muscle symptoms occurred after switching to an alternative statin; **AND**
  - Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease); **OR**
- The patient has been diagnosed with rhabdomyolysis associated with statin use
  - The diagnosis should be supported by acute neuromuscular illness or dark urine **AND** an acute elevation in creatine kinase (usually > 5,000 IU/L or 5 times the upper limit of normal [ULN])

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from therapy. Examples of unacceptable toxicity include the following: severe hypersensitivity, etc.; **AND**
- Patient has had a reduction in LDL-C when compared to the initial baseline labs; **AND**
- Patient continues to adhere to diet and background lipid lowering therapy (e.g., statin, ezetimibe, PCSK9-I, lomitapide, LDL apheresis)

EVOMELA® (MELPHALAN)

Length of Authorization:	Conditioning treatment: 6 Months, may not be renewed All other indications: 6 months and may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma**

- Patient is at least 18 years of age; **AND**
- Patient does not have a history of serious allergic reactions to melphalan; **AND**
- Patient must have had an intolerance to melphalan or Alkeran® IV prior to consideration of Evomela®; **AND**
- Used as high dose myeloablative conditioning treatment; **AND**
  - Patient will receive an autologous stem cell transplant (ASCT); **OR**
- Used as primary therapy for symptomatic disease in non-transplant candidates; **AND**
  - Used in combination with daratumumab, bortezomib, and prednisone; **AND**
  - Patient is unable to tolerate oral melphalan therapy; **OR**
- Used for the management of POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome; **AND**
  - Used in combination with dexamethasone; **AND**
  - Patient is unable to tolerate oral melphalan therapy; **AND**
  - Patient is transplant ineligible OR used as induction therapy if transplant eligible

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe gastrointestinal toxicity (e.g., nausea, vomiting, diarrhea, mucositis), severe hepatotoxicity, severe bone marrow suppression, hypersensitivity reactions, secondary malignancies (e.g., myeloproliferative syndrome, acute leukemia), etc.; **AND**

Conditioning Treatment

- Coverage cannot be renewed

All other Indications

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread

EVRYSDI® (RISDIPLAM)

Length of Authorization:	1 year, eligible for renewal
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Spinal Muscular Atrophy (SMA)**

- Patient is 2 months of age or older; **AND**
- Patient must not have previously received treatment with SMA gene therapy (e.g., onasemnogene abeparvovec-xioi); **AND**
- Patient will not use in combination with other agents for SMA (e.g., onasemnogene abeparvovec, nusinersen, etc.); **AND**
- Patient does NOT require invasive ventilation or have a tracheostomy; **AND**
- Patient retains meaningful voluntary motor function (e.g., manipulate objects using upper extremities, ambulate, etc.); **AND**
- Patient must have a diagnosis of 5q spinal muscular atrophy confirmed by either homozygous deletion of the *SMN1* gene or dysfunctional mutation of the *SMN1* gene; **AND**
- Patient must have one of the following SMA phenotypes:
  - SMA I confirmed by one of the following:
    - Patient must have 1–2 copies of the *SMN2* gene; **OR**
    - Patient has 3 copies of the *SMN2* gene in the absence of the c.859G>C single base substitution modification in exon 7; **OR**
  - SMA II with symptomatic disease (i.e., impaired motor function and/or delayed motor milestones); **OR**
  - SMA III with symptomatic disease (i.e., impaired motor function and/or delayed motor milestones); **AND**
- Baseline documentation of one or more of the following:
  - Motor function/milestones, including the following validated scales: Hammersmith Infant Neurologic Exam (HINE), Hammersmith Functional Motor Scale Expanded (HFMSE), Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), Bayley Scales of Infant and Toddler development Third Ed. (BSID-III), 6-minute walk test (6MWT), upper limb module (ULM), etc.
  - Respiratory function tests (e.g., forced vital capacity [FVC], etc.)
  - Exacerbations necessitating hospitalization and/or antibiotic therapy for respiratory infection in the preceding year/timeframe
  - Patient weight (for patients without a gastrostomy tube)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity that would preclude safe administration of the drug. Examples of unacceptable toxicity include the following: severe diarrhea, etc.; **AND**
- Patient has responded to therapy compared to pretreatment baseline in one or more of the following:
  - Stability or improvement in net motor function/milestones, including but not limited to, the following validated scales: Hammersmith Infant Neurologic Exam (HINE), Hammersmith Functional Motor Scale Expanded (HFMSE), Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), Bayley Scales of Infant and Toddler development Third Ed. (BSID-III), 6-minute walk test (6MWT), upper limb module (ULM), etc.
  - Stability or improvement in respiratory function tests (e.g., forced vital capacity [FVC], etc.)
  - Reduction in exacerbations necessitating hospitalization and/or antibiotic therapy for respiratory infection in the preceding year/timeframe
  - Stable or increased patient weight (for patients without a gastrostomy tube)
  - Slowed rate of decline in the aforementioned measures

EXONDYS51® (ETEPLIRSEN)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Duchenne muscular dystrophy (DMD)**

- Patient is not on concomitant therapy with other DMD-directed antisense oligonucleotides (e.g., golodirsen, casimersen, viltolarsen, etc.); **AND**
- Patient must have a confirmed mutation of the *DMD* gene that is amenable to exon 51 skipping; **AND**
- Patient has been on a stable dose of corticosteroids, unless contraindicated or intolerance, for at least 6 months; **AND**
- Patient retains meaningful voluntary motor function (e.g., patient is able to speak, manipulate objects using upper extremities, ambulate, etc.); **AND**
- Patient should be receiving physical and/or occupational therapy; **AND**
- Baseline documentation of one or more of the following:
  - Dystrophin level
  - 6-minute walk test (6MWT) or other timed function tests (e.g., time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB])
  - Upper limb function (ULM) test
  - North Star Ambulatory Assessment (NSAA)
  - Forced Vital Capacity (FVC) percent predicted

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hypersensitivity reactions, etc.; **AND**
- Patient has responded to therapy compared to pretreatment baseline in one or more of the following (not all-inclusive):
  - Increase in dystrophin level
  - Stability, improvement, or slowed rate of decline in 6MWT or other timed function tests (e.g., time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB])
  - Stability, improvement, or slowed rate of decline in ULM test
  - Stability, improvement, or slowed rate of decline in NSAA
  - Stability, improvement, or slowed rate of decline in FVC% predicted
  - Improvement in quality of life

EYSUVIS (LOTEPREDNOL ETABONATE)

Length of Authorization:	2 weeks (both initial and renewal)
Initiative:	MNC: Ophthalmics (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is ≥ 18 years of age; **AND**
- Patient has diagnosis of dry eye disease (DED); **AND**
- Prescribed by or in consultation with an ophthalmologist or optometrist; **AND**
- Patient does NOT have viral diseases of the cornea and conjunctiva (e.g., epithelial herpes simplex keratitis [dendritic keratitis], vaccinia, and varicella), mycobacterial infection of the eye, or fungal diseases of ocular structures; **AND**
- Prescriber attestation that causative factors cannot be mitigated; **AND**
- Patient has trial and failure of an ocular lubricant (e.g., artificial tears), including a preservative-free formulation.

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient has had an examination under magnification (e.g., slit lamp) and evaluation of the intraocular pressure (IOP); **AND**
- Patient is NOT a candidate for long-term treatment or alternative therapies (e.g., punctal occlusion, ophthalmic immunomodulators); **AND**
- Absence of unacceptable toxicity from the drug (e.g., infection, delayed healing, corneal or scleral thinning, increased IOP, cataracts); **AND**
- Prescriber attestation that signs and symptoms have improved, but continued treatment is needed.

FABRAZYME® (AGALSIDASE BETA)

Length of Authorization:	1 year, may be renewed
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Fabry Disease (alpha-galactosidase A deficiency)**

- Patient is 2 years of age or older; **AND**
- Documented diagnosis of Fabry disease with biochemical/genetic confirmation by one of the following:
  - Males only: α-galactosidase A (α-Gal A) activity in plasma, isolated leukocytes, and/or cultured cells; **OR**
  - Plasma or urinary globotriaosylceramide (Gb_3/GL-3) or globotriaosylsphingosine (lyso-Gb_3); **OR**
  - Detection of pathogenic mutations in the *GALA/GLA* gene by molecular genetic testing; **AND**
- Baseline value for plasma GL-3 and/or GL-3 inclusions; **AND**
- Must not be used in combination with migalastat

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by a reduction in plasma GL-3 and/or GL-3 inclusions compared to pre-treatment baseline; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: anaphylaxis and severe hypersensitivity reactions, severe infusion-associated reactions, compromised cardiac function, etc

FARYDAK® (PANOBINOSTAT)

Length of Authorization:	6 Months, may be renewed once up to a maximum of 16 cycles of therapy over 48 weeks
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **multiple myeloma**

- Patient is at least 18 years of age; **AND**
- Patient has a baseline QTcF < 450 msec prior to initiating therapy, as measured by electrocardiogram (ECG); **AND**
- Patient has an ECG prior to the start of therapy and repeated periodically during treatment, as clinically indicated; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with anti-arrhythmic drugs (e.g., amiodarone, disopyramide, procainamide, quinidine, sotalol, etc.) or QT-prolonging drugs (e.g., chloroquine, clarithromycin, methadone, moxifloxacin, bepridil, pimozide, etc.); **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient has relapsed or progressive disease and received at least two (2) prior therapies, including an immunomodulatory agent (i.e. lenalidomide, thalidomide or pomalidomide) and bortezomib; **AND**
  - Used in combination with bortezomib and dexamethasone**; OR**
  - Used in combination with carfilzomib; **OR**
  - Used in combination with lenalidomide and dexamethasone

CLINICAL CRITERIA FOR RENEWAL

- Patient has not received more than 16 cycles (48 weeks) of therapy; **AND**
- Patient has a QTcF < 480 msec, as measured by electrocardiogram (ECG)**; AND**
- Disease response with treatment defined as stabilization of disease or decrease in size of tumor or tumor spread ; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hemorrhage, hepatotoxicity, severe diarrhea, cardiac toxicities (cardiac ischemic events, severe arrhythmias, ECG changes), myelosuppression, localized and systemic infections, etc

FASENRA® (BENRALIZUMAB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Respiratory Agents: (IE 2462 / NCPDP 75)

STANDARD FORMULARY CRITERIA

PRECISION / PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Severe Asthma**

- Patient is at least 12 years of age; **AND**
- Must not be used in combination with another anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody (e.g., omalizumab, mepolizumab, reslizumab, dupilumab, etc.); **AND**
- Must NOT be used for either of the following:
  - Treatment of other eosinophilic conditions (e.g., allergic bronchopulmonary aspergillosis/mycosis, Churg-Strauss syndrome, hypereosinophilic syndrome, etc.)
  - Relief of acute bronchospasm or status asthmaticus; **AND**
- Patient must have severe disease; **AND**
- Patient must have asthma with an eosinophilic phenotype defined as blood eosinophils ≥ 150 cells/µL within 6 weeks of dosing; **AND**
- Must be use for add-on maintenance treatment in patients regularly receiving **both** of the following:
  - Medium to high-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifier); **AND**
- Patient must have two or more exacerbations in the previous year requiring daily oral corticosteroids for at least 3 days (in addition to the regular maintenance therapy defined above); **AND**
- Baseline measurement of at least one of the following for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV_1)

***Components of severity for classifying asthma as SEVERE may include any of the following (not all inclusive):**
• Symptoms throughout the day • Nighttime awakenings, often 7 times per week • SABA use for symptom control occurs several times per day • Extremely limited normal activities • Lung function (percent predicted FEV_1) < 60% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

Please continue below for additional formulary-specific criteria.

CRITERIA FOR RENEWAL

- Must not be used in combination with another anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody (e.g., omalizumab, mepolizumab, reslizumab, dupilumab, etc.); **AND**
- Absence of unacceptable toxicity from the drug (e.g., parasitic [helminth] infection, herpes zoster infection, severe hypersensitivity reactions); **AND**
- Treatment has resulted in clinical benefit:
  - Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
    - Use of systemic corticosteroids
    - Two- fold or greater decrease in inhaled corticosteroid use for at least 3 days
    - Hospitalizations
    - ER visits
    - Unscheduled visits to healthcare provider; **OR**
  - Improvement from baseline in forced expiratory volume in 1 second (FEV_1)

CORE FORMULARY CRITERIA

CRITERIA FOR INITIAL APPROVAL

For Fasenra: Patient must have a trial and failure of Nucala OR Dupixent

Diagnosis of **Severe Asthma**

- Patient is at least 12 years of age; **AND**
- Must not be used in combination with another anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody (e.g., omalizumab, mepolizumab, reslizumab, dupilumab, etc.); **AND**
- Must NOT be used for either of the following:
  - Treatment of other eosinophilic conditions (e.g., allergic bronchopulmonary aspergillosis/mycosis, Churg-Strauss syndrome, hypereosinophilic syndrome, etc.)
  - Relief of acute bronchospasm or status asthmaticus; **AND**
- Patient must have severe disease; **AND**
- Patient must have asthma with an eosinophilic phenotype defined as blood eosinophils ≥ 150 cells/µL within 6 weeks of dosing; **AND**
- Must be use for add-on maintenance treatment in patients regularly receiving **both** of the following:
  - Medium to high-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifier); **AND**
- Patient must have two or more exacerbations in the previous year requiring daily oral corticosteroids for at least 3 days (in addition to the regular maintenance therapy defined above); **AND**
- Baseline measurement of at least one of the following for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV_1)

*Components of severity for classifying asthma as SEVERE may include any of the following (not all inclusive):
• Symptoms throughout the day • Nighttime awakenings, often 7 times per week • SABA use for symptom control occurs several times per day • Extremely limited normal activities • Lung function (percent predicted FEV_1) < 60% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

CRITERIA FOR RENEWAL

- Must not be used in combination with another anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody (e.g., omalizumab, mepolizumab, reslizumab, dupilumab, etc.); **AND**
- Absence of unacceptable toxicity from the drug (e.g., parasitic [helminth] infection, herpes zoster infection, severe hypersensitivity reactions); **AND**
- Treatment has resulted in clinical benefit:
  - Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
    - Use of systemic corticosteroids
    - Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
    - Hospitalizations
    - ER visits
    - Unscheduled visits to healthcare provider; **OR**
  - Improvement from baseline in forced expiratory volume in 1 second (FEV_1)

DOSAGE AND ADMINISTRATION FOR ALL FORMULARIES

Indication	Dose
Severe Asthma with an eosinophilic phenotype	30 mg self-administered subcutaneously every 4 weeks for the first three doses and then once every 8 weeks thereafter.

Max syringes (per dose and over time):

Indication	# syringes to build in FirstTrax℠	Per # days*
Severe Asthma with an eosinophilic phenotype	**Loading Dose** (3 months total): 1 syringe or autoinjector every 28 days x 3 doses	28
	Maintenance Dose: 1 syringe or autoinjector	56

FASLODEX® (FULVESTRANT)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**

- Patient is at least 18 years of age; **AND**
- Patient is postmenopausal; premenopausal with ovarian ablation/suppression**;** or male with suppression of testicular steroidogenesis; **AND**
- Disease is advanced, metastatic, or recurrent; **AND**
  - Patient has hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease ; **AND**
    - Used as initial therapy; **AND**
      - Used as a single agent ; **OR**
      - Used in combination with ribociclib ; **OR**
      - Used in combination with palbociclib or abemaciclib in patients without visceral crisis; **OR**
      - Used in combination with a non-steroidal aromatase inhibitor (i.e., anastrozole, letrozole) in patients without visceral crisis; **OR**
    - Used as subsequent therapy; **AND**
      - Used as a single agent ; **OR**
      - Used in combination with a CDK 4/6 inhibitor (e.g., abemaciclib, palbociclib, or ribociclib) ; **OR**
      - Used in combination with everolimus in patients without visceral crisis; **OR**
      - Used in combination with alpelisib in patients without visceral crisis and patient has PIK3CA mutation positive disease; **OR**
  - Patient has HR-positive, HER2-positive disease**; AND**
    - Used as a single agent or in combination with trastuzumab

Diagnosis of **Ovarian Cancer (Epithelial, Fallopian Tube or Primary Peritoneal Cancers)**

- Patient is at least 18 years of age; **AND**
- Used as single agent therapy; **AND**
- Patient has recurrent or persistent low-grade serous carcinoma; **AND**
- Will not be used for immediate treatment of biochemical relapse (i.e., rising CA-125 and no radiographic evidence of disease)

Diagnosis of **Uterine Sarcoma (Uterine Neoplasms)**

- Patient is at least 18 years of age; **AND**
- Used as single agent therapy; **AND**
- Used in patients with a small tumor volume or an indolent growth pace; **AND**
- Used for low-grade endometrial stromal sarcoma (ESS) OR for ER/PR positive uterine leiomyosarcoma (uLMS)**; AND**
  - Used following total hysterectomy for stage II–IV disease; **OR**
  - Used for metastatic or recurrent disease**; OR**
  - Used for disease that is not suitable for primary surgery

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Endometrial Adenocarcinoma (Uterine Neoplasms)**

- Patient is at least 18 years of age; **AND**
- Used as single agent therapy; **AND**
- Patient has grade 1 or 2 endometrioid histology; **AND**
- Used in patients with a small tumor volume or an indolent growth pace; **AND**
- Used as **one** of the following**:**
  - Primary treatment in patients undergoing both brachytherapy and external beam radiation therapy (EBRT) with cervical involvement that is not suitable for surgery; **OR**
  - Primary treatment in patients with disease limited to the uterus or extrauterine disease that is not suitable for primary surgery; **OR**
  - Primary treatment in patients with distant metastatic disease; **OR**
  - Adjuvant treatment for locally advanced or metastatic (stage III–IV) disease; **OR**
  - Treatment for disseminated metastases or locoregional recurrence

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., bleeding abnormalities, severe injection site reactions)

FEMARA® (LETROZOLE)

Length of Authorization:	1 year
Initiative:	MNC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- This medication is covered for the diagnosis of breast cancer and will pay without prior authorization if the day supply submitted is greater than 12.
- This medication is **not** covered for infertility treatment in which claims are normally submitted for short-term use.

FERAHEME® (FERUMOXYTOL)

Length of Authorization:	35 days, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Iron Deficiency Anemia Due to Chronic Kidney Disease (CKD)**

- Patient must be18 years or older; **AND**
- Other causes of anemia (e.g., blood loss, vitamin deficiency) have been ruled out; **AND**
- The patient does not have a history of allergic reaction to any intravenous iron product; **AND**
- Other supplemental iron is to be discontinued prior to administration of ferumoxytol; **AND**
- Patient is not anticipated to require magnetic resonance imaging (MRI) during the 3-month period following the last ferumoxytol dose as it is known to alter these imaging studies; **AND**
- Laboratory values must be obtained within 28 days prior to the anticipated date of administration; **AND**
- Patient has a transferrin saturation (TSAT) ≤ 30 % **and** ferritin is ≤ 500 ng/mL; **AND**
  - The patient is hemodialysis-dependent (HDD-CKD); **AND**
    - Patient has a hemoglobin (Hb) < 11.5 g/dL; **OR**
  - The patient is not receiving dialysis (NDD-CKD); **AND**
    - Patient has a Hb < 11 g/dL; **AND**
    - Patient had an insufficient response or intolerance to a ≥ 1-month trial of oral iron

Diagnosis of **Iron deficiency anemia**

- Patient must be18 years or older; **AND**
- Other causes of anemia (e.g., blood loss, vitamin deficiency) have been ruled out; **AND**
- The patient does not have a history of allergic reaction to any intravenous iron product; **AND**
- Other supplemental iron is to be discontinued prior to administration of ferumoxytol; **AND**
- Patient is not anticipated to require magnetic resonance imaging (MRI) during the 3-month period following the last ferumoxytol dose as it is known to alter these imaging studies; **AND**
- Laboratory values must be obtained within 28 days prior to the anticipated date of administration; **AND**
- Patient had an intolerance or inadequate response to a minimum of 14 days of oral iron; **AND**
- The patient has a Hb < 12 g/dL for females or < 14 g/dL for males; **AND**
  - The patient has a TSAT ≤ 20%; **OR**
  - The patient has a ferritin ≤ 100 ng/mL

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Cancer and chemotherapy induced anemia**

- Patient must be18 years or older; **AND**
- Other causes of anemia (e.g., blood loss, vitamin deficiency) have been ruled out; **AND**
- The patient does not have a history of allergic reaction to any intravenous iron product; **AND**
- Other supplemental iron is to be discontinued prior to administration of ferumoxytol; **AND**
- Patient is not anticipated to require magnetic resonance imaging (MRI) during the 3-month period following the last ferumoxytol dose as it is known to alter these imaging studies; **AND**
- Laboratory values must be obtained within 28 days prior to the anticipated date of administration; **AND**
- May be considered in instances where the recommended IV iron preparations with demonstrated efficacy in patients with cancer (i.e., low-molecular-weight iron dextran, ferric gluconate, and iron sucrose) are not appropriate; **AND**
  - Used as a single agent; **AND**
    - Patient has a ferritin < 30 ng/mL **and** a TSAT < 20%; **OR**
    - Patient has a ferritin > 500–800 ng/mL **and** a TSAT < 50% **and** does not wish to have an allogenic transfusion; **OR**
  - Used in combination with erythropoiesis-stimulating agents (ESAs); **AND**
    - Patient has a ferritin < 30 ng/mL **and** a TSAT < 20% and failed to demonstrate an increase in Hb after 4 weeks of IV or oral iron therapy; **OR**
    - Patient has a ferritin 30–500 ng/mL **and** a TSAT < 50% and is receiving myelosuppressive chemotherapy

CLINICAL CRITERIA FOR RENEWAL

Refer to initial criteria

FERTILITY AGENTS

Length of Authorization:	1 year
Initiative:	SPC: Fertility Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

GONAL-F®/GONAL-F® RFF/REDI-JECT®

Diagnosis of **Infertility**:

- Patient of child-bearing age; **AND**
- Patient in whom clomiphene alone does not result in fertilization (unless contraindicated or participating in an assisted reproductive technology [ART] program); **AND**
  - Used for the induction of ovulation in the anovulatory infertile patient in whom the cause of infertility is not due to primary ovarian failure; **OR**
  - Patient's treatment is part of an ART program; **AND**
- ***For Follistim®: The patient must have a trial and failure of Gonal-F®.***

FOLLISTIM® AQ

Diagnosis of **Infertility**:

- Patient of child-bearing age; **AND**
- Patient in whom clomiphene alone does not result in fertilization (unless contraindicated or participating in an assisted reproductive technology [ART] program); **AND**
  - Used for the induction of ovulation in the anovulatory infertile patient in whom the cause of infertility is not due to primary ovarian failure; **OR**
  - Patient's treatment is part of an in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) cycle
- ***For Follistim®: The patient must have a trial and failure of Gonal-F®***

GONAL-F®/FOLLISTIM® AQ/MENOPUR®

Diagnosis of **Spermatogenesis Stimulation**

- Primary or Secondary hypogonadotropic hypogonadism not due to primary testicular failure; **AND**
- Must be used in combination with hCG
- ***For Follistim®: The patient must have a trial and failure of Gonal-f®***

MENOPUR®

Diagnosis of **Infertility**:

- Patient of child-bearing age; **AND**
- Patient in whom clomiphene alone does not result in fertilization (unless contraindicated or participating in an assisted reproductive technology [ART] program); **AND**
- Used for the development of multiple follicles as part of an ART program

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

CETROTIDE®/GANIRELIX®/LEUPROLIDE

Diagnosis of **Infertility**:

- Patient of child-bearing age; **AND**
- Patient in whom clomiphene alone does not result in fertilization (unless contraindicated or participating in an assisted reproductive technology [ART] program); **AND**
- Patient is undergoing controlled ovarian stimulation (COS); **AND**
- ***For Ganirelix® and any other generic cetrorelix products: the patient must have a trial and failure of Cetrotide®.***

LUPRON DEPOT®

Diagnosis of **Fertility Preservation Prior to Chemotherapy**:

- Patient is 18 years or older; **AND**
- Patient is pre-menopausal; **AND**
- Patient is receiving treatment with cytotoxic chemotherapy with the potential to cause ovarian damage/toxicity (e.g., cyclophosphamide, melphalan, procarbazine vinblastine, imatinib); **AND**
- Patient has failed or is not a candidate for other fertility preservation methods (e.g., cryopreservation)

Renewal:

- Patient is still receiving treatment with cytotoxic chemotherapy

OVIDREL®

Diagnosis of **Infertility**:

- Patient of child-bearing age; **AND**
- Patient in whom clomiphene alone does not result in fertilization (unless contraindicated or participating in an assisted reproductive technology [ART] program); **AND**
- Used for the induction of ovulation in the anovulatory infertile patient in whom the cause of infertility is not due to primary ovarian failure; **OR**
- Patient's treatment is part of an ART program

NOVAREL®/PREGNYL®/HUMAN CHORIONIC GONADOTROPIN (HCG)

Diagnosis of **Infertility**:

- Patient of child-bearing age; **AND**
- Patient in whom clomiphene alone does not result in fertilization (unless contraindicated or participating in an assisted reproductive technology [ART] program); **AND**
  - Used for the induction of ovulation in the anovulatory infertile patient in whom the cause of infertility is not due to primary ovarian failure; **OR**
  - Patient's treatment is part of an ART program; **OR**
  - Treatment of corpus luteum dysfunction (i.e., luteal phase support) after receiving ovulation induction protocol with FSH/LH (menotropins); **AND**
  - ***The patient must have a trial and failure of Ovidrel®.***

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

NOVAREL®/PREGNYL®/HUMAN CHORIONIC GONADOTROPIN (HCG) *(CONTINUED)*

Diagnosis of **Prepubertal Cryptorchidism**

- Patient's condition is not due to anatomical obstruction

Diagnosis of **Hypogonadotropic Hypogonadism**

- Patient has primary or secondary hypogonadotropic hypogonadism; **AND**
- Used alone or in combination with menotropins or follitropin therapy

FIRDAPSE® (AMIFAMPRIDINE)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Lambert-Eaton Myasthenic Syndrome (LEMS)**

- Patient is at least 18 years old; **AND**
- Will be used as a single agent or in combination with stable doses of peripherally acting cholinesterase inhibitors (e.g., pyridostigmine) or oral immunosuppressants (e.g., glucocorticoids); **AND**
- Patient has no past medical history of seizures (e.g., no active brain metastases, etc.); **AND**
- Patient is not on other medications which lower the seizure threshold (e.g., bupropion, clozapine, fluoroquinolones, etc.); **AND**
- Will not be used in combination with other aminopyridine type potassium-channel-blocker medications (e.g., dalfampridine, amifampridine, etc.); **AND**
  - Patient does not have a concurrent diagnosis of small cell lung cancer (SCLC); **OR**
  - Patient has SCLC that was previously treated and continues to have symptomatic disease; **AND**
- Patient must have had an intolerance to Ruzurgi® (amifampridine) prior to consideration of Firdapse; **AND**
- Patient has symptoms including progressive proximal lower extremity weakness, oculobulbar findings, recovery of lost deep tendon reflexes or improvement in muscle strength with brief muscle activation; **AND**
- Patient diagnosis is confirmed based on the following neurophysiological-electrodiagnostic and antibody testing:
  - Patient has a normal sensory study with low compound motor action potential (CMAP) which increase in amplitude ≥60% following 10s maximal isometric muscle activation (i.e., post-exercise facilitation) or during high-frequency nerve stimulation (RNS) testing; **AND**
  - Positive anti-P/Q type voltage-gated calcium channel (VGCC) antibody test; **AND**
- Patient is ambulatory and/or able to ambulate; **AND**
- Physician has assessed baseline disease severity including muscle weakness, reflexes, and using either the Quantitative Myasthenia Gravis (QMG) score or the triple-timed up-and-go [3TUG] test

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., seizures, anaphylaxis); **AND**
- Disease response as indicated by an improvement, stabilization or slowing in decline, when compared to baseline, in either the signs and symptoms of disease such as muscle weakness, reflexes, autonomic dysfunction **or** as evidenced on a disease activity scoring tool (e.g., QMG score, 3TUG time)

FIRMAGON® (DEGARELIX)

Length of Authorization:	1 year, may be renewed
Initiative:	SPC: Hormonal Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Advanced Prostate Cancer**

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: prolongation of the QT-interval, severe hypersensitivity reactions, etc.

FOLOTYN® (PRALATREXATE)

Length of Authorization:	6 months, and renewable
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **adult T-cell leukemia/lymphoma**

- Patient is at least 18 years of age; **AND**
- Used as a single agent in patients who have failed first line therapy for acute or lymphoma subtypes

Diagnosis of **mycosis fungoides/Sézary syndrome**

- Patient is at least 18 years of age; **AND**
- Patient does **not** have stage IA-IIA disease with B1 blood involvement

Diagnosis of **Hepatosplenic gamma-delta T-cell lymphoma**

- Patient is at least 18 years of age; **AND**
- Used as a single agent as subsequent therapy; **AND**
- Used for disease that is refractory to two previous primary treatment regimens

Diagnosis of **breast implant-associated anaplastic large cell lymphoma (ALCL)**

- Patient is at least 18 years of age; **AND**
- Used as subsequent therapy; **AND**
- Used as single agent therapy for relapsed or refractory disease

Diagnosis of **Extranodal NK/T-cell lymphoma**

- Patient is at least 18 years of age; **AND**
- Patient has nasal type disease; **AND**
- Used as single agent therapy for relapsed or refractory disease; **AND**
- Used as subsequent treatment following additional therapy with an alternate asparaginase-based combination chemotherapy regimen that was not previously used

Diagnosis of **Peripheral T-cell lymphoma (PTCL)**

- Patient is at least 18 years of age; **AND**
- Used as a single agent for relapsed or refractory disease; **AND**
- Patient has one of the following PTCL sub-types:
  - Anaplastic large cell lymphoma
  - Peripheral T-cell lymphoma not otherwise specified
  - Angioimmunoblastic T-cell lymphoma
  - Enteropathy-associated T-cell lymphoma
  - Monomorphic epitheliotropic intestinal T-Cell lymphoma
  - Nodal peripheral T-Cell lymphoma with TFH phenotype
  - Follicular T-Cell lymphoma

Diagnosis of **Primary cutaneous CD30+ T-cell lymphoproliferative disorders**

- Patient is at least 18 years of age; **AND**
- Used as a single agent as primary treatment or for relapsed or refractory disease: **AND**
  - Patient has primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions; **OR**
  - Patient has cutaneous ALCL with regional nodes (excluded systemic disease)

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., bone marrow suppression [e.g., neutropenia, anemia, and/or thrombocytopenia], mucositis, severe dermatologic reactions, tumor lysis syndrome [TLS], renal toxicity, hepatic toxicity)

FOTIVDA® (TIVOZANIB)

Length of Authorization:	6 months, eligible for renewal
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Renal Cell Carcinoma (RCC)**

- Patient is at least 18 years of age; **AND**
- Patient blood pressure is controlled prior to initiation of treatment (*Note: do not administer if systolic > 150 or diastolic > 100 mmHg*)**; AND**
- Patient must not have had a surgical procedure within the preceding 24 days or have a surgical wound that has not fully healed; **AND**
- Patient does not have unstable or untreated central nervous system (CNS) metastases; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Used as a single agent; **AND**
- Patient has relapsed or refractory advanced or metastatic disease with clear cell histology; **AND**
- Patient has progressed after at least two prior systemic therapies

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hypertension, cardiac ischemia, cardiac failure, cardiac infarction or stroke, venous thromboembolic event, hemorrhage, severe proteinuria, thyroid dysfunction, impaired wound healing, reversible posterior leukoencephalopathy syndrome (RPLS), tartrazine hypersensitivity reactions, etc.

GALAFOLD® (MIGALASTAT)

Length of Authorization:	1 year – May be renewed
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Fabry Disease (alpha-galactosidase A deficiency)**

- Patient is 18 years of age or older; **AND**
- Patient has **not** undergone or is scheduled to undergo kidney transplantation, or is currently on dialysis; **AND**
- Must not be used in combination with agalsidase beta (Fabrazyme); **AND**
- Documented diagnosis of Fabry disease with biochemical/genetic confirmation by one of the following:
  - Males only: α-galactosidase A (α-Gal A) activity in plasma, isolated leukocytes, and/or cultured cells; OR
  - Plasma or urinary globotriaosylceramide (Gb3/GL-3) or globotriaosylsphingosine (lyso-Gb3); OR
  - Detection of pathogenic mutations in the *GALA/GLA* gene by molecular genetic testing; **AND**
- Patient has an amenable galactosidase alpha gene (*GLA*) variant that is determined by or in consultation with a clinical genetics professional to be pathogenic; **AND**
- Baseline value for urine GL-3 and/or GL-3 inclusions

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by a reduction in urine GL-3 and/or GL-3 inclusions compared to pre-treatment baseline; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe kidney infections)

GAMIFANT® (EMAPALUMAB-LZSG)

Length of Authorization:	6 months – May be renewed
Initiative:	SPC: Miscellaneous PA required (IE: 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Hemophagocytic lymphohistiocytosis (HLH)**

- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Patient will receive prophylaxis for Herpes Zoster, Pneumocystis Jirovecii, and fungal infections; **AND**
- Patient does not have an active infection, including clinically important localized infections that are favored by interferon-gamma (e.g., infections caused by mycobacterium, histoplasma, etc.); **AND**
- Must not be administered concurrently with live or live attenuated vaccines; **AND**
- Patient has **not** received hematopoietic stem cell transplant (HSCT)*; **AND**
- Patient has a definitive diagnosis of HLH as indicated by the following:
  - Patient diagnosis of primary HLH based on identification of biallelic pathogenic gene variants from molecular genetic testing (e.g., *PRF1, UNC13D, STX11, or STXBP2)* or a family history consistent with primary HLH; **OR**
  - Patient has at least FIVE of the following eight documented criteria:
    - Prolonged fever (> 7 days)
    - Splenomegaly
    - Cytopenias affecting 2 of 3 lineages in the peripheral blood (hemoglobin < 9 g/dL, platelets < 100 x 10^9/L, neutrophils < 1 x 10^9/L)
    - Hypertriglyceridemia (fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL) and/or hypofibrinogenemia (≤ 1.5 g/L)
    - Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
    - Low or absent NK-cell activity
    - Ferritin ≥ 500 mcg/L
    - Soluble CD25 (aka soluble IL-2Rα receptor) ≥ 2400 U/mL; **AND**
- Patient has active, primary disease that is refractory, recurrent, or progressive during, or was intolerant of conventional HLH therapy (e.g., dexamethasone, etoposide, cyclosporine A, anti-thymocyte globulin, etc.); **AND**
- Used in combination with dexamethasone (patients currently on oral cyclosporine A, or intrathecal methotrexate and/or glucocorticoids may continue on therapy while treated with emapalumab)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., serious infections, severe infusion reactions); **AND**
- Patient is receiving ongoing monitoring every 2 weeks for adenovirus, EBV, and CMV viruses and as clinically indicated; **AND**
- Patient has **not** received hematopoietic stem cell transplant (HSCT)*; **AND**
- Patient continues to require therapy for treatment of HLH; **AND**
- Patient experienced a disease improvement in HLS abnormalities as evidenced by one of the following:
  - Complete response defined as normalization of all HLH abnormalities (i.e., no fever, no splenomegaly, neutrophils > $1x10^9$/L, platelets > $100x10^9$/L, ferritin < 2,000 µg/L, fibrinogen > 1.50 g/L, D-dimer < 500 µg/L, normal CNS symptoms, no worsening of sCD25 > 2-fold baseline); **OR**
  - Partial response defined as normalization of ≥ 3 HLH abnormalities; **OR**
  - HLH improvement defined as ≥ 3 HLH abnormalities improved by at least 50% from baseline; **OR**
- Dose escalation (up to the maximum dose and frequency specified below) requests based on clinical and laboratory parameters being interpreted as an unsatisfactory response are defined as at least **one** of the following:
  - Fever – persistence or recurrence
  - Platelet count
    - If baseline < 50,000/mm^3 and no improvement to >50,000/mm^3
    - If baseline > 50,000/mm^3 and less than 30% improvement
    - If baseline > 100,000/mm^3 any decrease to < 100,000/mm^3
  - Neutrophil count
    - If baseline < 500/mm^3 and no improvement to > 500/mm^3
    - If baseline > 500 -1000/mm^3 and decrease to < 500/mm^3
    - If baseline 1000-1500/mm^3 and decrease to < 1000/ mm^3
  - Ferritin (ng/mL)
    - If baseline ≥ 3000 ng/mL and < 20% decrease
    - If baseline < 3000 ng/mL and any increase to > 3000 ng/mL
  - Splenomegaly – any worsening
  - Coagulopathy (both D-dimer and fibrinogen must apply)
    - D-Dimer
      - If abnormal at baseline and no improvement
    - Fibrinogen
      - If baseline levels ≤ 100 mg/dL and no improvement
      - If baseline levels > 100 mg/dL and any decrease to < 100 mg/dL

**Patients should be evaluated for HSCT when a high risk of relapse and a high risk of mortality exists (e.g., homozygous or compound heterozygous HLH mutations exists, lack of response to initial HLH therapy, central nervous system involvement, and incurable hematologic malignancy).*

GAMMACORE

Length of Authorization:	6 months
Initiative:	SPC: Miscellaneous PA required (IE: 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Episodic cluster headaches** (attacks occur for less than one year without the pain free period or the pain free time lasts more than one month); **OR**

Migraine with or without aura; **AND**

- Patient is 18 years of age or greater; **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Patient has no contraindications to GammaCore therapy, such as
  - Active implantable medical device (e.g., pacemaker, hearing aid implant, or any implanted electrical device); **OR**
  - Diagnosed narrowing of the arteries (carotid atherosclerosis); **OR**
  - Had surgery to cur the vagus nerve in the neck (cervical vagotomy); **AND**
- Secondary causes of headache have been ruled out (e.g., alcohol, caffeine, light, infections, etc.); **AND**
- Patient must have tried and failed, or have documented contraindications to recommended acute treatments (e.g., oral, intranasal, or injectable formulations of triptans); **AND**
- Patient must have tried and failed or is currently on prophylactic therapy (e.g., verapamil, lithium, topiramate, divalproex sodium, sodium valproate, metoprolol, or propranolol).

GASTROINTESTINALS: PANCRELIPASE

STANDARD FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Gastrointestinals: IBS (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

PANCREAZE®, PERTZYE®, ULTRESA®, AND VIOKACE®:

- Patient must have a trial and failure of Creon® and Zenpep®

GASTROINTESTINALS: PPIS

Length of Authorization:	1 Year
Initiative:	MNC: Gastrointestinals: PPIs (IE 2462 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

- For Dexilant, there has been a trial and failure of **ONE** preferred within class medication (left side of table, RX or OTC)
- For all other non-preferred products:
  - There has been a trial and failure of **TWO** preferred within class medications (left side of table, RX or OTC)

CLINICAL CRITERIA FOR TWICE DAILY DOSING-QL OVERRIDE – TECHNICIANS MAY APPROVE

Diagnosis of **Helicobacter Pylori (H. Pylori)**

- Approve BID dosing for up to 1 month

Diagnosis of **Gastrointestinal Bleeding (GI Bleed) or Hemorrhagic Gastritis**

- Approve BID dosing for up to 1 year

Diagnosis of **GERD, Barrett's Esophagus, or ANY OTHER Diagnosis**

- Patient is experiencing uncontrolled symptoms following a 30-day trial of once daily PPI therapy.

Approve 6 months initial, 1 year for renewal

NO PA REQUIRED	STEP REQUIRED
Esomeprazole magnesium	Aciphex® (rabeprazole)/ Aciphex® Sprinkle (rabeprazole) (May approve sprinkle capsules for pediatric patients who have difficulty swallowing solid dosage forms)
Lansoprazole capsules (generic for Prevacid®)	Dexilant® (dexlansoprazole)
Omeprazole capsules (generic for Prilosec®)	Esomeprazole strontium
OTC Prilosec, OTC Prevacid, OTC Zegerid	Nexium® capsules (esomeprazole)
Pantoprazole tablets (generic for Protonix®)	Nexium® suspension packets (esomeprazole) (May approve for pediatric patients who have difficulty swallowing solid dosage forms, or the dosage needed is not available in capsule formulation)
Rabeprazole (generic for Aciphex®)	Omeprazole-sodium bicarb caps (generic for Zegerid®)
	Prevacid® capsules, SoluTab (lansoprazole)
	Prilosec® capsules, susp packets (omeprazole) (May approve suspension for pediatric patients who have difficulty swallowing solid dosage forms, or the dosage needed is not available in capsule formulation)
	Protonix® tablets, susp packets (pantoprazole) (May approve suspension for pediatric patients who have difficulty swallowing solid dosage forms, or the dosage needed is not available in tablet formulation)
	Zegerid® capsules, suspension packets (omeprazole/ sodium bicarbonate)

GASTROINTESTINAL: IBS, CONSTIPATION, DIARRHEA

STANDARD FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

Length of Authorization:	Lotronex: New: 8 weeks; renewals may be approved for 6 months Amitiza/Linzess/Motegrity/Movantik/Relistor tabs/Trulance/Zelnorm: 1 year
Initiative:	MNC: Gastrointestinals: IBS Agents (IE 2462 / NCPDP 75 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

RELISTOR TABLETS (NO GRANDFATHERING): [SEPARATE CRITERIA FOR RELISTOR INJECTION]

Confirmed diagnosis of **opioid-induced constipation; AND**

- Patient does not have known or suspected mechanical gastrointestinal obstruction; **AND**
- Patient is not pregnant or breastfeeding; **AND**
- ***Patient must try ONE of the following generics: lactulose or polyethylene glycol; AND***
- ***Patient must have failed a trial of Movantik or Symproic***

Length of Authorization: 1 year

LOTRONEX AND GENERIC ALOSETRON

Diagnosis of **severe, diarrhea predominant irritable bowel syndrome**

- Patient is female and at least 18 years of age; **AND**
- Patient has had chronic IBS symptoms for at least 6 months; **AND**
- Patient has tried and failed at least two of the following: antispasmodic agents (e.g., dicyclomine, hyoscyamine), antidiarrheal agents/opiates (e.g., loperamide, diphenoxylate/atropine, codeine), Antidepressants (e.g., Tricyclic antidepressants), or bulk producing agents (e.g., Psyllium, fiber), unless ALL are contraindicated.

Length of Authorization: 8 weeks initially; renewals may be approved for 6 months

MOVANTIK AND SYMPROIC (NO GRANDFATHERING)

- Patient has failed a trial of lactulose **or** polyethylene glycol

Length of Authorization: 1 year

TRULANCE (NO GRANDFATHERING)

Diagnosis of **chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C)**

- Patient is 18 years of age or older; **AND**
- Patient must not have known or suspected mechanical gastrointestinal obstruction; **AND**
- Patient must have failed a trial of lactulose **or** polyethylene glycol; **AND**
- Patient must have failed a trial of Linzess

Length of Authorization: 1 year

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

AMITIZA (NO GRANDFATHERING)

For opioid-induced constipation (OIC):

- Patient is 18 years of age or older; **AND**
- Patient must have a diagnosis of OIC; **AND**
- Patient must have failed a trial of lactulose **or** polyethylene glycol; **AND**
- Patient must have failed a trial of Movantik **or** Symproic

For IBS-C or chronic idiopathic constipation (CIC):

- Patient is 18 years of age or older; **AND**
- Patient must have a diagnosis of IBS-C **and** is female **or** have a diagnosis of CIC; **AND**
- Patient must have failed a trial of lactulose **or** polyethylene glycol; **AND**
- Patient must have failed a trial of Linzess

MOTEGRITY (NO GRANDFATHERING)

Diagnosis of chronic idiopathic constipation (CIC)

- Patient must be 18 years of age or older; **AND**
- Patient must not have known or suspected intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, or severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, and toxic megacolon/megarectum; **AND**
- Patient must have failed a trial of lactulose OR polyethylene glycol; **AND**
- Patient must have failed a trial of Linzess

ZELNORM (NO GRANDFATHERING)

Patient must have a diagnosis of **IBS-C**

- Patient must be female; **AND**
- Patient must be 18 years of age to less than 65 years of age; **AND**
- Patient must not have a history of myocardial infarction, stroke, transient ischemic attack, angina, ischemic colitis, or other form of intestinal ischemia, bowel obstruction, symptomatic gallbladder disease, suspected sphincter of Oddi dysfunction, or abdominal adhesions; **AND**
- Patient must have failed a trial of lactulose **or** polyethylene glycol; **AND**
- Patient must have failed a trial of Linzess.

Length of Authorization: 1 year

STEP CRITERIA (NO GRANDFATHERING)

LINZESS: (NO GRANDFATHERING)

- Patient must have had a trial and failure of Polyethylene glycol or lactulose

PRECISION/PLUS FORMULARY CRITERIA

CORE FORMULARY CRITERIA

Length of Authorization:	Lotronex: New: 8 weeks; renewals may be approved for 6 months Linzess: 1 year
Initiative:	MNC: Gastrointestinals: IBS Agents (IE 2462 / NCPDP 75, 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

LOTRONEX AND GENERIC ALOSETRON

Diagnosis of **severe, diarrhea predominant irritable bowel syndrome**

- Patient is female and at least 18 years of age; **AND**
- Patient has had chronic IBS symptoms for at least 6 months; **AND**
- Patient has tried and failed at least two of the following: antispasmodic agents (e.g., dicyclomine, hyoscyamine), antidiarrheal agents/opiates (e.g., loperamide, diphenoxylate/atropine, codeine), Antidepressants (e.g., Tricyclic antidepressants), or bulk producing agents (e.g., Psyllium, fiber), unless ALL are contraindicated.

Length of Authorization:	8 weeks initially; renewals may be approved for 6 months

MOTEGRITY (NO GRANDFATHERING)

- Patient must be 18 years of age or older; **AND**
- Patient must have a diagnosis of **chronic idiopathic constipation (CIC)**; **AND**
- Patient must not have known or suspected intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, or severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, or toxic megacolon/megarectum; **AND**
- Patient must have failed a trial of lactulose OR polyethylene glycol; **AND**
- Patient must have failed a trial of Linzess

Length of Authorization:	1 year

ZELNORM (NO GRANDFATHERING)

Patient must have a diagnosis of **IBS-C**

- Patient must be female; **AND**
- Patient must be 18 years of age to less than 65 years of age; **AND**
- Patient must not have a history of myocardial infarction, stroke, transient ischemic attack, angina, ischemic colitis, or other form of intestinal ischemia, bowel obstruction, symptomatic gallbladder disease, suspected sphincter of Oddi dysfunction, or abdominal adhesions; **AND**
- Patient must have failed a trial of lactulose **or** polyethylene glycol; **AND**
- Patient must have failed a trial of Linzess.

Length of Authorization:	1 year

SYMPROIC (NO GRANDFATHERING)

- Patient must have failed a trial of lactulose or polyethylene glycol

Length of Authorization: 1 year

STEP CRITERIA (NO GRANDFATHERING)

LINZESS

- Patient must have had a trial and failure of Polyethylene glycol **OR** lactulose

GATTEX® (TEDUGLUTIDE)

Length of Authorization:	1 Year
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Short Bowel Syndrome (or Intestinal Failure due to Short Bowel Syndrome)**

- Patient is dependent on parenteral nutrition for at least 12 months (initial approval only); **AND**
- Patient is receiving parenteral nutrition at least 3 times weekly (initial approval only)

CLINICAL CRITERIA FOR RENEWAL

- The patient has seen at least a 20% decrease in parental nutrition requirements; **AND**
- The patient does not have any side effects or contraindications to the medication

GAVRETO™ (PRALSETINIB)

Length of Authorization:	6 months, and renewable
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years old; **AND**
- Must be used as a single agent; **AND**
- Patient does not have uncontrolled hypertension; **AND**
- Patient has not had recent major surgery within the previous 14 days; **AND**
- Therapy will not be used concomitantly with other RET-type targeted therapies (e.g., selpercatinib, cabozantinib, vandetanib, etc.); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, etc.); **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with combined P-gp and strong CYP3A inhibitors (e.g., azole-antifungals, cobicistat, HIV protease inhibitors, idelalisib, boceprivir, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has RET rearrangement positive disease as detected by an FDA-approved or CLIA compliant test; **AND**
- Patient has recurrent, advanced, or metastatic disease *(excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease)* or mediastinal lymph node recurrence with prior radiation therapy

CLINICAL CRITERIA FOR INITIAL APPROVAL (CONTINUED)

Diagnosis of **thyroid cancer**

- Patient is at least 12 years of age; **AND**
- Must be used as a single agent; **AND**
- Patient does not have uncontrolled hypertension; **AND**
- Patient has not had recent major surgery within the previous 14 days; **AND**
- Therapy will not be used concomitantly with other RET-type targeted therapies (e.g., selpercatinib, cabozantinib, vandetanib, etc.); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, etc.); **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with combined P-gp and strong CYP3A inhibitors (e.g., azole-antifungals, cobicistat, HIV protease inhibitors, idelalisib, boceprivir, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has RET-fusion positive Follicular, Hürthle Cell, or Papillary carcinoma; **AND**
  - Patient is at least 12 years of age; **AND**
  - Patient has metastatic, advanced, or unresectable locoregional recurrent or persistent disease; **AND**
  - Patient is radioactive iodine (RAI) therapy refractory or is not amenable to RAI therapy; **OR**
- Patient has RET-mutation positive medullary thyroid cancer (MTC); **AND**
  - Patient is at least 12 years of age; **AND**
    - Patient has symptomatic or progressive unresectable locoregional disease; **OR**
    - Patient has advanced or metastatic disease; **OR**
  - Patient has RET-fusion positive Anaplastic carcinoma; **AND**
    - Used as neoadjuvant therapy for borderline resectable locoregional disease; **OR**
    - Used as first- or second-line therapy for metastatic disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include interstitial lung disease or pneumonitis, severe hypertension, severe hepatotoxicity, severe or life-threatening hemorrhage, tumor lysis syndrome, impaired wound healing, etc.

GAZYVA® (OBINUTUZUMAB)

Length of Authorization:	• **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) combination therapy**: Coverage is provided for six 28-day cycles (6 months) and may **not** be renewed • **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) monotherapy**: Coverage is provided for eight 21-day cycles (6 months) and may **not** be renewed • All other indications: Coverage is provided for six months and may be renewed for up to a maximum of two years of maintenance therapy
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Lymphatic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**

- Patient is at least 18 years of age; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Used as first-line therapy:
  - Used in combination with chlorambucil; **OR**
  - Used in combination with acalabrutinib; **OR**
  - Used in combination with venetoclax; **OR**
  - Used as single agent therapy for disease with del(17p)/TP53 mutation; **OR**
  - Used in combination with bendamustine for disease without del(17p)/TP53 mutation (*excluding use in frail patients with significant comorbidity [i.e., not able to tolerate purine analogs]*); **OR**
- Used for as subsequent therapy; **AND**
  - Used as single agent therapy for disease without del(17p)/TP53 mutation

Diagnosis of **B-Cell Lymphomas**

- Patient is at least 18 years of age; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Follicular Lymphoma (Grade 1-2)
  - Used as first-line therapy; **AND**
    - Used in combination with chemotherapy (e.g., bendamustine or CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone] or CVP [cyclophosphamide, vincristine, prednisone]); **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL (CONTINUED)

  - Used as subsequent therapy, if not previously used as first-line therapy, for refractory or progressive disease; **AND**
    - Used in combination with chemotherapy (e.g., bendamustine or CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone] or CVP [cyclophosphamide, vincristine, prednisone]); **OR**
    - Used as first-line therapy; **OR**
    - Used in combination with lenalidomide; **OR**
  - Used as a single agent for maintenance therapy; **AND**
    - Used as first-line consolidation therapy or extended dosing following chemoimmunotherapy; **OR**
    - Used as second-line consolidation therapy or extended dosing in patients who are refractory to rituximab; **OR**
    - Used in patients with histologic transformation to diffuse-large B-cell lymphoma with extensive co-existing follicular lymphoma who achieve a complete response to chemoimmunotherapy; **OR**
  - Used as a substitute for rituximab in patients with intolerance or experiencing rare complications such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis
- MALT Lymphoma (Gastric or Non-Gastric) or Marginal Zone Lymphoma (Splenic or Nodal); **AND**
  - Used as first-line therapy *(Nodal Marginal Zone Lymphoma only*); **AND**
    - Used in combination with chemotherapy [e.g., bendamustine or CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or CVP (cyclophosphamide, vincristine, prednisone)]; **OR**
  - Used in combination with bendamustine ; **AND**
    - Used as subsequent therapy, if not previously treated with bendamustine, for recurrent disease after prior treatment with rituximab (*Splenic Marginal Zone Lymphoma only*); **OR**
    - Used as subsequent therapy, if not previously treated with bendamustine, for relapsed or progressive disease (*Gastric MALT Lymphoma only*); **OR**
    - Used as subsequent therapy, if not previously treated with bendamustine, for refractory or progressive disease (*Nodal Marginal Zone Lymphoma only*); **OR**
    - Used as subsequent therapy, if not previously treated with bendamustine, for recurrent or progressive disease (*Non-Gastric MALT Lymphoma only*); **OR**
  - Used as a single agent for maintenance therapy as second-line consolidation or extended dosing in rituximab refractory patients treated with obinutuzumab and bendamustine for recurrent disease; **OR**
  - Used as a substitute for rituximab in patients with intolerance or experiencing rare complications such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis.
- Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma, mantle cell lymphoma, Diffuse Large B-Cell Lymphoma, High Grade B-Cell Lymphomas, Burkitt Lymphoma, AIDS Related B Cell Lymphomas, post-transplant lymphoproliferative disorders, or Castleman's disease
  - Used as a substitute for rituximab in patients with intolerance or experiencing rare complications such as mucocutaneous reactions including paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

CLINICAL CRITERIA FOR RENEWAL

Coverage can be renewed for other indications based upon the following criteria:

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe neutropenia/febrile neutropenia, severe thrombocytopenia, severe infusion-related reactions, hypersensitivity reactions including serum sickness, tumor lysis syndrome (TLS), serious bacterial, fungal, or viral infections, etc.; **AND**
- Patient has been evaluated for the presence of progressive multifocal leukoencephalopathy (PML) and has been found to be negative; **AND**
- **CLL/SLL**: Authorizations may not be renewed
- **Maintenance treatment of B-Cell Lymphomas**: Length of therapy does not exceed 2 years

GEMZAR® (GEMCITABINE)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Coverage is provided in the following conditions:

- **Breast cancer**
- **Non-small cell lung cancer (NSCLC)**
- **Ovarian cancer**
- **Pancreatic adenocarcinoma**
- **Kaposi sarcoma**
- **Bladder cancer/urothelial carcinoma**
  - Bladder cancer
  - Upper genitourinary (GU) tract tumors
  - Urothelial carcinoma of the prostate
  - Primary carcinoma of the urethra including non-urothelial and urothelial with variant histologies
- **Bone cancer**
  - Osteosarcoma
  - Ewing's sarcoma (excluding mesenchymal chondrosarcoma
- **Gestational trophoblastic neoplasia**
- **Squamous cell carcinoma of the head and neck (SCCHN)**
  - Cancer of the nasopharynx (including very advanced head and neck cancer)
- **Hepatobiliary cancers**
  - Gallbladder cancer
  - Intrahepatic cholangiocarcinoma
  - Extrahepatic cholangiocarcinoma
- **Hodgkin lymphoma**
  - Nodular Lymphocyte-Predominant Hodgkin Lymphoma
  - Classic Hodgkin Lymphoma
  - Pediatric Hodgkin Lymphoma
- **Kidney cancer (non-clear cell histology only)**
- **Malignant pleural mesothelioma**
- **B-cell lymphomas**
  - Follicular lymphoma
  - Diffuse large B-cell lymphoma (DLBCL)
  - Histologic transformation of nodal marginal zone lymphoma to DLBCL
  - Mantle cell lymphoma
  - High-grade B-cell lymphomas
  - Burkitt lymphoma
  - AIDS-related B-cell lymphoma
  - Post-transplant lymphoproliferative disorders

- **Occult primary**
- **Primary cutaneous lymphoma**s
  - Mycosis fungoides/Sézary syndrome
  - Primary cutaneous CD30-positive T-cell lymphoproliferative disorders
- **Small bowel adenocarcinoma**
- **Small cell lung cancer**
- **Soft tissue sarcoma**
  - Pleomorphic Rhabdomyosarcoma
  - Retroperitoneal/intra-abdominal sarcoma
  - Extremity/Body wall sarcoma
  - Head/neck sarcoma
  - Angiosarcoma
  - Solitary Fibrous Tumor
- **T-cell lymphomas**
  - Peripheral T-cell lymphoma (PTCL)
  - Adult T-cell leukemia/lymphoma
  - Extranodal NK/T-cell lymphoma, nasal type
  - Hepatosplenic gamma-delta T-cell lymphoma
  - Breast Implant-Associated Anaplastic Large Cell Lymphoma (ALCL)
- **Testicular cancer**
- **Thymomas and thymic carcinomas**
- **Uterine sarcoma**

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe myelosuppression, pulmonary toxicity/respiratory failure, hemolytic-uremic syndrome (HUS), hepatotoxicity, exacerbation of radiation therapy toxicity, capillary leak syndrome, posterior reversible encephalopathy syndrome (PRES), etc.

GILOTRIF® (AFATINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is 18 years of age or older; **AND**
- Patient has metastatic disease with squamous-cell histology that progressed after platinum-based therapy; **AND**
  - Used as single agent therapy; **OR**
- Patient has non-resistant epidermal growth factor receptor (EGFR) mutation(s) as detected by an FDA or CLIA-compliant test; **AND**
  - Used for recurrent, advanced or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
    - Used as a single agent; **AND**
      - Used as first-line therapy; **OR**
      - Used as continuation of therapy following progression on afatinib for asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited* metastases; **OR**
    - Used as subsequent therapy in combination with cetuximab; **AND**
      - Patient progressed on EGFR tyrosine kinase inhibitor therapy and has asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited* metastases; **OR**
      - Patient has T790M mutation-negative disease that progressed on EGFR tyrosine kinase inhibitor therapy and has multiple symptomatic systemic lesions; **OR**
      - Patient has T790M mutation-positive disease that progressed on osimertinib and has multiple symptomatic systemic lesions

**Limited number is undefined, but clinical trials have included 3 to 5 metastases.*

In addition to the above criteria:

- ***In patients with metastatic NSCLC and EGFR exon 19 deletions or exon 21 substitution mutations, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic erlotinib***

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe or prolonged diarrhea, severe cutaneous reactions, interstitial lung disease, hepatotoxicity, gastrointestinal perforation, ulcerative keratitis); **AND**
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **OR**
  - For continuation therapy following afatinib progression, disease response is defined as lack of continued disease progression, improvement in tumor size, or improvement in patient symptoms.

GIMOTI (METOCLOPRAMIDE)

Length of Authorization:	Initial: 8 weeks; Renewal: 8 weeks
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is at least 18 years of age; **AND**
- Patient has confirmed diagnosis of diabetic gastroparesis diagnosed with either of the following:
  - gastric emptying with scintigraphy of digestible solids at 15-minute intervals for 4 hours following food consumption; **OR**
  - ^{13}C octanoic acid breath test; **AND**
- Prescriber attestation that the patient does NOT have any of the following:
  - a history of signs or symptoms of tardive dyskinesia (TD);
  - a history of a dystonic reaction to metoclopramide;
  - circumstances where stimulation of gastrointestinal (GI) motility could be dangerous (e.g., GI hemorrhage, mechanical obstruction, or perforation);
  - a pheochromocytoma or other catecholamine-releasing paragangliomas;
  - epilepsy or a seizure disorder;
  - hypersensitivity to metoclopramide (e.g., laryngeal and glossal angioedema, bronchospasm); **AND**
- Patient has initiated appropriate dietary changes (e.g., low-fat, low-fiber diet) along with appropriate glycemic control measures for management of blood glucose in diabetic patients; **AND**
- Prescriber provides attestation that 1 course of treatment, with all dosage forms and routes of administration of metoclopramide, will NOT be for more than 12 weeks; **AND**
- Patient must have an adequate trial and failure of an oral formulation of metoclopramide (e.g., tablet, solution, orally disintegrating tablet) OR patient must NOT be a candidate for an oral formulation (e.g., demonstrated or documented erratic absorption of oral medications); **AND**
- Patient must NOT have moderate or severe renal impairment (creatinine clearance [CrCl] < 60 mL/minute) (**note**: It is not recommended to use Gimoti and these drugs concomitantly; however, it is at the provider's discretion):
  - antipsychotics;
  - strong CYP2D6 inhibitors (e.g., quinidine, bupropion, fluoxetine, paroxetine);
  - central nervous system (CNS) depressants (e.g., alcohol, sedatives, hypnotics, opiates, anxiolytics);
  - dopaminergic agonists (e.g., apomorphine, bromocriptine, cabergoline, levodopa, pramipexole, ropinirole, rotigotine);
  - monoamine oxidase inhibitors (MAOIs);
  - Phenergan.

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet initial authorization criteria; **AND**
- At least 2 weeks have passed since completion of a previous course of treatment, with all dosage forms and routes of administration of metoclopramide; **AND**
- Patient must have demonstrated improvement in signs and symptoms of diabetic gastroparesis (e.g., nausea, vomiting, early satiety, postprandial fullness, bloating, upper abdominal pain); **AND**
- Prescriber attestation that the patient has NOT experienced any signs or symptoms of tardive dyskinesia; **AND**
- Patient has NOT experienced any other treatment-restricting adverse effects (e.g., extrapyramidal symptoms [EPS]; parkinsonian symptoms; motor restlessness; neuroleptic malignant syndrome [NMS]; depression including suicidal ideation and suicide; increased blood pressure [e.g., hypertension]; fluid retention; hyperprolactinemia [e.g., resulting in galactorrhea, amenorrhea, gynecomastia or impotence])

GIVLAARI™ (GIVOSIRAN)

Length of Authorization:	6 months, may be renewed annually after that
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **acute hepatic porphyria (AHP)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid known triggers of porphyria attacks (e.g., alcohol, smoking, exogenous hormones, hypocaloric diet/fasting, certain medications such as barbiturates, hydantoins, sulfa-antibiotics, anti-epileptics, etc.); **AND**
- Patient has not had or is not anticipating a liver transplant; **AND**
- Patient has a definitive diagnosis of acute hepatic porphyria* (including acute intermittent porphyria, variegate porphyria, hereditary coproporphyria, or ALA dehydratase deficient porphyria) as evidenced by one of the following:
  - Patient has had elevated urinary or plasma PBG (porphobilinogen) and ALA (delta-aminolevulinic acid) levels within the previous year; **OR**
  - Patient has a mutation in an affected gene as identified on molecular genetic testing; **AND**
- Patient has a history of at least two documented porphyria attacks (i.e., requirement of hospitalization, urgent healthcare visit or intravenous administration of hemin) OR one severe attack with CNS involvement (e.g., hallucinations, seizures, etc.) during the previous six months; **AND**
- Patients currently receiving prophylactic intravenous hemin therapy will discontinue hemin within 3 to 6 months following initiation of givosiran

*Acute Hepatic Porphyria	Urine delta-aminolevulinic acid (ALA)	Urine porphobilinogen (PBG)	Urine porphyrins	Gene
Acute Intermittent Porphyria (AIP)	Elevated	Elevated	Increased uroporphyrin	*HMBS*
Hereditary Coproporphyria (HCP)	Elevated	Elevated	Increased coproporphyrin	*CPOX*
Variegate Porphyria (VP)	Elevated	Elevated	Increased coproporphyrin	*PPOX*
ALA Dehydratase-Deficiency Porphyria (ADP)	Elevated	Normal	Increased coproporphyrin	*ALAD*

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: anaphylactic reactions, severe hepatic toxicity, severe renal toxicity, severe injection site reactions, etc.; **AND**
- Disease response as evidenced by a decrease in the frequency of acute porphyria attacks, and/or hospitalizations/urgent care visits, and/or a decrease requirement of hemin intravenous infusions for acute attacks; **AND**
- Patient has a reduction/normalization of biochemical markers (i.e., ALA, PBG) compared to baseline; **AND**
- Patient will not use in combination with **prophylactic** intravenous hemin therapy; **AND**
- Patient has not received a liver transplant.

GLAUCOMA

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Ophthalmics (IE 2462 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

BRAND XALATAN AND BRAND TRAVATAN Z

The patient has tried and failed one of the following: bimatoprost, latanoprost, Lumigan, travoprost, Xelpros

PRECISION FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Ophthalmics (IE 2462 / NCPDP 75 – HICL)

STEP CRITERIA (NO GRANDFATHERING)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

GLEEVEC® (IMATINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myeloid Leukemia (CML)**

- Patient is at least 1 year of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has Philadelphia chromosome-positive (Ph+) or *BCR-ABL1* positive disease

In addition to the above criteria:

- *For Standard and Precision:* ***For brand Gleevec® for CML, for new starts only: patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic imatinib OR Bosulif®*** (***following the NCCN guidelines surrounding genetic mutations)***

Diagnosis of **Adult Acute Lymphoblastic Leukemia (ALL)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has Philadelphia chromosome-positive (Ph+) disease

Diagnosis of **Pediatric Acute Lymphoblastic Leukemia (ALL)**

- Patient is 1 year of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has Philadelphia chromosome-positive (Ph+) B-ALL; **OR**
- Patient has relapsed or refractory T-ALL with ABL-class translocation

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Myelodysplastic/Myeloproliferative Disease (Such as Chronic Myelomonocytic Leukemia) (MDS/MPD)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has platelet-derived growth factor receptor beta (PDGFRβ) gene rearrangements with 5q31-33 translocations or t(5;12) translocations

Diagnosis of **Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)**

- Patient is 18 years of age or older**; AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

Diagnosis of **Dermatofibrosarcoma Protuberans (DFSP)**

- Patient is 18 years of age or older**; AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

  Note: Tumors lacking the t(17;22) translocation may not respond to imatinib

Diagnosis of **Aggressive Systemic Mastocytosis (ASM)**

- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient is 18 years of age or older; **AND**
  - Eosinophilia is present with FIP1L1-PDGFRA fusion gene; **OR**
  - Patient does not have the D816V c-Kit mutation

  Note: If c-Kit mutational status is unknown; coverage is provided for 3 months only (renewal will only be considered after determination of c-Kit mutational status).

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

Diagnosis of **Cutaneous Melanoma**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has an activating KIT mutation as detected by a CLIA- or CAP-compliant diagnostic test (e.g., FISH)

Diagnosis of **Desmoid Tumors (aggressive fibromatosis)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

Diagnosis of **Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumors (PVNS/TGCT)**

- Patient is 18 years of age or older**; AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

Diagnosis of **Chordoma**

- Patient is 18 years of age or older; **AND**
- Patient has conventional or chondroid chordoma; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **AIDS-Related Kaposi Sarcoma**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

Diagnosis of **Chronic Graft Versus Host Disease (GVHD)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has steroid-refractory chronic GVHD after hematopoietic cell transplantation

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Gene**

- Patient is 18 years of age or older**; AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has eosinophilia and FIP1L1-PDGFRA, PDGFRB, or ABL1 gene rearrangement

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hematologic toxicity (e.g., anemia, neutropenia, thrombocytopenia), severe hepatotoxicity, severe congestive heart failure and left ventricular dysfunction, edema and severe fluid retention, hemorrhage, gastrointestinal perforation, bullous dermatologic reactions, tumor lysis syndrome, renal toxicity, hypereosinophilic cardiac toxicity, hypothyroidism, growth retardation in children and adolescents, etc; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Patient has been adherent to therapy; **AND**

Chronic GVHD only:

- Response to therapy with an improvement in one or more of the following:
  - Clinician assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score)
  - Patient-reported symptoms (e.g., Lee Symptom Scale)

Aggressive Systemic Mastocytosis (ASM) only:

- Patientdoes not have the D816V c-Kit mutation

Chronic Myelogenous Leukemia (CML) only:

- Treatment response as indicated by one of the following *BCR-ABL1* (IS) transcript levels:
  - ≤ 10% at 3 months; **OR**
  - ≤ 10% at 6 months; **OR**
  - ≤ 1% at 12 months

Note: cytogenetic assessment of response may be used if quantitative RT-PCR (QPCR) using International Scale (IS) for *BCR-ABL1* is not available

Acute Lymphoblastic Leukemia (ALL) only:

- Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH
- Note: Patients meeting all of the following criteria may be candidates for discontinuation provided they received counseling on, and have consented to, the risks (including TKI withdrawal) and benefits of stopping TKI therapy:
  - Patient is 18 years or older; **AND**
  - Patient has received TKI therapy for ≥ 3 years; **AND**
  - Patient has no history of accelerated or blast phase CML (i.e., chronic phase only); **AND**
  - Patient had a stable molecular response (MR4; *BCR-ABL1* ≤0.01% IS) for ≥ 2 years (as documented on ≥ 4 tests performed ≥ 3 months apart); **AND**
  - Patient has quantifiable *BCR-ABL1* transcripts; **AND**
  - Patient can meet the ongoing monitoring requirements after discontinuation

ENHANCED FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myeloid Leukemia (CML)**

- Patient is at least 1-year old; **AND**
- *For Enhanced:* ***For brand Gleevec® for CML, for new starts only: patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic imatinib OR Bosulif® OR Sprycel*** (***following the NCCN guidelines surrounding genetic mutations)***
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has Philadelphia chromosome-positive (Ph+) or *BCR-ABL1* positive disease

Diagnosis of **Adult Acute Lymphoblastic Leukemia (ALL)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has Philadelphia chromosome-positive (Ph+) disease

Diagnosis of **Pediatric Acute Lymphoblastic Leukemia (ALL)**

- Patient is 1 year of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has Philadelphia chromosome-positive (Ph+) B-ALL; **OR**
- Patient has relapsed or refractory T-ALL with ABL-class translocation

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Myelodysplastic/Myeloproliferative Disease (Such as Chronic Myelomonocytic Leukemia) (MDS/MPD)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has platelet-derived growth factor receptor beta (PDGFRβ) gene rearrangements with 5q31-33 translocations or t(5;12) translocations

Diagnosis of **Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)**

- Patient is 18 years of age or older**; AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

Diagnosis of **Dermatofibrosarcoma Protuberans (DFSP)**

- Patient is 18 years of age or older**; AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

  Note: Tumors lacking the t(17;22) translocation may not respond to imatinib

Diagnosis of **Aggressive Systemic Mastocytosis (ASM)**

- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient is 18 years of age or older; **AND**
  - Eosinophilia is present with FIP1L1-PDGFRA fusion gene; **OR**
  - Patient does not have the D816V c-Kit mutation

  Note: If c-Kit mutational status is unknown; coverage is provided for 3 months only (renewal will only be considered after determination of c-Kit mutational status).

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

Diagnosis of **Cutaneous Melanoma**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has an activating KIT mutation as detected by a CLIA- or CAP-compliant diagnostic test (e.g., FISH)

Diagnosis of **Desmoid Tumors (aggressive fibromatosis)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

Diagnosis of **Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumors (PVNS/TGCT)**

- Patient is 18 years of age or older**; AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

Diagnosis of **Chordoma**

- Patient is 18 years of age or older; **AND**
- Patient has conventional or chondroid chordoma; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **AIDS-Related Kaposi Sarcoma**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

Diagnosis of **Chronic Graft Versus Host Disease (GVHD)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has steroid-refractory chronic GVHD after hematopoietic cell transplantation

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Gene**

- Patient is 18 years of age or older**; AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has eosinophilia and FIP1L1-PDGFRA, PDGFRB, or ABL1 gene rearrangement

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hematologic toxicity (e.g., anemia, neutropenia, thrombocytopenia), severe hepatotoxicity, severe congestive heart failure and left ventricular dysfunction, edema and severe fluid retention, hemorrhage, gastrointestinal perforation, bullous dermatologic reactions, tumor lysis syndrome, renal toxicity, hypereosinophilic cardiac toxicity, hypothyroidism, growth retardation in children and adolescents, etc; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Patient has been adherent to therapy; **AND**

Chronic GVHD only:

- Response to therapy with an improvement in one or more of the following:
  - Clinician assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score)
  - Patient-reported symptoms (e.g., Lee Symptom Scale)

Aggressive Systemic Mastocytosis (ASM) only:

- Patientdoes not have the D816V c-Kit mutation

Chronic Myelogenous Leukemia (CML) only:

- Treatment response as indicated by one of the following *BCR-ABL1* (IS) transcript levels:
  - ≤ 10% at 3 months; **OR**
  - ≤ 10% at 6 months; **OR**
  - ≤ 1% at 12 months

Note: cytogenetic assessment of response may be used if quantitative RT-PCR (QPCR) using International Scale (IS) for *BCR-ABL1* is not available

Acute Lymphoblastic Leukemia (ALL) only:

- Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH
- Note: Patients meeting all of the following criteria may be candidates for discontinuation provided they received counseling on, and have consented to, the risks (including TKI withdrawal) and benefits of stopping TKI therapy:
  - Patient is 18 years or older; **AND**
  - Patient has received TKI therapy for ≥ 3 years; **AND**
  - Patient has no history of accelerated or blast phase CML (i.e., chronic phase only); **AND**
  - Patient had a stable molecular response (MR4; *BCR-ABL1* ≤0.01% IS) for ≥ 2 years (as documented on ≥ 4 tests performed ≥ 3 months apart); **AND**
  - Patient has quantifiable *BCR-ABL1* transcripts; **AND**
  - Patient can meet the ongoing monitoring requirements after discontinuation

CORE FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myeloid Leukemia (CML)**

- Patient is at least 1-year old; **AND**
- ***For Core Formulary: For brand Gleevec® for CML, for new starts only: patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic imatinib*** (***following the NCCN guidelines surrounding genetic mutations)***
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has Philadelphia chromosome-positive (Ph+) or *BCR-ABL1* positive disease

Diagnosis of **Adult Acute Lymphoblastic Leukemia (ALL)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has Philadelphia chromosome-positive (Ph+) disease

Diagnosis of **Pediatric Acute Lymphoblastic Leukemia (ALL)**

- Patient is 1 year of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has Philadelphia chromosome-positive (Ph+) B-ALL; **OR**
- Patient has relapsed or refractory T-ALL with ABL-class translocation

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Myelodysplastic/Myeloproliferative Disease (Such as Chronic Myelomonocytic Leukemia) (MDS/MPD)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has platelet-derived growth factor receptor beta (PDGFRβ) gene rearrangements with 5q31-33 translocations or t(5;12) translocations

Diagnosis of **Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)**

- Patient is 18 years of age or older**; AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

Diagnosis of **Dermatofibrosarcoma Protuberans (DFSP)**

- Patient is 18 years of age or older**; AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

  Note: Tumors lacking the t(17;22) translocation may not respond to imatinib

Diagnosis of **Aggressive Systemic Mastocytosis (ASM)**

- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient is 18 years of age or older; **AND**
  - Eosinophilia is present with FIP1L1-PDGFRA fusion gene; **OR**
  - Patient does not have the D816V c-Kit mutation

  Note: If c-Kit mutational status is unknown; coverage is provided for 3 months only (renewal will only be considered after determination of c-Kit mutational status).

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

Diagnosis of **Cutaneous Melanoma**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has an activating KIT mutation as detected by a CLIA- or CAP-compliant diagnostic test (e.g., FISH)

Diagnosis of **Desmoid Tumors (aggressive fibromatosis)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

Diagnosis of **Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumors (PVNS/TGCT)**

- Patient is 18 years of age or older**; AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

Diagnosis of **Chordoma**

- Patient is 18 years of age or older; **AND**
- Patient has conventional or chondroid chordoma; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **AIDS-Related Kaposi Sarcoma**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.)

Diagnosis of **Chronic Graft Versus Host Disease (GVHD)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has steroid-refractory chronic GVHD after hematopoietic cell transplantation

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Gene**

- Patient is 18 years of age or older**; AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has eosinophilia and FIP1L1-PDGFRA, PDGFRB, or ABL1 gene rearrangement

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hematologic toxicity (e.g., anemia, neutropenia, thrombocytopenia), severe hepatotoxicity, severe congestive heart failure and left ventricular dysfunction, edema and severe fluid retention, hemorrhage, gastrointestinal perforation, bullous dermatologic reactions, tumor lysis syndrome, renal toxicity, hypereosinophilic cardiac toxicity, hypothyroidism, growth retardation in children and adolescents, etc; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Patient has been adherent to therapy; **AND**

Chronic GVHD only:

- Response to therapy with an improvement in one or more of the following:
  - Clinician assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score)
  - Patient-reported symptoms (e.g., Lee Symptom Scale)

Aggressive Systemic Mastocytosis (ASM) only:

- Patientdoes not have the D816V c-Kit mutation

Chronic Myelogenous Leukemia (CML) only:

- Treatment response as indicated by one of the following *BCR-ABL1* (IS) transcript levels:
  - ≤ 10% at 3 months; **OR**
  - ≤ 10% at 6 months; **OR**
  - ≤ 1% at 12 months

Note: cytogenetic assessment of response may be used if quantitative RT-PCR (QPCR) using International Scale (IS) for *BCR-ABL1* is not available

Acute Lymphoblastic Leukemia (ALL) only:

- Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH
- Note: Patients meeting all of the following criteria may be candidates for discontinuation provided they received counseling on, and have consented to, the risks (including TKI withdrawal) and benefits of stopping TKI therapy:
  - Patient is 18 years or older; **AND**
  - Patient has received TKI therapy for ≥ 3 years; **AND**
  - Patient has no history of accelerated or blast phase CML (i.e., chronic phase only); **AND**
  - Patient had a stable molecular response (MR4; *BCR-ABL1* ≤0.01% IS) for ≥ 2 years (as documented on ≥ 4 tests performed ≥ 3 months apart); **AND**
  - Patient has quantifiable *BCR-ABL1* transcripts; **AND**
  - Patient can meet the ongoing monitoring requirements after discontinuation

GOUT AGENTS

Length of Authorization:	1 year
Initiative:	MNC: Gout Agents (IE 2462 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

Uloric and generic febuxostat may be approved if **one** of the following is true:

- If there has been a therapeutic failure of allopurinol.

Mitigare may be approved if **one** of the following is true:

- If there has been a therapeutic failure of generic colchicine.

CLINICAL CRITERIA FOR INITIAL APPROVAL

GLOPERBA

- Patient is 18 years old or older; **AND**
- Patient has a need for prophylaxis of gout flares; **AND**
- Patient had a trial and failure, or has a contraindication or intolerance to generic colchicine tablets

RENEWAL CRITERIA:

- Patient continues to meet the above criteria; **AND**
- Patient has demonstrated clinical improvement or maintenance in response to treatment; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use.

GROWTH HORMONE

Length of Authorization:	1 year, eligible for renewal (see *Criteria for Renewal* below)
Initiative:	SPC: Growth Hormone (IE 2462 / NCPDP 75) **NOTE:** NORDITROPIN IS THE PREFERRED AGENT (PA is required)

CLINICAL CRITERIA FOR INITIAL APPROVAL FOR PEDIATRIC PATIENTS (UNDER 18)

Diagnosis of **Growth Hormone Deficiency (GHD)** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin®; AND**
- Open bony epiphyses; **AND**
- Patient has short stature as defined by height that is 2 SD or more below the mean for chronological age; **AND**
  - Patient has hypothalamic-pituitary defect (i.e. major congenital malformation, tumor, or irradiation) and a deficiency of at least one additional pituitary hormone; **OR**
  - Patient had an inadequate response to GH provocation tests on 2 separate stimulation tests as defined as a serum peak GH concentration < 10 ng/mL; **OR**
- Patient is a newborn; **AND**
  - Patient has congenital hypopituitarism with hypoglycemia; **AND**
  - Patient cannot attain a serum GH level > 5 mcg/L; **AND**
  - Patient has a deficiency of at least one additional pituitary hormone and/or the classical imaging triad (ectopic posterior pituitary and pituitary hyperplasia with abnormal stalk)

Diagnosis of **Noonan Syndrome** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin®; AND**
- Open bony epiphyses; **AND**
- Patient has a confirmed diagnosis of Noonan syndrome; **AND**
- Patient is prepubertal; **AND**
- Patient has short stature as defined by height that is 2 SD or more below the mean for chronological age

Diagnosis of **Turner Syndrome** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin®; AND**
- Open bony epiphyses; **AND**
- Diagnosis is confirmed by karyotyping; **AND**
- Patient has short stature as defined by height that is 2 SD or more below the mean for chronological age

Diagnosis of **Small for Gestational Age (SGA)** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin®; AND**
- Open bony epiphyses; **AND**
- Patient is 2 years of age or older; **AND**
- Patient failed to achieve catch-up growth by 2 to 4 years of age (i.e. obtaining a height of ≥ 3rd percentile); **AND**
- Patient has short stature as defined by height that is 2 SD or more below the mean for chronological age

Diagnosis of **Idiopathic Short Stature (ISS)** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin®; AND**
- Open bony epiphyses; **AND**
- All other causes of short stature have been excluded (i.e. renal, neoplastic, pulmonary, cardiac, gastrointestinal, immunologic, endocrine, metabolic, or any other disease than may result in short stature); **AND**
- Patient has short stature as defined by height that is 2.25 SD or more below the mean for chronological age

Diagnosis of **Prader-Willi Syndrome (PWS)** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin®; AND**
- Open bony epiphyses; **AND**
- Patient must not be severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment; **AND**
- Diagnosis is confirmed by DNA-methylation genetic analysis; **AND**
- Patient has short stature as defined by height that is 2 SD or more below the mean for chronological age

Diagnosis of **Short Stature Homeobox-Containing Gene (SHOX) Deficiency** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin®; AND**
- Open bony epiphyses; **AND**
- Diagnosis is confirmed by molecular or genetic analysis; **AND**
- Patient has short stature as defined by height that is 2 SD or more below the mean for chronological age

Diagnosis of **Growth Failure Secondary to Chronic Kidney Disease (CKD)** **(Pediatric Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin®; AND**
- Open bony epiphyses; **AND**
- Patient has evidence of growth impairment as defined by one of the following:
  - Patient has short stature as defined height velocity Z-score is < -1.88; **OR**
  - Height velocity for age is less than the 3rd percentile that persists beyond 3 months; **AND**
- eGFR < 75 mL/min/1.73 m^2

CLINICAL CRITERIA FOR RENEWAL FOR PEDIATRIC PATIENTS (UNDER 18)

- **Patient must have a documented failure, contraindication, intolerance, or ineffective response with trial of Norditropin®; AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include increased risk of neoplasms, intracranial hypertension, pancreatitis, glucose intolerance/development of diabetes mellitus, hypothyroidism, hypoadrenalism, severe hypersensitivity, fluid retention, slipped capital femoral epiphysis in pediatric patients, progression of preexisting scoliosis in pediatric patients, lipoatrophy, etc.; **AND**
- Patient has shown a beneficial response to treatment as evidenced by one or more of the following:
  - Improvement in height compared to pre-treatment baseline
  - Improvement in growth velocity compared to pre-treatment baseline

CLINICAL CRITERIA FOR INITIAL APPROVAL FOR ADULT PATIENTS (18+)

Diagnosis of **Growth Hormone Deficiency (GHD)** **(Adult Patient)**

- Other causes of growth failure must be ruled out (e.g., malnutrition, hypothyroidism, hypocortisolism); **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accentual trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin®; AND**
- Patient has organic GHD with ≥ 3 documented pituitary hormone deficiencies and low serum IGF-1 levels (< -2.0 standard deviation score [SDS]); **OR**
- Patient has organic GHD with ≤ 2 documented pituitary hormone deficiencies, low serum IGF-1 levels (< 0 SDS), and deficient GH levels; **OR**
- Patient has a history of one of the following: hypothalamic-pituitary tumors, surgery, cranial irradiation, empty sella, pituitary apoplexy, traumatic brain injury, subarachnoid hemorrhage, autoimmune hypophysitis, or Rathke's cleft cyst; **AND**
  - Patient has high clinical suspicion of GHD; **AND**
  - Patient has low serum IGF-1 levels (< 0 SDS); **AND**
  - Patient has deficient GH levels ; **OR**
- Patient is in transition from child-onset GHD; **AND**
  - Patient has organic GHD or congenital and/or genetic hypothalamic-pituitary defects with ≥ 3 documented pituitary hormone deficiencies and low serum IGF-1 levels (< -2.0 SDS); **OR**
  - Patient has organic GHD with ≤ 2 documented pituitary hormone deficiencies, low serum IGF-1 levels (< 0 SDS), and deficient GH levels; **OR**
  - Patient has idiopathic isolated childhood GHD or suspected hypothalamic GHD; **AND**
    - Patient has high clinical suspicion of GHD; **AND**
    - Patient has low serum IGF-1 levels (< 0 SDS); **AND**
    - Patient has deficient GH levels

Examples of Organic, Congenital, or Genetic Hypothalamic Pituitary Defects
Organic
• Suprasellar mass with previous surgery and cranial irradiation
Congenital/Genetic
• Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2) • GHRH receptor-gene defects • GH-gene defects • GH-receptor/post-receptor defects • Associated with brain structural defects • Single central incisor • Cleft lip/palate • Perinatal insults

Examples of Pituitary Hormones
• Adrenocorticotropic hormone (ACTH) • Antidiuretic hormone (ADH) • Follicle stimulating hormone (FSH) • Growth hormone (GH) • Luteinizing hormone (LH) • Thyroid stimulating hormone (TSH) • Prolactin

Adult GH Deficiency Determination/Testing
• Patient has deficient GH levels as confirmed by any one of the following tests: – Insulin tolerance test (ITT): < 5 mcg/L; **OR** – Macimorelin-stimulation test: < 2.8 mcg/L; **OR** – Glucagon-stimulation test: • ≤ 3 mcg/L for patients with BMI < 25 kg/m^2 • ≤ 3 mcg/L for patients with BMI 25-30 kg/m^2 with a high pre-test probability • ≤ 1 mcg/L for patients with BMI 25-30 kg/m^2 with a low pre-test probability • ≤ 1 mcg/L for patients with BMI > 30 kg/m^2

CLINICAL CRITERIA FOR RENEWAL FOR ADULT PATIENTS (18+)

- **Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Norditropin**; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include increased risk of neoplasms, intracranial hypertension, pancreatitis, glucose intolerance/development of diabetes mellitus, hypothyroidism, hypoadrenalism, severe hypersensitivity, fluid retention, slipped capital femoral epiphysis in pediatric patients, progression of preexisting scoliosis in pediatric patients, lipoatrophy, etc.; **AND**
- Patient has shown a beneficial response to treatment as evidenced by at least one of the following:
  - Improvement in quality of life based on Quality of Life in Adult Growth Hormone Deficiency Assessment (QoL-AGHDA)
  - Objective improvements in biochemistry, body composition, or bone mineral density

DRUG-SPECIFIC INFORMATION

SEROSTIM®

Diagnosis of **HIV Diagnosis with Wasting or Cachexia**

- Patient is at least 18 years old; **AND**
- Patient is receiving concomitant antiretroviral therapy; **AND**
- Patient does not have acute critical illness due to complications following surgery, accidental trauma, or acute respiratory failure; **AND**
- Patient does not have the presence of any active pre-existing malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- Patient has documented HIV infection or AIDS; **AND**
- Failure of at least one alternative appetite stimulant therapy (e.g., corticosteroids, dronabinol, megestrol, cyproheptadine); **AND**
  - Documented 10% unintentional weight loss compared to baseline body weight; **OR**
  - Documented body mass index (BMI) < 20 kg/m^2 that cannot be attributed to any condition other than HIV infection; **OR**
  - Documented 5% unintentional weight loss over 6 months persisting for at least 1 year
- Approval is for 6 months

RENEWAL FOR SEROSTIM®

- Adequate documentation of disease stability and/or improvement with treatment (i.e., Greater than or equal to 2% increase in body weight and/or BCM); **AND**
- Absence of unacceptable toxicity from the drug (e.g., intracranial hypertension, severe fluid retention/carpal tunnel syndrome, pancreatitis, impaired glucose tolerance/diabetes, development of neoplasms, serious hypersensitivity reactions, lipoatrophy)

ZORBTIVE

Diagnosis of **treatment of short bowel syndrome**

- Patient is at least 18 years of age; **AND**
- Patient does not have an active malignancy; **AND**
- Patient does not have acute critical illness due to complications following open heart surgery, abdominal surgery, multiple accidental trauma, or acute respiratory failure; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- Patient must currently be dependent on intravenous parenteral nutrition for nutritional support
- Approval is for 4 weeks only and is not eligible for renewal

HALAVEN® (ERIBULIN)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has metastatic disease ; **AND**
  - Used as a single agent for patients who have previously received at least two chemotherapy regimens for the treatment of metastatic disease; **AND**
  - Prior therapy includes treatment with an anthracycline and a taxane in either the adjuvant or metastatic setting; **OR**
- Patient has recurrent or metastatic disease; **AND**
  - Used as a single agent for human epidermal growth factor receptor 2 (HER2)-negative disease and one of the following:
    - Disease is hormone receptor negative; **OR**
    - Disease is hormone receptor positive with visceral crisis or refractory to endocrine therapy; **OR**
  - Used in combination with trastuzumab for HER2-positive disease

Diagnosis of **Liposarcoma**

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Patient has unresectable metastatic or recurrent disease; **AND**
- Patient has received prior anthracycline-based therapy (e.g., doxorubicin)

Diagnosis of **Soft Tissue Sarcoma (STS)**

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Patient has been diagnosed with one of the following types of STS**:**
  - Angiosarcoma; **AND**
    - Used as palliative therapy
  - Pleomorphic rhabdomyosarcoma; **AND**
    - Used as subsequent therapy for advanced or metastatic disease
  - Retroperitoneal/Intra-abdominal; **AND**
    - Used as palliative subsequent therapy for recurrent unresectable or stage IV disease
  - Extremity/body wall, head/neck; **AND**
    - Used as palliative subsequent therapy for advanced or metastatic disease with disseminated metastases
  - Solitary fibrous tumor

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by lack of disease progression, improvement in tumor size and/or improvement in patient symptoms; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe QT-prolongation, severe neutropenia [ANC < 500/m^3], peripheral neuropathy)

HEALTHCARE REFORM COVERAGE OF CONTRACEPTIVES

Length of Authorization:	12 months
Initiative:	ADM: A drugs (IE 2462 / NCPDP 75)

ADMINISTRATIVE CRITERIA

- The patient is using the medication for contraception; **AND**
- The patient demonstrates failure, contraindication, or intolerance to at least 3 (if 3 exists) from the zero-cost sharing alternatives of the same chemical entity; **AND**
- The patient demonstrates failure, contraindication, or intolerance to at least **two** zero-cost sharing contraceptives including one medication from each of two additional chemical entities or other contraceptive methods.

Note: A chemical entity is considered the same estrogen/progesterone combination though the ratios of active medications may vary.

HEMATOPOEITIC AGENTS

Length of Authorization:	Non-ESRD: 45 days, may be renewed ESRD on Dialysis: 12 months, may be renewed Reduction of Allogeneic Blood Transfusions in Elective, Non-Cardiac, Non-Vascular Surgery: Coverage may not be renewed.
Initiative:	SPC: Hematopoietic Agents (IE 2462 / NCPDP 75)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

ARANESP

Aranesp covered for the following indications:

- **Anemia Secondary to Myelodysplastic Syndrome (MDS)**
  - Patient is 18 years of age or older; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
  - Patient has lower risk disease (i.e., defined as IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]); **AND**
  - Patient has symptomatic anemia
- **Anemia Secondary to Myeloproliferative Neoplasms (MPN) - Myelofibrosis**
  - Patient is 18 years of age or older; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Endogenous serum erythropoietin level of ≤ 500 mUnits/mL

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

ARANESP *(CONTINUED)*

- **Anemia Secondary to Chemotherapy Treatment**
  - Patient is 18 years of age or older; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient is receiving concomitant myelosuppressive chemotherapy; **AND**
  - Patient's chemotherapy is not intended to cure their disease (i.e., palliative treatment); **AND**
  - There is a minimum of two additional months of planned chemotherapy
- **Anemia Secondary to Chronic Kidney Disease (Non-Dialysis Patients)**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30%; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient is one month or older
- **Anemia Secondary to Chronic Kidney Disease (dialysis patients)**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30%; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient age is 1 month or older

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

PROCRIT/EPOGEN

Procrit/Epogen covered for the following indications:

- **Anemia Secondary to Myelodysplastic Syndrome (MDS)**
  - Patient is 18 years of age or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal); **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
  - Patient has lower risk disease (i.e., defined as IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]); **AND**
  - Patient has symptomatic anemia; **AND**
  - **Standard, Precision/Plus, Core or Enhanced:** Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of Aranesp or Retacrit; **OR**
  - Patient continuing treatment with Epogen/Procrit
- **Anemia Secondary to Myeloproliferative Neoplasms (MPN) - Myelofibrosis**
  - Patient is 18 years of age or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*****; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
  - Endogenous serum erythropoietin level of < 500 mUnits/mL

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

PROCRIT/EPOGEN *(CONTINUED)*

- **Anemia Secondary to Chemotherapy Treatment**
  - Patient is 5 years of age or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*****; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient is receiving concomitant myelosuppressive chemotherapy; **AND**
  - Patient's chemotherapy is not intended to cure their disease (i.e., palliative treatment); **AND**
  - There is a minimum of two additional months of planned chemotherapy; **AND**
  - **Standard, Precision/Plus, Core or Enhanced:** Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of Aranesp or Retacrit; **OR**
  - Patient continuing treatment with Epogen/Procrit
- **Anemia Secondary to Chronic Kidney Disease (Non-Dialysis Patients)**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*****; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient is 1 month or older; **AND**
  - **Standard, Precision/Plus, Core or Enhanced:** Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of Aranesp or Retacrit; **OR**
  - Patient continuing treatment with Epogen/Procrit
- **Anemia secondary to chronic kidney disease (dialysis patients)**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Prior to initiation of therapy, patient should have adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20%*****; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient is 1 month or older; **AND**
  - **Standard, precision/plus, core or Enhanced:** Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of Aranesp or Retacrit; **OR**
  - Patient continuing treatment with Epogen/Procrit

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

PROCRIT/EPOGEN *(CONTINUED)*

- **Anemia Secondary to Zidovudine-Treated, HIV-Infected Patients**
  - Patient is 8 months or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*****; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient is receiving zidovudine administered at ≤ 4200 mg/week; **AND**
  - Endogenous serum erythropoietin level of ≤ 500 m Units/mL
- **Reduction of Allogeneic Blood Transfusions in Elective, Non-Cardiac, Non-Vascular Surgery**
  - Patient is 18 years of age or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*****; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Hemoglobin (Hb) > 10 g/dL and ≤ 13 g/dL and/or Hematocrit (Hct) > 30% and ≤ 39%; **AND**
  - Patient is at high-risk of blood-loss from surgery that is elective, non-cardiac and non-vascular; **AND**
  - Patient is unwilling or unable to participate in an autologous blood donation program prior to surgery

RETACRIT

Retacrit covered for the following indications:

- **Anemia Secondary to Myelodysplastic Syndrome (MDS)**
  - Patient is 18 years of age or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*****; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
  - Patient has lower risk disease (i.e., defined as IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]); **AND**
  - Patient has symptomatic anemia

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

RETACRIT *(CONTINUED)*

- **Anemia Secondary to Myeloproliferative Neoplasms (MPN) - Myelofibrosis**
  - Patient is 18 years of age or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*****; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
  - Endogenous serum erythropoietin level of < 500 mUnits/mL
- **Anemia Secondary to Chemotherapy Treatment**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal) *****; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient is 5 years of age or older; **AND**
  - Patient is receiving concurrent myelosuppressive chemotherapy; **AND**
  - Patient's chemotherapy is not intended to cure their disease (i.e., palliative treatment); **AND**
  - There is a minimum of two additional months of planned chemotherapy
- **Anemia Secondary to Chronic Kidney Disease (Non-Dialysis Patients)**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*****; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Patient is 1 month or older; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

RETACRIT *(CONTINUED)*

- **Anemia Secondary to Chronic Kidney Disease (dialysis patients)**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*****; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
  - Patient is 1 month or older; **AND**
  - Patient does not have uncontrolled hypertension
- **Anemia Secondary to Zidovudine-Treated, HIV-Infected Patients**
  - Patient is 8 months or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*****; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Endogenous serum erythropoietin level of ≤ 500 mUnits/mL; **AND**
  - Patient is receiving zidovudine administered at ≤ 4200 mg/week
- **Reduction of Allogeneic Blood Transfusions in Elective, Non-Cardiac, Non-Vascular Surgery**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*****; **AND**
  - Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30% (unless otherwise specified); **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
  - Hemoglobin (Hb) >10 g/dL and ≤13 g/dL and/or Hematocrit (Hct) >30% and ≤39%; **AND**
  - Patient is at high-risk of blood-loss from surgery that is elective, non-cardiac and non-vascular; **AND**
  - Patient is unwilling or unable to participate in an autologous blood donation program prior to surgery

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

MIRCERA

Approval is for 1 year and may be renewed

- Anemia Secondary to Chronic Kidney Disease Adults (18 years or older) receiving dialysis; **OR**
- Pediatric patients (5 years or older); **AND**
  - Patient is receiving hemodialysis; **AND**
  - Patient is converting from another erythropoiesis stimulating agent (ESA) after their hemoglobin was stabilized
- Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
- Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal); **AND**
- Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30%; **AND**
- Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency) have been ruled out; **AND**
- Patient does not have uncontrolled hypertension; **AND**
- **Standard, Precision/Plus, Core or Enhanced:** Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of **Aranesp or Retacrit**; **OR**
- Patient continuing treatment with Mircera

Approval is for 45 days and may be renewed

- **Anemia secondary to chronic kidney disease (adult non-dialysis patients)**
  - Patient is 18 years or older; **AND**
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
  - Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal); **AND**
  - Initiation of therapy hemoglobin (Hb) < 10 g/dL and/or Hematocrit (HCT) < 30%; **AND**
  - Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out; **AND**
  - Patient does not have uncontrolled hypertension; **AND**
- **Standard, Precision/Plus, Core or Enhanced:** Patient must have a documented failure, contraindication, or intolerance or ineffective response with minimum 3-month trial of **Aranesp or Retacrit**; **OR**
- Patient continuing treatment with Mircera

CLINICAL CRITERIA FOR RENEWAL

Coverage can be renewed based upon the following criteria:

- Previous dose was administered within the past 60 days(otherwise follow "Initial" criteria); **AND**
- Anemia response compared to pretreatment baseline; **AND**
- Absence of unacceptable toxicity from the drug.
  - Examples of unacceptable toxicity for Aranesp include: pure red cell aplasia, severe allergic reactions (anaphylaxis, angioedema, bronchospasm, etc.), severe cardiovascular events (stroke, myocardial infarction, congestive heart failure, thromboembolism, etc.), uncontrolled hypertension, seizures, increased risk of tumor progression/recurrence in patients with cancer, severe cutaneous reactions (erythema multiforme, Stevens-Johnson Syndrome [SJS]/Toxic Epidermal Necrolysis [TEN], etc.), etc.
  - Examples of unacceptable toxicity for Epogen, Procrit and Retacrit include: severe cardiovascular events (stroke, myocardial infarction, congestive heart failure, thromboembolism, etc.), uncontrolled hypertension, increased risk of tumor progression/ recurrence in patients with cancer, seizures, pure red cell aplasia, serious allergic reactions (anaphylaxis, angioedema, bronchospasm, etc.), severe cutaneous reactions (erythema multiforme, Stevens-Johnson Syndrome [SJS]/Toxic Epidermal Necrolysis [TEN], etc.), "gasping syndrome" (central nervous system depression, metabolic acidosis, gasping respirations) due to benzyl alcohol preservative, etc.; **AND**
  - **Anemia Secondary to Myelodysplastic Syndrome** (MDS):
    - Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (HCT) < 36%
  - **Anemia Secondary to Myeloproliferative Neoplasms-- Myelofibrosis**
    - Hemoglobin (Hb) < 10g/dL and/or Hematocrit (HCT) < 30%
  - **Reduction of Allogeneic Blood Transfusions in Elective, Non-Cardiac, Non-Vascular Surgery**
    - Coverage may not be renewed
  - **Anemia Secondary to Chemotherapy Treatment**
    - Refer to initial criteria
  - **Anemia Secondary to Zidovudine Treated, HIV-Infected Patients**:
    - Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (HCT) < 36%
    - Patient is receiving zidovudine administered at ≤ 4200 mg/week
  - **Anemia Secondary to Chronic Kidney Disease (dialysis and non-dialysis):**
    - Pediatric patients: Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (HCT) < 36%
    - Adults: Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (HCT) < 33%
  - **All other indications:**
    - Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (HCT) < 33%

Omontys:

Only approve for patients with CKD (chronic kidney disease) receiving dialysis///VOLUNTARY RECALL 02/24/2012

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

- Symptoms of severe anemia include extreme weakness and fatigue, cold intolerance, tachycardia (rapid heartbeat), pulmonary distress, hypotension, angina, and congestive heart failure

HEPATITIS B THERAPY: INJECTABLE

Length of Authorization:	48 weeks **total,** **not eligible for renewal**
Initiative:	SPC: Antivirals: Hepatitis (IE 2462 / NCPDP 75)

CLINICAL CRITERIA APPLY

See specific criteria if request is for DUAL HCV THERAPY, for ***HCV THERAPY***, or for ***SOVALDI THERAPY***. The criteria below are related to use *for Hepatitis B only*.

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Hepatitis B *without* Cirrhosis – HBeAg *positive***

- Documented HBeAg positive for at least 6 months; **AND**
- Patient is 12 years of age and older; **AND**
- Documented HBsAg positive for at least 6 months; **AND**
- Patient without decompensated liver disease; **AND**
- Documented evidence of active virus replication (HBV DNA level > 20,000 IU/mL); **AND**
- Documented evidence of active liver disease demonstrated by **one** of the following:
  - Persistent elevation in serum ALT 2 times Upper Limits of Normal (ULN)
  - Moderate to severe hepatitis or fibrosis on biopsy;
  - Necroinflammation on biopsy
  - Evidence of icteric ALT flares

Diagnosis of **Chronic Hepatitis B *without* Cirrhosis – HBeAg *negative***

- Documented HBeAg negative; **AND**
- Patient is 12 years of age and older; **AND**
- Documented HBsAg positive for at least 6 months; **AND**
- Documented HBV DNA level ≥ 2000 IU/mL; **AND**
- Documented evidence of active liver disease demonstrated by **one** of the following:
  - Persistent elevation in serum ALT 2 times Upper Limits of Normal (ULN)
  - Moderate to severe hepatitis or fibrosis on biopsy;
  - Necroinflammation on biopsy
  - Evidence of icteric ALT flares

Diagnosis of **Chronic Hepatitis B *with* Compensated Cirrhosis**

- Patient has compensated cirrhosis; **AND**
- Patient is 12 years of age and older; **AND**
- Documented HBsAg positive for at least 6 months; **AND**
- Persistent elevation in serum ALT 2 times Upper Limits of Normal (ULN); **or** Documented HBV DNA level ≥ 2000 IU/Ml

HEPATITIS B THERAPY: ORAL

Length of Authorization:	1 year **eligible for renewal**
Initiative:	SPC: Antivirals (IE 2462 / NCPDP 75)

CLINICAL CRITERA FOR INITIAL APPROVAL

Diagnosis of **Chronic Hepatitis B without cirrhosis *(including patients also co-infected with hepatitis C)*—HBeAg POSITIVE**

- Patient is 2 years of age and older for Baraclude, 12 years of age or older for Hepsera, 16 years of age or older for Tyzeka; **AND**
- Patient has been evaluated and screened for the presence of human immunodeficiency virus (HIV) prior to initiating treatment; **AND**
- Medication is prescribed by or in consultation with an infectious disease physician, gastroenterologist, hepatologist, oncologist or a transplant physician; **AND**
- Patient will not receive concurrent treatment with products containing tenofovir disoproxil fumarate or tenofovir alafenamide (i.e., Viread or Vemlidy) **For Hepsera**; **AND**
- Documented HBeAg positive; **AND**
- Documented HBsAg positive for at least 6 months; **AND**
- Evidence of active virus replication (HBV DNA level > 20,000 IU/mL); **AND**
- Documented evidence of immune-active liver disease demonstrated by **ONE** of the following:
  - Persistent elevation in serum ALT ≥ 2 times Upper Limits of Normal (ULN) [ULN is defined as an ALT of 35 U/L for males and 25 U/L for females]
  - Moderate to severe fibrosis (F2 or higher)
  - Moderate to severe necroinflammation (A2 or higher)

Diagnosis of **Chronic Hepatitis B without cirrhosis *(including patients also co-infected with hepatitis C)*—HBeAg NEGATIVE**

- Patient is 2 years of age and older for Baraclude, 12 years of age or older for Hepsera, 16 years of age or older for Tyzeka; **AND**
- Patient has been evaluated and screened for the presence of human immunodeficiency virus (HIV) prior to initiating treatment; **AND**
- Medication is prescribed by or in consultation with an infectious disease physician, gastroenterologist, hepatologist, oncologist or a transplant physician; **AND**
- Patient will not receive concurrent treatment with products containing tenofovir disoproxil fumarate or tenofovir alafenamide (e.g., Viread or Vemlidy) **For Hepsera**; **AND**
- Documented HBeAg negative; **AND**
- HBV DNA level ≥ 2000 IU/mL; **AND**
- Documented evidence of immune-active liver disease demonstrated by **ONE** of the following:
  - Persistent elevation in serum ALT ≥ 2 times Upper Limits of Normal (ULN) [ULN is defined as an ALT of 35 U/L for males and 25 U/L for females]
  - Moderate to severe fibrosis (F2 or higher)
  - Moderate to severe necroinflammation (A2 or higher)

CLINICAL CRITERA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Chronic Hepatitis B with Compensated or Decompensated Cirrhosis *(including patients also co-infected with hepatitis C)***

- Patient is 2 years of age and older for Baraclude, 12 years of age or older for Hepsera, 16 years of age or older for Tyzeka; **AND**
- Medication is prescribed by or in consultation with an infectious disease physician, gastroenterologist, hepatologist, oncologist or a transplant physician; **AND**
- Patient will not receive concurrent treatment with products containing tenofovir disoproxil fumarate or tenofovir alafenamide (e.g., Viread or Vemlidy) **For Hepsera**; **AND**
- Patient has been evaluated and screened for the presence of human immunodeficiency virus (HIV) prior to initiating treatment; **AND**
- Patient has compensated or decompensated cirrhosis; **AND**
- Documented HBsAg positive for at least 6 months; **AND**
- Documented HBV DNA level ≥ 2000 IU/mL

Diagnosis of **Hepatitis B - Liver Transplant:**

- Patient is 2 years of age and older for Baraclude, 12 years of age or older for Hepsera, 16 years of age or older for Tyzeka; **AND**
- Patient has been evaluated and screened for the presence of human immunodeficiency virus (HIV) prior to initiating treatment; **AND**
- Medication is prescribed by or in consultation with an infectious disease physician, gastroenterologist, hepatologist, oncologist or a transplant physician; **AND**
- Patient will not receive concurrent treatment with products containing tenofovir disoproxil fumarate or tenofovir alafenamide (e.g., Viread or Vemlidy) **For Hepsera**; **AND**
- Patient is a documented HBsAg-positive pre-transplant; **OR**
- Patient is a HBsAg-negative recipient of a HBsAg-negative but anti-HBc-positive graft

Diagnosis of **HBV carriers currently on cancer chemotherapy or immunosuppressive therapy (For Baraclude only):**

- Patient is 2 years of age and older for Baraclude; **AND**
- Patient has been evaluated and screened for the presence of human immunodeficiency virus (HIV) prior to initiating treatment; **AND**
- Medication is prescribed by or in consultation with an infectious disease physician, gastroenterologist, hepatologist, oncologist or a transplant physician; **AND**
- Patient is carrier of HBV as confirmed by documented HBsAg-positive and anti-HBc-positive tests prior to starting cancer chemotherapy or immunosuppressive therapy; **AND**
- Patient has baseline HBV DNA level < 2,000 IU/mL

Note: Patients that are HBsAg-negative and anti-HBc-positive are at lower risk of HBV reactivation and may be monitored and treated with on-demand antiviral therapy at the first sign of HBV reactivation.

CLINICAL CRITERA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Chronic Hepatitis B in patients co-infected with HIV (For Baraclude only):**

- Patient is 2 years of age and older for Baraclude; **AND**
- Patient has been evaluated and screened for the presence of human immunodeficiency virus (HIV) prior to initiating treatment; **AND**
- Medication is prescribed by or in consultation with an infectious disease physician, gastroenterologist, hepatologist, oncologist or a transplant physician; **AND**
- Patient is unable to receive tenofovir; **AND**
- Used in combination with a highly active anti-retroviral therapy (HAART) that includes either lamivudine or emtricitabine

CLINICAL CRITERIA FOR RENEWAL

Coverage can be renewed based upon the following criteria:

- Patient has not experienced viral breakthrough; **AND**
- Absence of unacceptable toxicity from the drug (e.g., nephrotoxicity; lactic acidosis, and severe hepatomegaly with steatosis); **AND**
- Patient has decompensated cirrhosis or is post liver transplant; **OR**
- (For Baraclude only) **Currently on Chemotherapy/Immunosuppressive Therapy with baseline HBV DNA level < 2,000 IU/mL**:
  - Patient is continuing prophylactic HBV treatment while receiving concurrent chemotherapy or immunosuppressive therapy; **OR**
  - Patient will continue to receive prophylactic HBV treatment for at least 6 months after completion of chemotherapy or immunosuppressive therapy **OR**
- **HBeAg Positive Only**:
  - Confirmation patient has **not** achieved HbeAg seroconversion to anti-Hbe; **OR**
  - Patient is HbsAg positive; **OR**
  - Patient has **not** completed at least 12 months of additional treatment after achievement of persistently normal ALT and undetectable HBV-DNA levels; **OR**
- **HBeAg Negative Only**:
  - Confirmation patient has **not** achieved loss of HBsAg; **OR**
  - Patient has elevated ALT and/or HBV DNA level ≥ 2000 IU/mL; **OR**
- **HIV Co-infection only**—Baraclude: Patient will continue on a HAART regimen

HEPATITIS B THERAPY: VEMLIDY®

Length of Authorization:	6 months initial, 1 year renewal
Initiative:	SPC: Antivirals (IE 2462 / NCPDP 75)

CLINICAL CRITERA FOR INITIAL APPROVAL

- Be 18 years old or older; **AND**
- Have diagnosis of hepatitis B virus; **AND**
- Not concurrently be using any of the following P-gp inducers: oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, or St. John's wort; **AND**
- Not have decompensated liver disease; **AND**
- Not be taking concurrent tenofovir disoproxil fumarate (Viread); **AND**
- Not be human immunodeficiency virus (HIV)-1 positive and using TAF as monotherapy (must have additional antiviral therapy if HIV-1 positive for coverage of both disease states); **AND**
- Patient has an ineffective response to previous therapy with entecavir/Baraclude unless there is a contraindication or intolerance (e.g., resistance to lamivudine pregnancy, HIV-coinfection)
  - Lamivudine resistant patients have higher rates of resistance to entecavir than to tenofovir (AASLD guidelines state tenofovir is preferred in this population)
  - tenofovir category B; entecavir category C (AASLD recommends tenofovir over entecavir in this population)
  - HIV-coinfection: more data with tenofovir

DOSING INFORMATION

- Be prescribed a dose of 1 tablet once daily and patient is *not* currently using carbamazepine; **OR**
- Be prescribed a dose of 2 tablets once daily and patient is currently using carbamazepine.

HEPATITIS C – EPCLUSA® AND SOFOSBUVIR/VELPATASVIR

Length of Authorization:	Varies, see below
Initiative:	SPC: Antivirals Hepatitis (IE 2462 / NCPDP 75)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

LENGTH OF AUTHORIZATION/QUANTITY LIMIT

Length of Authorization

- Approval is to be entered for full length of therapy
- Enter accurate number of occurrences

12 weeks	– All other indications
24 weeks	– Decompensated cirrhosis (Child-Pugh B or C) and ribavirin ineligible – Decompensated cirrhosis (Child-Pugh B or C) in combination with ribavirin with prior sofosbuvir- or NS5A inhibitor-based regimen – Post liver transplant and treatment-experienced with decompensated cirrhosis

Quantity Limit

- One tablet daily

CLINICAL CRITERIA FOR APPROVAL

Diagnosis of **Hepatitis C**

- Patient 3 years of age or older; **AND**
- Prescriber must have consulted with or be a gastroenterologist, hepatologists, or an infectious disease physician

Core: For any non-preferred agent (Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Technivie, Viekira, Zepatier), patient must step through ALL preferred agents: ledipasvir/sofosbuvir, Mavyret, sofosbuvir/velpatasvir, and Vosevi

SUBSTANCE ABUSE

- It is recommended that the patient be evaluated for current history of substance and/or alcohol abuse with validated screening instruments such as Alcohol Use Disorders Identification Test (AUDIT C) or CAGE alcohol screen, or NIDA's drug screening tool.
- If patient has a recent prior history, within the past 6 months, of substance or alcohol abuse, it is recommended to:
  - Have the patient participate (if not already completed) in a recovery program, receive substance or alcohol abuse counseling services, or see an addiction specialist as part of HCV treatment.

DISEASE SEVERITY/RISK FOR COMPLICATIONS

- Effective 10/01/2016, disease severity (as measured by fibrosis score) will no longer be a requirement for approval. Sovaldi will be covered for patients with Metavir F0-F4.

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

- Patient will not receive concurrent treatment with any of the following anti-hepatitis, anti-viral drugs: ledipasvir/sofosbuvir (Harvoni®), glecaprevir/pibrentasvir (Mavyret®), sofosbuvir (Sovaldi®), sofosbuvir/velpatasvir/voxilaprevir (Vosevi®), or elbasvir/grazoprevir (Zepatier®); **AND**
- Patient will avoid concomitant therapy with **all** of the following:
  - Coadministration with drugs that are inducers of P-gp and/or moderate to strong inducers of CYP2B6, CYP2C8, or CYP3A4 (e.g., rifampin, St. John's wort, carbamazepine); **AND**
  - Coadministration with amiodarone *(**NOTE: If there are no other viable treatment options and amiodarone must be used, cardiac monitoring is recommended)*; **AND**

HBV SCREENING

- Prior to initiating therapy, patient should be screened for HBV, including testing for hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc); **AND**
- Confirmation that patients with serologic evidence of HBV infection will be monitored for clinical and laboratory signs of hepatitis flare or HBV reactivation during treatment with sofosbuvir/ velpatasvir and during post-treatment follow-up

GENOTYPE-SPECIFIC INFORMATION

- Patient has a documented diagnosis of chronic hepatitis C infection; **AND**
  - Patient does not have cirrhosis or has compensated cirrhosis (Child-Pugh A); **AND**
    - Patient has genotype 1, 2, 4, 5, or 6; **AND**
      - Patient is treatment naïve or treatment-experienced with previous peginterferon/ribavirin regimen; **OR**
      - Patient is genotype 3; **AND**
        - Patient is treatment naïve (Note: Must be used with ribavirin for compensated cirrhosis **with** a NS5A RAS Y93H mutation for velpatasvir)
  - Patient has decompensated cirrhosis (Child-Pugh B or C); **AND**
    - Patient has genotype 1, 2, 3, 4, 5, or 6; **AND**
      - Used in combination with ribavirin, unless patient is ribavirin treatment ineligible (Note: Patients who have failed on previous treatment with sofosbuvir or NSA5 inhibitor-based therapy must use in combination with ribavirin); **OR**
  - Patient is post liver transplant; **AND**
    - Patient has genotype 1, 2, 3, 4, 5, or 6; **AND**
      - Patient is treatment-naïve or treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A); **OR**
      - Patient is treatment-naïve or treatment-experienced with decompensated cirrhosis (Child-Pugh B or C); **AND**
        - Used in combination with ribavirin

GENOTYPE SPECIFIC INFORMATION *(CONTINUED)*

Drug specific PI mechanism		
NS5B	**NS5A**	**NS3/4A**
– Sofosbuvir	– Elbasvir	– Grazoprevir
– Dasabuvir	– Ledipasvir	– Paritaprevir
	– Ombitasvir	– Voxilaprevir
	– Velpatasvir	– Glecaprevir
	– Pibrentasvir	

Direct-Acting Antivirals (DAA) *note: not all inclusive*	
– Epclusa	(sofosbuvir; velpatasvir)
– Harvoni	(ledipasvir; sofosbuvir)
– Mavyret	(glecaprevir; pibrentasvir)
– Sovaldi	(sofosbuvir)
– Vosevi	(sofosbuvir; velpatasvir; voxilaprevir)
– Zepatier	(elbasvir; grazoprevir)

Genotype	Standard, Precision, Enhanced Formulary Preferred Agent(s) – PA required	Standard, Precision, Enhanced Formulary Non-Preferred Agent(s) – PA required
1	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Viekira®, Sovaldi®, Zepatier®
2	Sovaldi®; Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	
3	Sovaldi® + RBV; Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Sovaldi® + Daklinza™
4	Harvoni®, ledipasvir/sofosbuvir, Sovaldi®, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Zepatier®
5	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	
6	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	

Core Formulary Preferred Agent(s) – PA required	Core Formulary Non-Preferred Agent(s) – PA required
ledipasvir/sofosbuvir, Mavyret, sofosbuvir/velpatasvir, Vosevi	Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Technivie, Viekira, Zepatier

HEPATITIS C – HARVONI® (LEDIPASVIR; SOFOSBUVIR)

Length of Authorization:	Varies, see table below
Initiative:	SPC: Antivirals: Hepatitis (IE 2462 / NCPDP 75)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

TREATMENT LENGTH/QUANTITY LIMIT

TREATMENT LENGTH

- Length of authorization FOR TREATMENT DURATION: 8, 12, or 24 weeks depending on indication.
- Approval is to be entered for the full length of therapy.
- Enter accurate number of occurrences.

8 weeks	• Genotype 1 patients without cirrhosis who are treatment-naive with pre-treatment HCV RNA < 6 million IU/mL
12 weeks	• All other indications
24 weeks	• Decompensated cirrhosis (Child-Pugh B or C) and are ribavirin ineligible • Decompensated cirrhosis (Child-Pugh B or C) in combination with ribavirin with prior sofosbuvir- or NS5A inhibitor-based regimen • Post liver transplant and treatment-experienced with decompensated cirrhosis • Pediatric genotype 1 infection, treatment-experienced with compensated cirrhosis

QUANTITY LIMIT

One ledipasvir 90 mg/sofosbuvir 400 mg tablet per day (28 tablets/28 days)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Hepatitis C**

- Prescriber must have consulted with or be a gastroenterologist, hepatologists, or an infectious disease physician.
- **Core:** For any non-preferred agent (Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Technivie, Viekira, Zepatier), patient must step through ALL preferred agents: ledipasvir/sofosbuvir, Mavyret, sofosbuvir/velpatasvir, and Vosevi

SUBSTANCE ABUSE

- It is recommended that the patient be evaluated for current history of substance and/or alcohol abuse with validated screening instruments such as Alcohol Use Disorders Identification Test (AUDIT C) or CAGE alcohol screen, or NIDA's drug screening tool.
- If patient has a recent prior history, within the past 6 months, of substance or alcohol abuse, it is recommended to:
  - Have the patient participate (if not already completed) in a recovery program, receive substance or alcohol abuse counseling services, or see an addiction specialist as part of HCV treatment.

DISEASE SEVERITY/RISK FOR COMPLICATIONS

Effective 10/01/2016: disease severity (as measured by fibrosis score) will no longer be a requirement for approval. Harvoni will be covered for patients with Metavir F0-F4.

ADDITIONAL CLINICAL FACTORS FOR CONSIDERATION

- Patient will not receive concurrent treatment with any of the following agents due to the potential for clinically significant drug interactions: carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, rifapentine, tipranavir/ritonavir, simeprevir, St. John's wort, rosuvastatin, and amiodarone (****Note**: If there are no other alternative viable treatment options and amiodarone must be used, cardiac monitoring is recommended); **AND**
- Patient will not receive concurrent treatment with any of the following anti-hepatitis, anti-viral drugs: sofosbuvir/velpatasvir (Epclusa®), glecaprevir/pibrentasvir (Mavyret®), sofosbuvir (Sovaldi®), sofosbuvir/velpatasvir/voxilaprevir (Vosevi®), or elbasvir/grazoprevir (Zepatier™)

HBV SCREENING

- Prior to initiating therapy, patient should be screened for HBV, including testing for hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc); **AND**
- Confirmation that patients with serologic evidence of HBV infection will be monitored for clinical and laboratory signs of hepatitis flare or HBV reactivation during treatment with ledipasvir/sofosbuvir and during post-treatment follow-up

GENOTYPE-SPECIFIC INFORMATION

Adults with Chronic Hepatitis C (HCV)

- Patient is 18 years or age or older; **AND**
- Patient has a documented diagnosis of chronic hepatitis C infection; **AND**
- Patient has genotype 1a/b, 4, 5, or 6 (excluding 6e); **AND**
  - Patient does not have cirrhosis or has compensated cirrhosis (Child-Pugh A); **AND**
    - Patient is treatment-naïve or treatment-experienced with previous peginterferon/ribavirin regimen; **OR**
  - Patient has decompensated cirrhosis (Child-Pugh B or C); **AND**
    - Used in combination with ribavirin, unless patient is ribavirin treatment ineligible *(Note: Patients who have failed on previous treatment with sofosbuvir or NSA5 inhibitor-based therapy must use in combination with ribavirin)*; **OR**
  - Patient is post liver transplant; **AND**
    - Patient is treatment-naïve or treatment-experienced; **AND**
      - Patient does not have cirrhosis or has compensated cirrhosis (Child-Pugh A); **OR**
      - Patient has decompensated cirrhosis (Child-Pugh B & C); **AND**
        - Used in combination with ribavirin

Pediatrics and Adolescents with Chronic Hepatitis C (HCV)

- Patient is at least 3 years of age; **AND**
- Patient has a documented diagnosis of chronic hepatitis C infection; **AND**
  - Patient does not have cirrhosis or has compensated cirrhosis (Child-Pugh A); **AND**
    - Patient has genotype 1, 4, 5, or 6; **AND**
      - Patient is treatment-naïve or treatment-experienced with previous interferon therapy; **OR**
      - Patient has prior exposure to interferon (+/- ribavirin) plus an HCV protease inhibitor regimen; **OR**
  - Patient has decompensated cirrhosis (Child-Pugh B or C) ; **AND**
      - Patient has genotype 1: **AND**
      - Patient is treatment-naïve or treatment-experienced with previous peginterferon alfa; **AND**
      - Used in combination with ribavirin; **OR**
  - Patient is post liver transplant; **AND**
    - Patient has genotype 1, or 4; **AND**
    - Used in combination with ribavirin; **AND**
    - Patient is treatment-naïve or treatment-experienced; **AND**
        - Patient does not have cirrhosis or with compensated cirrhosis (Child-Pugh A)

GENOTYPE-SPECIFIC INFORMATION *(CONTINUED)*

Drug specific PI mechanism		
NS5B – Sofosbuvir – Dasabuvir	**NS5A** – Elbasvir – Ledipasvir – Ombitasvir – Velpatasvir – Pibrentasvir	**NS3/4A** – Grazoprevir – Paritaprevir – Voxilaprevir – Glecaprevir

Direct-Acting Antivirals (DAA) *note: not all inclusive*	
– Epclusa	(sofosbuvir; velpatasvir)
– Harvoni	(ledipasvir; sofosbuvir)
– Mavyret	(glecaprevir; pibrentasvir)
– Sovaldi	(sofosbuvir)
– Vosevi	(sofosbuvir; velpatasvir; voxilaprevir)
– Zepatier	(elbasvir; grazoprevir)

Genotype	Standard, Precision, Enhanced Formulary Preferred Agent(s) – PA required	Standard, Precision, Enhanced Formulary Non-Preferred Agent(s) – PA required
1	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Viekira Pak®, Sovaldi®, Zepatier®
2	Sovaldi®; Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	
3	Sovaldi® + RBV; Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Sovaldi® + Daklinza™
4	Harvoni®, ledipasvir/sofosbuvir, Sovaldi®, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Zepatier®
5	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	
6	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	

Core Formulary Preferred Agent(s) – PA required	Core Formulary Non-Preferred Agent(s) – PA required
ledipasvir/sofosbuvir, Mavyret, sofosbuvir/velpatasvir, Vosevi	Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Technivie, Viekira, Zepatier

HEPATITIS C – MAVYRET® (GLECAPREVIR; PIBRENTASVIR)

Length of Authorization:	Varies, see table below
Initiative:	SPC: Antivirals: Hepatitis (IE 2462 / NCPDP 75)

TREATMENT LENGTH/QUANTITY LIMIT

TREATMENT LENGTH

- Length of authorization FOR TREATMENT DURATION: 8, 12, or 16 weeks depending on indication.
- Approval is to be entered for the full length of therapy.
- Enter accurate number of occurrences.

8 weeks	• Treatment naïve or treatment-experienced with previous peginterferon/interferon.
12 weeks	• Kidney or liver transplant recipient
16 weeks	• Treatment-experienced with glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/ voxilaprevir. • Treatment-experienced with a previous sofosbuvir-based regimen

QUANTITY LIMIT

- Three tablets per day (84 tablets/28 days).
- Limited to one course of therapy per lifetime.

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Hepatitis C**

- Patient is at least 3 years of age; **AND**
- Prescriber must have consulted with or be a gastroenterologist, hepatologists, or an infectious disease physician.

SUBSTANCE ABUSE

- It is recommended that the patient be evaluated for current history of substance and/or alcohol abuse with validated screening instruments such as Alcohol Use Disorders Identification Test (AUDIT C) or CAGE alcohol screen, or NIDA's drug screening tool.
- If patient has a recent prior history, within the past 6 months, of substance or alcohol abuse, it is recommended to have the patient participate (if not already completed) in a recovery program, receive substance or alcohol abuse counseling services, or see an addiction specialist as part of HCV treatment.

DISEASE SEVERITY/RISK FOR COMPLICATIONS

- Effective 10/01/2016, disease severity (as measured by fibrosis score) will no longer be a requirement for approval. Mavyret® will be covered for patients with Metavir F0-F4.

ADDITIONAL CLINICAL FACTORS FOR CONSIDERATION

- Patient will not receive concurrent treatment with any of the following agents due to the potential for clinically significant drug interactions: carbamazepine, rifampin, ethinyl estradiol-containing medications such as combined oral contraceptives, St. John's wort, atazanavir, darunavir, lopinavir, ritonavir, efavirenz, atorvastatin, lovastatin, simvastatin, and cyclosporine doses >100 mg/day; **AND**
- Patient will not receive concurrent treatment with any of the following anti-hepatitis, anti-viral drugs: sofosbuvir/velpatasvir (Epclusa®), ledipasvir/sofosbuvir (Harvoni®), sofosbuvir (Sovaldi®), sofosbuvir/velpatasvir/voxilaprevir (Vosevi®), or elbasvir/grazoprevir (Zepatier®); **AND**
- Patient does not currently have or have a history of decompensated cirrhosis (Child-Pugh B or C)

HBV SCREENING

- Prior to initiating therapy, patient should be screened for HBV, including testing for hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc); **AND**
- Confirmation that patients with serologic evidence of HBV infection will be monitored for clinical and laboratory signs of hepatitis flare or HBV reactivation during treatment with glecaprevir/pibrentasvir and during post-treatment follow-up

GENOTYPE SPECIFIC INFORMATION

- Patient has a documented diagnosis of chronic hepatitis C infection; **AND**
  - Patient does not have cirrhosis or has compensated cirrhosis (Child-Pugh A); **AND**
    - Patient has genotype 1, 2, 3, 4, 5, or 6; **AND**
      - Patient is treatment naïve or treatment-experienced with previous peginterferon/ribavirin regimen; **OR**
      - Patient is treatment-experienced with previous glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir; **AND**
        - Used in combination with sofosbuvir and ribavirin; **OR**
      - Patient is treatment-experienced with a previous sofosbuvir-based regimen *(Note: excludes prior exposure to an NS5A/NS3/4 inhibitors [e.g., Zepatier, etc.] or genotype 3 infection with sofosbuvir/NS5A inhibitor experience)*; **OR**
      - Patient is a kidney or liver transplant recipient; **AND**
        - Patient is treatment naïve or treatment-experienced (Note: kidney transplant only applies to treatment naïve or NON-direct acting antiviral treatment experienced patients)

Drug specific PI mechanism		
NS5B	NS5A	NS3/4A
– Sofosbuvir	– Elbasvir	– Grazoprevir
– Dasabuvir	– Ledipasvir	– Paritaprevir
	– Ombitasvir	– Voxilaprevir
	– Velpatasvir	– Glecaprevir
	– Pibrentasvir	

Direct-Acting Antivirals (DAA) *note: not all inclusive*	
– Epclusa	(sofosbuvir; velpatasvir)
– Harvoni	(ledipasvir; sofosbuvir)
– Mavyret	(glecaprevir; pibrentasvir)
– Sovaldi	(sofosbuvir)
– Vosevi	(sofosbuvir; velpatasvir; voxilaprevir)
– Zepatier	(elbasvir; grazoprevir)

GENOTYPE SPECIFIC INFORMATION *(CONTINUED)*

Genotype	Standard, Precision, Enhanced Formulary Preferred Agent(s) – PA required	Standard, Precision, Enhanced Formulary Non-Preferred Agent(s) – PA required
1	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Viekira Pak®, Sovaldi®, Zepatier®
2	Sovaldi®; Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	
3	Sovaldi® + RBV; Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Sovaldi® + Daklinza™
4	Harvoni®, ledipasvir/sofosbuvir, Sovaldi®, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Zepatier®
5	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	
6	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	

Core Formulary Preferred Agent(s) – PA required	Core Formulary Non-Preferred Agent(s) – PA required
ledipasvir/sofosbuvir, Mavyret, sofosbuvir/velpatasvir, Vosevi	Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Technivie, Viekira, Zepatier

HEPATITIS C – PEGINTERFERON

Length of Authorization:	Refer to tables below
Initiative:	SPC: Antivirals: Hepatitis (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

PEGINTRON®

Hepatitis C	**Adults:** • Combination therapy for interferon alpha naïve patients with genotypes 1, 4, 5, or 6 – Initial treatment: 12 weeks – 1st renewal: 12 weeks – 2nd renewal: 24 weeks and may not be renewed thereafter • Combination therapy for interferon alpha naïve patients with genotypes 2 or 3 – Initial treatment: 12 weeks – Renewal: 12 weeks and may not be renewed thereafter • Combination therapy for re-treatment for patients with genotypes 1, 2, 3, 4, 5, or 6 – Initial treatment: 12 weeks – 1st renewal: 12 weeks – 2nd renewal: 24 weeks and may not be renewed thereafter • Monotherapy for patients with genotypes 1, 2, 3, 4, 5, or 6 – Initial treatment: 12 weeks – 1st renewal: 12 weeks – 2nd renewal: 24 weeks and may renewed every 6 months for up to 1 year **Pediatrics** • Genotypes 1, 4, 5, or 6: – Initial treatment: 12 weeks – 1st renewal: 12 weeks – 2nd renewal: 24 weeks and may not be renewed thereafter • Genotypes 2 or 3: 24 weeks and may not be renewed
Hepatitis B	Coverage will be provided for 48 weeks and may not be renewed
Histiocytic Neoplasms	Coverage will be provided for 6 months and may be renewed

Chronic Hepatitis C

- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Documented diagnosis of chronic hepatitis C; **AND**
- Patient has compensated liver disease; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL (CONTINUED)

PEGINTRON® (CONTINUED)

- Baseline (pre-treatment) HCV-RNA has been obtained prior to initiating therapy; **AND**
  - Patient is at least 18 years of age; **AND**
    - Patient has genotype 1; **AND**
      - Patient is treatment-naïve or treatment-experienced with previous alpha interferon/ribavirin; **AND**
      - Used in combination with ribavirin and an NS3/4A protease inhibitor; **OR**
      - Used in combination with ribavirin in patients that are unable to tolerate or have contraindications to an NS3/4A protease inhibitor; **OR**
    - Patient has genotypes 2, 3, 4, 5, or 6; **AND**
      - Patient is treatment-naïve or treatment-experienced with previous alpha interferon/ribavirin; **AND**
      - Used in combination with ribavirin; **OR**
    - Patient has genotypes 1, 2, 3, 4, 5, or 6; **AND**
      - Patient is treatment-naïve; **AND**
      - Used as monotherapy in patients that have a significant intolerance or contraindication to ribavirin; **OR**
  - Patient is 3 to 17 years of age; **AND**
    - Patient is treatment naïve; **AND**
    - Patient has genotypes 1, 2, 3, 4, 5, or 6; **AND**
    - Used in combination with ribavirin

Chronic Hepatitis B

- Patient must be 18 years or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Patient must have been HBsAg positive for at least 6 months; **AND**

Patients without cirrhosis: • Patient has elevated serum ALT ≥ 2 times Upper Limit of Normal (ULN); **OR** • Patient has evidence of significant histologic disease (e.g., significant inflammation and/or fibrosis) plus one of the following: – HBV DNA > 2,000 IU/mL (HBeAg negative); **OR** – HBV DNA > 20,000 IU/mL (HBeAg positive)
Patients with compensated cirrhosis: • HBV DNA > 2,000 IU/mL; **OR** • Patient has elevated serum ALT > 2 times Upper Limit of Normal (ULN)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

PEGINTRON® *(CONTINUED)*

Histiocytic Neoplasms – Erdheim-Chester Disease (ECD)

- Patient must be 18 years or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Used as first-line or subsequent therapy as a single agent; **AND**
  - Patient has symptomatic disease; **OR**
  - Patient has relapsed or refractory disease

** **Note:** Please consult the current AASLD clinical practice guidelines for recommended agents for use in the treatment of Chronic Hepatitis B and Chronic Hepatitis C.

PEGASYS®

Hepatitis C	**Adults** • **Genotypes 1, 2, 3, 4, 5, or 6 and used in combination with ribavirin plus an additional HCV antiviral drug(s) OR as monotherapy:** Coverage will be provided for 48 weeks and may not be renewed • **Genotype 1 and used in combination with ribavirin alone or as monotherapy:** – Initial treatment: 12 weeks – 1st renewal: 12 weeks – 2nd renewal: 24 weeks and may not be renewed thereafter • **Genotype 4 and used in combination with ribavirin alone:** Coverage will be provided for 48 weeks and may not be renewed • **Genotypes 2 or 3 and used in combination with ribavirin alone:** Coverage will be provided for 24 weeks and may not be renewed **Pediatrics** • **Genotypes 1, 4, 5 or 6:** Coverage will be provided for 48 weeks and may not be renewed • **Genotypes 2 or 3:** Coverage will be provided for 24 weeks and may not be renewed
Hepatitis B	Coverage will be provided for 48 weeks and may not be renewed
Myeloproliferative Neoplasms, Mastocytosis, Mycosis Fungoides (MF)/Sezary Syndrome (SS), Primary Cutaneous CD30+ Cutaneous T-Cell Lymphoproliferative Disorders, Histiocytic Neoplasms – Erdheim-Chester Disease, Hairy Cell Leukemia	Coverage will be provided for 6 months and may be renewed
Adult T-Cell Leukemia/ Lymphoma (given in combination with zidovudine)	Coverage will be provided for 6 months and may be renewed up to a total length of therapy of 52 weeks (12 months)
Adult T-Cell Leukemia/ Lymphoma (given in combination with arsenic trioxide)	Coverage will be provided for 8 weeks and may not be renewed

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

PEGASYS® *(CONTINUED)*

Chronic Hepatitis C

- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]) with cirrhosis; **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Patient has compensated liver disease; **AND**
- Patient has not had a solid organ transplantation; **AND**
- Patient has genotype 1, 2, 3, 4, 5, or 6 (including patients with and without HIV coinfection); **AND**
- Baseline (pre-treatment) HCV-RNA for patients with genotype 1 only; **AND**
  - Patient is at least 18 years of age; **AND**
    - Used in combination with ribavirin in patients who have not failed on previous interferon-alpha therapy; **OR**
    - Used in combination with ribavirin plus an additional HCV antiviral drug(s); **OR**
    - Used as a single agent in patients who have not failed on previous interferon-alpha therapy and have a significant intolerance or contraindication to other HCV antiviral drugs; **OR**
  - Patient is at least 5 years of age; **AND**
    - Used in combination with ribavirin in patients who have not failed on previous interferon-alpha therapy

Chronic Hepatitis B

- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]) with cirrhosis; **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Patient must have been HBsAg positive for at least 6 months; **AND**
- Patient is at least 3 years old; **AND**

Patients without cirrhosis: • Patient has elevated serum ALT ≥ 2 times upper limit of normal (ULN); **OR** • Patient has evidence of significant histologic disease (e.g., significant inflammation and/or fibrosis) plus one of the following: – HBV DNA > 2,000 IU/mL (HBeAg negative); **OR** – HBV DNA > 20,000 IU/mL (HBeAg positive)
Patients with compensated cirrhosis: • HBV DNA > 2,000 IU/mL; **OR** • Patient has elevated serum ALT > 2 times upper limit of normal (ULN)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

PEGASYS® *(CONTINUED)*

Myeloproliferative Neoplasms

- Patient must be 18 years or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]) with cirrhosis; **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Patient must have one of the following myeloproliferative diseases:
  - Myelofibrosis; **AND**
    - Patient has symptomatic lower risk disease; **OR**
  - Essential thrombocythemia; **AND**
    - Patient has symptomatic very low-risk, low-risk, or intermediate-risk disease with potential indications for cytoreductive therapy; **O**
    - Patient has high-risk disease; **OR**
    - Patient had an inadequate response or loss of response to hydroxyurea, or anagrelide; **AND**
      - Patient has not received previous treatment with peginterferon alfa-2a; **OR**
  - Polycythemia vera; **AND**
    - Patient has symptomatic low-risk disease with potential indications for cytoreductive therapy; **OR**
    - Patient has high risk disease; **OR**
    - Patient had an inadequate response or loss of response to hydroxyurea or interferon therapy; **AND**
      - Patient has not received previous treatment with peginterferon alfa-2a

Systemic Mastocytosis

- Patient must be 18 years or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Used as a single agent or in combination with prednisone; **AND**
  - Patient has aggressive disease; **OR**
  - Patient has disease with an associated hematologic neoplasm (SM-AHN), when the SM component requires more immediate treatment; **OR**
- Used in patients with osteopenia or osteoporosis with refractory bone pain and/or worsening bone mineral density while on bisphosphonate therapy; **OR**
- Used as a single agent for indolent or smoldering disease; **AND**
  - Patient has severe, refractory mediator symptoms or bone disease not responsive to anti-mediator therapy or bisphosphonates

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

PEGASYS® *(CONTINUED)*

Mycosis Fungoides (MF)/Sezary Syndrome (SS)

- Patient must be 18 years or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis

Adult T-Cell Leukemia/Lymphoma

- Patient must be 18 years or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Used in combination with zidovudine for chronic/smoldering or acute disease; **OR**

Histiocytic Neoplasms – Erdheim-Chester Disease

- Patient must be 18 years or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Used as first-line or subsequent therapy as a single agent; **AND**
  - Patient has symptomatic disease; **OR**
  - Patient has relapsed or refractory disease

Hairy Cell Leukemia

- Patient must be 18 years or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Used as a single agent; **AND**
  - Used for less than complete response following initial treatment with cladribine or pentostatin; **OR**
  - Used for relapse within 2 years of complete response

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

PEGASYS® *(CONTINUED)*

Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders

- Patient must be 18 years or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Used as single agent for primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions

** **Note:** Please consult the current AASLD clinical practice guidelines for recommended agents for use in the treatment of Chronic Hepatitis B and Chronic Hepatitis C.

CLINICAL CRITERIA FOR RENEWAL

PEGINTRON®

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: neuropsychiatric events, cardiovascular events, endocrine disorders, ophthalmologic disorders, ischemic and hemorrhagic cerebrovascular, bone marrow toxicity, development/exacerbation of autoimmune disorders, pancreatitis, colitis, pulmonary disorders, hepatic failure, renal insufficiency, serious hypersensitivity reactions/cutaneous eruptions, abnormal laboratory test results, dental and periodontal disorders, growth inhibition in pediatric patients, elevated triglycerides, peripheral neuropathy, etc; **AN**D

Chronic Hepatitis C in Adults

- Combination therapy for interferon alpha-naïve patients; **AND**
  - Genotypes 1, 4, 5, or 6; **AND**
  - 1st renewal at treatment week 12: HCV-RNA is at least a 2 log10 reduction from baseline; **AND**
    - May be renewed for an additional 12 weeks; **AND**
  - 2nd renewal at treatment week 24: HCV-RNA is undetectable; **AND**
    - May be renewed for an additional 24 weeks for a total of 48 weeks of treatment and may not be renewed thereafter
- Combination therapy for interferon alpha-naïve patients; **AND**
  - Genotypes 2 or 3; **AND**
  - 1st renewal at treatment week 12: HCV-RNA is at least a 2 log10 reduction from baseline; **AND**
  - May be renewed for an additional 12 weeks for a total of 24 weeks of treatment and may not be renewed thereafter
- Combination therapy for re-treatment; **AND**
  - Genotypes 1, 2, 3, 4, 5, or 6; **AND**
  - 1st renewal at treatment week 12: HCV-RNA is at least a 2 log10 reduction from baseline; **AND**
    - May be renewed for an additional 12 weeks; **AND**
  - 2nd renewal at treatment week 24: HCV-RNA is undetectable; **AND**
    - May be renewed for an additional 24 weeks for a total of 48 weeks of treatment and may not be renewed thereafter

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

Chronic Hepatitis C in Adults *(Continued)*

- Monotherapy; **AND**
  - Genotypes 1, 2, 3, 4, 5, or 6; **AND**
  - 1st renewal at treatment week 12: HCV-RNA is at least a 2 log10 reduction from baseline; **AND**
    - May be renewed for an additional 12 weeks; **AND**
  - 2nd renewal at treatment week 24: HCV-RNA is undetectable; **AND**
    - May be renewed every 6 months for a maximum of 1 year of treatment

Chronic Hepatitis C in Pediatrics

- Genotypes 1, 4, 5, or 6; **AND**
  - 1st renewal at treatment week 12: HCV-RNA is at least a 2 $\log_{10}$ reduction from baseline; **AND**
    - May be renewed for an additional 12 weeks; **AN**
  - 2nd renewal at treatment week 24: HCV-RNA is undetectable; **AND**
    - May be renewed for an additional 24 weeks for a total of 48 weeks of treatment and may not be renewed thereafter
- Genotypes 2 or 3; **AND**
  - May not be renewed

Chronic Hepatitis B

- May not be renewed

Histiocytic Neoplasms – Erdheim-Chester Disease

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

PEGASYS®

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: neuropsychiatric reactions, cardiovascular disorders, bone marrow suppression, development/exacerbation of autoimmune disorders, endocrine disorders, ophthalmologic disorders, cerebrovascular disorders, hepatic failure/hepatitis exacerbations, pulmonary disorders, infections, colitis, pancreatitis, severe hypersensitivity reactions, growth inhibition in pediatric patients, serious skin reactions, peripheral neuropathy, abnormal laboratory test results, etc.; **AND**

Chronic Hepatitis C in Adults

- Patients with genotype 1 and receiving treatment in combination with ribavirin alone or as monotherapy; **AND**
  - 1st renewal at treatment week 12: HCV-RNA is at least a 2 $\log_{10}$ reduction from baseline; **AND**
    - May be renewed for an additional 12 weeks; **AND**
  - 2nd renewal at treatment week 24: HCV-RNA is undetectable; **AND**
    - May be renewed for an additional 24 weeks for a total of 48 weeks of treatment and may not be renewed thereafter; **OR**
- Patients receiving treatment in any other setting than noted above: Authorizations may **not** be renewed

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

Chronic Hepatitis C in Pediatrics

- Authorizations may **not** be renewed

Chronic Hepatitis B

- Authorizations may **not** be renewed

Myeloproliferative Neoplasms

- Treatment response with a decrease in spleen size or improvements in other myeloproliferative symptoms (e.g., fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding)

Adult T-Cell Leukemia/Lymphoma

- When used in combination with zidovudine: Patient has **not** received more than 52 weeks of therapy; **OR**
- When used in combination with arsenic trioxide: Patient has **not** received more than 8 weeks of therapy

Systemic Mastocytosis, Mycosis Fungoides (MF)/Sezary Syndrome (SS), Histiocytic Neoplasms – Erdheim-Chester Disease, Hairy Cell Leukemia, Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorder

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

HEPATITIS C – RIBAVIRIN (REBETOL®, RIBASPHERE®, RIBAPAK®)

Length of Authorization:	• Patients with genotypes 2 or 3: Coverage will be provided for 24 weeks and may not be renewed. • Patients with genotypes 1, 4, 5, or 6: Coverage will be provided for 6 months and may be renewed for up to a total of 48 weeks of therapy
Initiative:	SPC: Antivirals: Hepatitis (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Hepatitis C Virus infection**

- Patient is at least 3 years of age; **AND**
- Patients of child-bearing potential must have a negative pregnancy test prior to treatment; **AND**
- Patients of reproductive potential must use effective contraception during treatment with therapy and for at least six months after the last dose; **AND**
- Patient does not have a history of significant or unstable cardiac disease; **AND**
- Patient has a diagnosis of chronic hepatitis C infection with genotype 1, 2, 3, 4, 5, or 6; **AND**
- Must be used as part of a combination regimen (i.e., interferon or pegylated-interferon)

** ***Note:*** *Please consult the current AASLD clinical practice guidelines for recommended agents for use in the treatment of Chronic Hepatitis B and Chronic Hepatitis C.*

CLINICAL CRITERIA FOR RENEWAL

- Disease response as indicated by reduction of HCV RNA levels; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: pancreatitis, pulmonary disorders, new/worsening ophthalmologic disorders, pancytopenia and bone marrow suppression, severe anemia, hepatic failure, severe hypersensitivity reactions, dental/periodontal disorders, growth inhibition in pediatric patients, abnormal laboratory test results, etc.; **AND**

Chronic Hepatitis C Virus Infection

- Genotypes 2 or 3:
  - May not be renewed; **OR**
- Genotypes 1, 4, 5, and 6
  - May be renewed for a total of 48 weeks

HEPATITIS C – SOVALDI®

Length of Authorization:	Varies, see table below
Initiative:	SPC: Antivirals Hepatitis (IE 2462 / NCPDP 75)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

LENGTH OF AUTHORIZATION/QUANTITY LIMIT

Length of Authorization

- Approval is to be entered for full length of therapy
- Enter accurate number of occurrences **for treatment duration**: 12, 24 or 48 weeks depending on indication

12 weeks	• Genotypes 1,2,4
24 weeks	• Genotype 3
48 weeks	• Patients with Hepatocellular Carcinoma (HCC) awaiting liver transplant (up to 48 weeks or until the time of liver transplantation)

Quantity Limit

- **Sovaldi® (sofosbuvir):** One 400 mg tablet per day (28 tablets/28 days)
- Patients must be treatment-naïve to all parts of sofosbuvir therapy. Limited to one course of therapy per lifetime

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Hepatitis C**

- Prescriber must have consulted with or be a gastroenterologist, hepatologists, or an infectious disease physician

Core: For any non-preferred agent (Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Technivie, Viekira, Zepatier), patient must step through ALL preferred agents: ledipasvir/sofosbuvir, Mavyret, sofosbuvir/velpatasvir, and Vosevi

SUBSTANCE ABUSE

- It is recommended that the patient be evaluated for current history of substance and/or alcohol abuse with validated screening instruments such as Alcohol Use Disorders Identification Test (AUDIT C) or CAGE alcohol screen, or NIDA's drug screening tool.
- If patient has a recent prior history, within the past 6 months, of substance or alcohol abuse, it is recommended to:
  - Have the patient participate (if not already completed) in a recovery program, receive substance or alcohol abuse counseling services, or see an addiction specialist as part of HCV treatment

DISEASE SEVERITY/RISK FOR COMPLICATIONS

- Effective 10/01/2016, disease severity (as measured by fibrosis score) will no longer be a requirement for approval. Sovaldi® will be covered for patients with Metavir F0-F4.

ADDITIONAL SOFOSBUVIR INFORMATION TO AID IN THE FINAL DECISION

- Patient will not receive concurrent treatment with any of the following anti-hepatitis, anti-viral drugs: sofosbuvir/velpatasvir (Epclusa®), glecaprevir/pibrentasvir (Mavyret®), ledipasvir/sofosbuvir (Harvoni®), sofosbuvir/velpatasvir/voxilaprevir (Vosevi®), or elbasvir/grazoprevir (Zepatier®); **AND**
- Patient will not receive concurrent treatment with any of the following agents due to the potential for clinically significant drug interactions: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, St. John's wort, tipranavir/ritonavir, amiodarone (****Note**: If there are no other alternative viable treatment options and amiodarone must be used, cardiac monitoring is recommended); **AND**
- Patient does not currently have or have a history of decompensated cirrhosis (Child-Pugh B or C)

HBV SCREENING

- Prior to initiating therapy, patient should be screened for HBV, including testing for hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc); **AND**
- Confirmation that patients with serologic evidence of HBV infection will be monitored for clinical and laboratory signs of hepatitis flare or HBV reactivation during treatment with sofosbuvir and during post-treatment follow-up

GENOTYPE-SPECIFIC INFORMATION

Adults with Chronic Hepatitis C (HCV)

- Patient does **not** have cirrhosis **OR** has compensated cirrhosis (Child-Pugh A); **AND**
  - Patient has Genotype 1 or 4; **AND**
    - Patient is treatment naïve; **AND**
    - Patient is 18 years or older; **AND**
    - Used in combination with peginterferon alfa and ribavirin or with ribavirin alone in those who are ineligible to receive treatment with an interferon-based regimen; **OR**
  - Patient has Genotype 2 or 3; **AND**
    - Patient is treatment-naïve **OR** treatment-experienced with prior peg-interferon alfa; **AND**
    - Patient is 3 years or older; **AND**
    - Used in combination with ribavirin; **OR**
- Patient has hepatocellular carcinoma; **AND**
  - Patient is awaiting liver transplantation; **AND**
  - Used to prevent post-transplant HCV re-infection; **AND**
  - Used in combination with ribavirin

GENOTYPE-SPECIFIC INFORMATION *(CONTINUED)*

Drug-specific PI mechanism		
NS5B – Sofosbuvir – Dasabuvir	**NS5A** – Elbasvir – Ledipasvir – Ombitasvir – Velpatasvir – Pibrentasvir	**NS3/4A** – Grazoprevir – Paritaprevir – Voxilaprevir – Glecaprevir

Direct-Acting Antivirals (DAA) *note: not all inclusive*	
– Epclusa	(sofosbuvir; velpatasvir)
– Harvoni	(ledipasvir; sofosbuvir)
– Mavyret	(glecaprevir; pibrentasvir)
– Sovaldi	(sofosbuvir)
– Vosevi	(sofosbuvir; velpatasvir; voxilaprevir)
– Zepatier	(elbasvir; grazoprevir)

** ***Note:*** *Please consult the current AASLD clinical practice guidelines for recommended agents for use in the treatment of Chronic Hepatitis B and Chronic Hepatitis C.*

Genotype	Standard, Precision, Enhanced Formulary Preferred Agent(s) – PA required	Standard, Precision, Enhanced Formulary Non-Preferred Agent(s) – PA required
1	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Viekira Pak®, Sovaldi®, Zepatier®
2	Sovaldi®; Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	
3	Sovaldi®+ RBV; Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Sovaldi®+ Daklinza™
4	Harvoni®, ledipasvir/sofosbuvir, Sovaldi®, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Zepatier®
5	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	
6	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	

Core Formulary Preferred Agent(s) – PA required	Core Formulary Non-Preferred Agent(s) – PA required
ledipasvir/sofosbuvir, Mavyret, sofosbuvir/velpatasvir, Vosevi	Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Technivie, Viekira, Zepatier

HEPATITIS C – VIEKIRA®

Length of Authorization:	Varies
Initiative:	SPC: Antivirals hepatitis (IE 2462 / NCPDP 75)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Length of Authorization:

Viekira Pak (dasabuvir + ombitasvir/paritaprevir/ritonavir)

FOR TREATMENT DURATION: 12 or 24 weeks depending on indication.

- Approval is to be entered for full length of therapy
- Enter accurate number of occurrences
- One dasabuvir + ombitasvir/paritaprevir/ritonavir pack per 28 days.
- Patient must be treatment-naïve to all parts of the dasabuvir/ombitasvir/paritaprevir therapy. Limited to one course of therapy per lifetime.

CLINICAL CRITERIA FOR APPROVAL

Diagnosis of **Hepatitis C**

- Patient is > 18 years old; **AND**
- Prescriber must have consulted with or be a gastroenterologist, hepatologists, or an infectious disease specialist
- **Core:** For any non-preferred agent (Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Technivie, Viekira, Zepatier), patient must step through ALL preferred agents: ledipasvir/sofosbuvir, Mavyret, sofosbuvir/velpatasvir, and Vosevi

SUBSTANCE ABUSE

- It is recommended that the patient be evaluated for current history of substance and/or alcohol abuse with validated screening instruments such as Alcohol Use Disorders Identification Test (AUDIT C) or CAGE alcohol screen, or NIDA's drug screening tool.
- If patient has a recent prior history, within the past 6 months, of substance or alcohol abuse, it is recommended to have the patient participate (if not already completed) in a recovery program, receive substance or alcohol abuse counseling services, or see an addiction specialist as part of HCV treatment.

DISEASE SEVERITY/RISK FOR COMPLICATIONS

- Effective 10/01/2016, disease severity (as measured by fibrosis score) will no longer be a requirement for approval. Viekira will be covered for patients with Metavir F0-F4.

ADDITIONAL CLINICAL FACTORS FOR CONSIDERATION

- Patient does not have concomitant therapy with any of the following contraindicated medications: alfuzosin, colchicine, carbamazepine, phenytoin, phenobarbital, gemfibrozil, rifampin, ergotamine, dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol-containing contraceptives, St. John's wort, lovastatin, simvastatin, pimozide, efavirenz, sildenafil (when dosed for the treatment of pulmonary arterial hypertension), triazolam, and/or orally administered midazolam.
- Patients have been evaluated for potential clinically significant drug interactions, including the following:
  - Concomitant therapy with Viekira Pak could increase concentrations of the following interacting medications: Antiarrhythmics (amiodarone, bepridil, disopyramide, flecainide, lidocaine (systemic), mexiletine, propafenone, quinidine), Antifungals (ketoconazole), Calcium Channel Blockers (amlodipine), Corticosteroids (fluticasone), Diuretics (furosemide), HMG CoA Reductase Inhibitors (rosuvastatin, pravastatin), Immunosuppressants (cyclosporine, tacrolimus), Narcotic Analgesics (buprenorphine), Sedatives/Hypnotics (alprazolam).
  - Concomitant therapy with Viekira Pak could decrease concentrations of the following interacting medications: Proton Pump Inhibitors (omeprazole).
  - Concomitant therapy with Viekira Pak has been shown to interact with the following medications and coadministration is **not** recommended: certain Antifungals (voriconazole), certain HIV Antivirals (darunavir/ritonavir, lopinavir/ritonavir, rilpivirine), and certain Long acting beta-agonists (salmeterol).
- Patients **should not** be receiving concomitant therapy with a hepatitis C protease inhibitor (e.g., simeprevir [Olysio]).
- Viekira Pak **should not** be used in patients diagnosed with HCV genotypes 2, 3, 4, 5, or 6.
- Viekira Pak **should not** be used in patients with a known hypersensitivity to ritonavir.
- Viekira Pak **should not** be used in combination with ribavirin in women who are pregnant or may become pregnant or men whose female partners are pregnant due to the risks for birth defects and fetal death associated with ribavirin.
- Viekira Pak is **contraindicated and should not** be used in patients with Child-Pugh score greater than 6 (class B or C).
- Hepatic laboratory testing including bilirubin, albumin, and INR should be monitored at baseline and during the first four weeks of initiating therapy and as clinically indicated. Persistent elevations in hepatic labs during treatment could be a sign of hepatic decompensation. Viekira Pak should be discontinued in patients showing evidence of hepatic decompensation. Consider discontinuing Viekira Pak if ALT levels remain *persistently* greater than 10 times the ULN.

HBV SCREENING

- HBV reactivation has been reported with direct acting antivirals (DAAs), most commonly between 4 and 8 weeks after starting DAAs.
- Prior to initiation of any DAA, patient should be screened for HBV, including testing for hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (anti-HBs) and hepatitis B core antibody (anti-HBc).
- HBsAg
  - Patients with a positive HBsAg should receive an HBV DNA test prior to DAA therapy. Those with active HBV infection should initiate HBV therapy (if not already on suppressive therapy) prior to or upon initiation of DAA therapy.
  - Patients with a negative HBsAg but with a positive anti-HBc and negative anti-HBs should be reassessed for HBV infection status due to an unclear interpretation.
- Anti-HBc
  - Patients with a negative anti-HBc should receive the hepatitis B vaccination series if not already administered.
  - Patients with a positive anti-HBc (even if HBsAg negative) should receive an HBV DNA test prior to DAA therapy. Those with active HBV infection should initiate HBV therapy prior to or upon initiation of DAA therapy.
  - Patients with a positive anti-HBc and not on HBV suppressive therapy should have their HBV DNA monitored every 4 weeks during DAA therapy and upon completion of DAA therapy for HBV reactivation.

GENOTYPE SPECIFIC INFORMATION

For Documented Diagnosis of **Chronic HCV Genotype 1a** – 12 weeks of therapy (patient must meet **all** the following criteria in order to be approved):

- Patient does not have cirrhosis (Metavir F0-F3); **AND**
- Patient is treatment naïve or treatment experienced with compensated cirrhosis (Child-Pugh A) with previous prior relapse or partial response to IFN + RBV treatment; **AND**
- **Must** have concurrent (or planning to start) therapy with ribavirin when starting dasabuvir + ombitasvir/paritaprevir/ritonavir for a 12-week duration; **AND**
- Must have a trial and failure or contraindication to preferred agents

For Documented Diagnosis of **Chronic HCV Genotype 1a with Cirrhosis** – 12 weeks of therapy (patient must meet **all** the following criteria in order to be approved):

- Patient does have compensated cirrhosis (Metavir F4); **AND**
- Treatment-experienced with prior relapse or partial response to IFN + RBV; **AND**
- **Must** have concurrent (or planning to start) therapy with ribavirin when starting dasabuvir + ombitasvir/paritaprevir/ritonavir for a 12-week duration; **AND**
- Must have a trial and failure or contraindication to preferred agents

For Documented Diagnosis of **Chronic HCV Genotype 1a with Cirrhosis** – 24 weeks of therapy (patient must meet **all** the following criteria in order to be approved)

- Patient does have compensated cirrhosis (Metavir F4); **AND**
- Patient is treatment experienced NULL responder to previous IFN + RBV; **AND**
- **Must** have concurrent (or planning to start) therapy with ribavirin when starting dasabuvir + ombitasvir/paritaprevir/ritonavir for a 24-week duration ; **AND**
- Must have a trial and failure or contraindication to preferred agents

GENOTYPE SPECIFIC INFORMATION *(CONTINUED)*

For Documented Diagnosis of **Chronic HCV Genotype 1b without Cirrhosis** – 12 weeks of therapy (patient must meet **all** the following criteria in order to be approved):

- Patient does not have cirrhosis (Metavir F0-F3); **AND**
- Treatment naïve **or** treatment experienced with IFN + RBV; **AND**
- Must have a trial and failure or contraindication to preferred agents

For Documented Diagnosis of **Chronic HCV Genotype 1b with Cirrhosis** – 12 weeks of therapy (patient must meet **all** the following criteria in order to be approved):

- Patient does have compensated cirrhosis (Metavir F4); **AND**
- Treatment Naïve or Treatment-experienced with IFN + RBV; **AND**
- Must have a trial and failure or contraindication to preferred agents

For Documented Diagnosis of **Chronic HCV Genotype 1 with Early Stage Fibrosis Post Liver Transplant** – 24 weeks of therapy (patient must meet **all** the following criteria in order to be approved):

- Patient already has received a liver transplant; **AND**
- Patient must have early stage fibrosis (Metavir F0 – F2); **AND**
- **Must** have concurrent (or planning to start) therapy with ribavirin when starting dasabuvir + ombitasvir/paritaprevir/ritonavir for a 24-week duration; **AND**
- Must have a trial and failure or contraindication to preferred agents

LENGTH OF AUTHORIZATION

- Approve for full duration of therapy

Genotype	Standard, Precision, Enhanced Formulary Preferred Agent(s) – PA required	Standard, Precision, Enhanced Formulary Non-Preferred Agent(s) – PA required
1	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Viekira Pak®, Sovaldi®, Zepatier®
2	Sovaldi®; Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	
3	Sovaldi® + RBV; Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Sovaldi® + Daklinza™
4	Harvoni®, ledipasvir/sofosbuvir, Sovaldi®, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Zepatier®
5	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	
6	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	

Core Formulary Preferred Agent(s) – PA required	Core Formulary Non-Preferred Agent(s) – PA required
ledipasvir/sofosbuvir, Mavyret, sofosbuvir/velpatasvir, Vosevi	Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Technivie, Viekira, Zepatier

HEPATITIS C – VOSEVI® (SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR)

Length of Authorization:	See below
Initiative:	SPC: Antivirals: Hepatitis (IE 2462 / NCPDP 75)

LENGTH OF AUTHORIZATION

24 weeks	Treatment-experienced with prior sofosbuvir/velpatasvir/voxilaprevir and used in combination with ribavirin
12 weeks	All other indications.

- Enter accurate number of occurrences

Quantity Limit

- One tablet per day (28 tablets/28 days).
- Limited to one course of therapy per lifetime.

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Hepatitis C**

- Patient is 18 years or older; **AND**
- Prescriber must have consulted with or be a gastroenterologist, hepatologists, or an infectious disease physician

SUBSTANCE ABUSE

- It is recommended that the patient be evaluated for current history of substance and/or alcohol abuse with validated screening instruments such as Alcohol Use Disorders Identification Test (AUDIT C) or CAGE alcohol screen, or NIDA's drug screening tool.
- If patient has a recent prior history, within the past 6 months, of substance or alcohol abuse, it is recommended to have the patient participate (if not already completed) in a recovery program, receive substance or alcohol abuse counseling services, or see an addiction specialist as part of HCV treatment (a CLIA-certified laboratory should be used for ongoing lab monitoring).

DISEASE SEVERITY/RISK FOR COMPLICATIONS

- Effective 10/01/2016, disease severity (as measured by fibrosis score) will no longer be a requirement for approval. Technivie will be covered for patients with Metavir F0-F4.

ADDITIONAL FACTORS TO CONSIDER

- Patient will not receive concurrent treatment with any of the following anti-hepatitis, anti-viral drugs: sofosbuvir/velpatasvir (Epclusa®), ledipasvir/sofosbuvir (Harvoni®), glecaprevir/pibrentasvir (Mavyret®), sofosbuvir (Sovaldi®), or elbasvir/grazoprevir (Zepatier®); **AND**
- Patient will not receive concurrent treatment with any of the following agents due to the potential for clinically significant drug interactions: carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, rifapentine, atazanavir, lopinavir, tipranavir/ritonavir, efavirenz, St. John's wort, rosuvastatin, pitavastatin, cyclosporine, and amiodarone (**NOTE: If there are no other alternative viable treatment options and amiodarone must be used, cardiac monitoring is recommended); **AND**
- Patient does not have decompensated cirrhosis (Child-Pugh B or C)

HBV SCREENING

- Prior to initiating therapy, patient should be screened for HBV, including testing for hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc); **AND**
  - Confirmation that patients with serologic evidence of HBV infection will be monitored for clinical and laboratory signs of hepatitis flare or HBV reactivation during treatment with glecaprevir/pibrentasvir and during post-treatment follow-up

GENOTYPE SPECIFIC INFORMATION

- Patient has a documented diagnosis of chronic hepatitis C infection; **AND**
- Patient does not have cirrhosis or has compensated cirrhosis (Child-Pugh A); **AND**
  - Patient has genotype 1, 2, 3, 4, 5, or 6; **AND**
    - Patient is treatment-naïve with the NS5A RAS Y93H mutation for velpatasvir; **AND**
      - Patient has genotype 3 infection with compensated cirrhosis; **OR**
    - Patient is treatment-experienced with a previous sofosbuvir-based regimen (*Note: For genotype 3 infections must be used in combination with ribavirin*); **OR**
    - Patient is treatment-experienced with previous glecaprevir/pibrentasvir; **OR**
    - Patient is treatment-experienced with previous sofosbuvir/ velpatasvir/ voxilaprevir; **AND**
      - Used in combination with ribavirin; **OR**
    - Patient is a post-liver or -kidney transplant; **AND**
      - Patient is treatment-experienced with prior direct-acting antivirals; **AND**
      - Used in combination with ribavirin in patients with compensated cirrhosis

Drug-specific PI mechanism		
NS5B	**NS5A**	**NS3/4A**
– Sofosbuvir	– Elbasvir	– Grazoprevir
– Dasabuvir	– Ledipasvir	– Paritaprevir
	– Ombitasvir	– Voxilaprevir
	– Velpatasvir	– Glecaprevir
	– Pibrentasvir	

Direct-Acting Antivirals (DAA) (*note: not all inclusive*)	
– Epclusa	(sofosbuvir; velpatasvir)
– Harvoni	(ledipasvir; sofosbuvir)
– Mavyret	(glecaprevir; pibrentasvir)
– Sovaldi	(sofosbuvir)
– Vosevi	(sofosbuvir; velpatasvir; voxilaprevir)
– Zepatier	(elbasvir; grazoprevir)

Genotype	Standard, Precision, Enhanced Formulary Preferred Agent(s) – PA required	Standard, Precision, Enhanced Formulary Non-Preferred Agent(s) – PA required
1	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Viekira Pak®, Sovaldi®, Zepatier®;
2	Sovaldi®; Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	
3	Sovaldi® + RBV; Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Sovaldi® + Daklinza™
4	Harvoni®, ledipasvir/sofosbuvir, Sovaldi®, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Zepatier®
5	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	
6	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	

Core Formulary Preferred Agent(s) – PA required	Core Formulary Non-Preferred Agent(s) – PA required
ledipasvir/sofosbuvir	Daklinza
Mavyret	Epclusa
sofosbuvir/velpatasvir	Harvoni
Vosevi	Olysio
	Sovaldi
	Technivie
	Viekira
	Zepatier

HEPATITIS C – ZEPATIER® (ELBASVIR; GRAZOPREVIR)

Length of Authorization:	Varies: see table below
Initiative:	SPC: Antivirals Hepatitis (IE 2462 / NCPDP 75)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

LENGTH OF AUTHORIZATION/QUANTITY LIMIT

Length of Authorization

- Approval is to be entered for full length of therapy
- Enter accurate number of occurrences
- **For treatment duration**: 12 or 16 weeks depending on indication

12 weeks	All other indications
16 weeks	• Genotype 1a with polymorphisms & Genotype 4 treatment-experienced

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Hepatitis C**

- Patient is 18 years or older; **AND**
- Prescriber must have consulted with or be a gastroenterologist, hepatologists, or an infectious disease physician

Core: For any non-preferred agent (Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Technivie, Viekira, Zepatier), patient must step through ALL preferred agents: ledipasvir/sofosbuvir, Mavyret, sofosbuvir/velpatasvir, and Vosevi

SUBSTANCE ABUSE

- It is recommended that the patient be evaluated for current history of substance and/or alcohol abuse with validated screening instruments such as Alcohol Use Disorders Identification Test (AUDIT C) or CAGE alcohol screen, or NIDA's drug screening tool.
- If patient has a recent prior history, within the past 6 months, of substance or alcohol abuse, it is recommended to have the patient participate (if not already completed) in a recovery program, receive substance or alcohol abuse counseling services, or see an addiction specialist as part of HCV treatment.

DISEASE SEVERITY/RISK FOR COMPLICATIONS

- Effective 10/01/2016, disease severity (as measured by fibrosis score) will no longer be a requirement for approval. Zepatier will be covered for patients with Metavir F0-F4.

ADDITIONAL ZEPATIER INFORMATION TO AID IN THE FINAL DECISION

- Patient will not receive concurrent treatment with any of the following anti-hepatitis, anti-viral drugs: ledipasvir/sofosbuvir (Harvoni®), glecaprevir/pibrentasvir (Mavyret®), sofosbuvir (Sovaldi®), sofosbuvir/velpatasvir/voxilaprevir (Vosevi®), or sofosbuvir/velpatasvir (Epclusa®); **AND**
- Patient will not receive concurrent treatment with any of the following agents due to the potential for clinically significant drug interactions: nafcillin, oral ketoconazole, bosentan, etravirine, cobicistat-containing regimens, and modafinil; **AND**
- Patient will not receive concurrent treatment with any of the following agents as concomitant use is contraindicated: OATP1B1/3 inhibitors (atazanavir, darunavir, lopinavir, saquinavir, tipranavir, cyclosporine) and strong CPP3A inducers (phenytoin, carbamazepine, rifampin, St. John's wort, efavirenz); **AND**
- Patient does not have decompensated cirrhosis (Child-Pugh B or C)

HBV SCREENING

- Prior to initiating therapy, patient should be screened for HBV, including testing for hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc); **AND**
  - Confirmation that patients with serologic evidence of HBV infection will be monitored for clinical and laboratory signs of hepatitis flare or HBV reactivation during treatment with sofosbuvir/ velpatasvir and during post-treatment follow-up

GENOTYPE SPECIFIC INFORMATION

- Patient has a documented diagnosis of chronic hepatitis C infection; **AND**
- Patient does not have cirrhosis **OR** has compensated cirrhosis (Child-Pugh A); **AND**
- Patient has one of the following Genotypes:
  - Genotype 1a or 1b
    - Patient is treatment-naïve **OR** treatment-experienced with prior peg-interferon alfa plus ribavirin; **AND**
      - Genotype 1a ONLY: Patient does not have NS5A polymorphisms (resistance-associated substitutions [RAS]) **OR** has polymorphisms/RAS at amino acid position 28, 30, 31, or 93; **OR**
    - Patient is treatment-experienced with prior peg-interferon alfa plus ribavirin plus HCV NS3/4A protease inhibitor*****
  - Genotype 4
    - Patient is treatment-naïve **OR** treatment-experienced with prior peg-interferon alfa plus ribavirin*****

    *******Must be used in combination with ribavirin*

Drug specific PI mechanism		
NS5B	**NS5A**	**NS3/4A**
– Sofosbuvir	– Elbasvir	– Grazoprevir
– Dasabuvir	– Ledipasvir	– Paritaprevir
	– Ombitasvir	– Voxilaprevir
	– Velpatasvir	– Glecaprevir
	– Pibrentasvir	

Direct-Acting Antivirals (DAA) (*note: not all inclusive*)	
– Epclusa	(sofosbuvir; velpatasvir)
– Harvoni	(ledipasvir; sofosbuvir)
– Mavyret	(glecaprevir; pibrentasvir)
– Sovaldi	(sofosbuvir)
– Vosevi	(sofosbuvir; velpatasvir; voxilaprevir)
– Zepatier	(elbasvir; grazoprevir)

GENOTYPE SPECIFIC INFORMATION *(CONTINUED)*

Genotype	Standard, Precision, Enhanced Formulary Preferred Agent(s) – PA required	Standard, Precision, Enhanced Formulary Non-Preferred Agent(s) – PA required
1	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Viekira Pak®, Sovaldi®, Zepatier®
2	Sovaldi®; Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Sovaldi® + Daklinza™
3	Sovaldi® + RBV; Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	Zepatier®
4	Harvoni®, ledipasvir/sofosbuvir, Sovaldi®, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	
5	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	
6	Harvoni®, ledipasvir/sofosbuvir, Epclusa®, sofosbuvir/velpatasvir, Mavyret®, Vosevi®	

Core Formulary Preferred Agent(s) – PA required	Core Formulary Non-Preferred Agent(s) – PA required
ledipasvir/sofosbuvir	Daklinza
Mavyret	Epclusa
sofosbuvir/velpatasvir	Harvoni
Vosevi	Olysio
	Sovaldi
	Technivie
	Viekira
	Zepatier

HERCEPTIN HYLECTA™ (TRASTUZUMAB AND HYALURONIDASE-OYSK)

Length of Authorization:	6 months, may be renewed Use in the adjuvant setting is limited to a total of 52 weeks of treatment
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**:

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-positive* disease as determined by an FDA-approved CLIA compliant test; **AND**
- Therapy will not be substituted with or for ado-trastuzumab emtansine (Kadcyla) or fam-trastuzumab deruxtecan-nxki (Enhertu); **AND**
- Will not be used in combination with intravenous chemotherapy agents; **AND**
- Will not be used in combination with trastuzumab (or any of its biosimilar products [e.g., Ogivri, Kanjinti, Trazimera, Herzuma, Ontruzant]) or pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); **AND**
- Used as adjuvant therapy as a single agent following anthracycline-based therapy; **OR**
- Used for metastatic disease as a single agent in patients who have received one or more prior treatments for metastatic disease

- ***FOR NEW STARTS ONLY, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Kanjinti OR Trazimera***
- ***Note: For Core Formulary, all trastuzumab products are non-formulary.***

NOTE: Coverage for Herceptin Hylecta will **NOT** encompass all FDA approved indications. Coverage will be **ONLY** provided when the above criteria are met .

FDA approved indications:

Adjuvant treatment of adults with HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer:

- As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
- As part of a treatment regimen with docetaxel and carboplatin
- As a single agent following multi-modality anthracycline based therapy

Metastatic treatment of adults:

- In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
- As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease

*HER2-positive overexpression criteria:

- Immunohistochemistry (IHC) assay 3+; **OR**
- Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number ≥ 4.0 signals/cell; **OR**
- Dual-probe in situ hybridization (ISH) assay **and** concurrent IHC indicating one of the following:
  - HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number < 4.0 signals/cell **and** concurrent IHC 3+; **OR**
  - HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 6.0 signals/cell **and** concurrent IHC 2+ or 3+; **OR**
  - HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 4.0 and < 6.0 signals/cell **and** concurrent IHC 3+

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: cardiotoxicity (e.g., left ventricular dysfunction, cardiomyopathy, etc.), pulmonary toxicity (e.g., dyspnea, interstitial pneumonitis, etc.), neutropenia, severe administration-related reactions (e.g. hypersensitivity, anaphylaxis).; **AND**
  - LVEF is within the institutional normal limits, but has not had an **absolute** decrease of ≥ 16% from pre-treatment baseline (LVEF results must be within the previous 3 months); **OR**
  - LVEF is below the institutional lower limits of normal, but has not had an **absolute** decrease of ≥ 10% from pre-treatment baseline (LVEF results must be within the previous 3 months); **AND**
- For the adjuvant treatment of breast cancer, the patient has not exceeded a maximum of 52 weeks of therapy.

HERCEPTIN® (TRASTUZUMAB), HERZUMA® (TRASTUZUMAB-PKRB), KANJINTI® (TRASTUZUMAB-ANNS), OGIVRI™ (TRASTUZUMAB-DKST), ONTRUZANT® (TRASTUZUMAB-DTTB), AND TRAZIMERA™ (TRASTUZUMAB-QYYP)

Length of Authorization:	6 months, may be renewed Use in the neo-adjuvant and adjuvant setting is limited to a total of 52 weeks of treatment
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

For Herceptin®, Herzuma®, Ogivri™, and Ontruzant®: for new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Kanjinti® OR Trazimera.

Note: For Core Formulary, all trastuzumab products are non-formulary.

Diagnosis of **Breast Cancer**:

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Therapy will not be substituted with or for ado-trastuzumab emtansine (Kadcyla) or fam-trastuzumab deruxtecan-nxki (Enhertu); **AND**
- Therapy will not be used in combination with trastuzumab and hyaluronidase-oysk (Herceptin Hylecta) or pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); **AND**
- Used as adjuvant therapy; **AND**
  - Used in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.) ; **OR**
  - Used as a single agent following chemotherapy; **OR**
  - Used in combination with pertuzumab for locally advanced, node positive disease or inflammatory disease; **OR**
- Used as neoadjuvant or preoperative; **AND**
  - Patient has locally advanced, node positive disease or inflammatory disease; **AND**
  - Used in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.) with or without pertuzumab; **OR**
- Used for recurrent, unresectable, or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
  - Used as a single agent in patients who have received one or more prior chemotherapy regimens for metastatic disease; **OR**
  - Used as first-line therapy in combination with paclitaxel; **OR**
  - Used in combination with endocrine therapy (e.g., tamoxifen, fulvestrant, or aromatase inhibition with or without lapatinib) in patients with hormone-receptor positive disease; **AND**
    - Patient is post-menopausal; **OR**
    - Patient is pre-menopausal and is treated with ovarian ablation/suppression; **OR**
    - Patient is a male receiving concomitant suppression of testicular steroidogenesis; **OR**
  - Used in combination with one of the following:
    - Cytotoxic chemotherapy as third-line therapy and beyond
    - Lapatinib (without cytotoxic therapy) as third-line therapy and beyond
    - Capecitabine plus tucatinib as second- to fourth-line therapy
    - Pertuzumab and a taxane (e.g., docetaxel, paclitaxel) as first-line therapy
    - Pertuzumab with or without cytotoxic subsequent therapy in patients who were previously treated with chemotherapy and trastuzumab without pertuzumab

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Central Nervous System Cancer**

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Therapy will not be substituted with or for ado-trastuzumab emtansine (Kadcyla) or fam-trastuzumab deruxtecan-nxki (Enhertu); **AND**
- Therapy will not be used in combination with trastuzumab and hyaluronidase-oysk (Herceptin Hylecta) or pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); **AND**
- Patient has leptomeningeal metastases from breast cancer; **AND**
  - Trastuzumab will be administered intrathecally; **OR**
- Patient has brain metastases from breast cancer; **AND**
  - Used in combination with capecitabine and tucatinib; **AND**
  - Patient previously received at least one HER2-directed therapy; **AND**
    - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
    - Patient has recurrent limited brain metastases; **OR**
    - Used for relapsed disease in patients with limited brain metastases and either stable systemic disease or reasonable systemic treatment options; **OR**
    - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

Diagnosis of **Gastric, Esophageal and Esophagogastric Junction Cancers**

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Therapy will not be substituted with or for ado-trastuzumab emtansine (Kadcyla) or fam-trastuzumab deruxtecan-nxki (Enhertu); **AND**
- Therapy will not be used in combination with trastuzumab and hyaluronidase-oysk (Herceptin Hylecta) or pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); **AND**
- Patient has unresectable (or medically inoperable) locally advanced, recurrent, or metastatic adenocarcinoma; **AND**
- Used as first-line therapy in combination with chemotherapy *(excluding use with anthracyclines or in combination with DCF [docetaxel, carboplatin, and fluorouracil])*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Uterine Cancer (Endometrial Carcinoma)**

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Therapy will not be substituted with or for ado-trastuzumab emtansine (Kadcyla) or fam-trastuzumab deruxtecan-nxki (Enhertu); **AND**
- Therapy will not be used in combination with trastuzumab and hyaluronidase-oysk (Herceptin Hylecta) or pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); **AND**
- Used in combination with carboplatin and paclitaxel; **AND**
- Patient has advanced (stage III/IV) or recurrent uterine serous carcinoma.

Diagnosis of **Colorectal Adenocarcinoma**

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Therapy will not be substituted with or for ado-trastuzumab emtansine (Kadcyla) or fam-trastuzumab deruxtecan-nxki (Enhertu); **AND**
- Therapy will not be used in combination with trastuzumab and hyaluronidase-oysk (Herceptin Hylecta) or pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); **AND**
- Used for RAS and BRAF wild-type (WT) disease in combination with pertuzumab or lapatinib; **AND**
- Patient has not previously received HER2-targeted therapy; **AND**
  - Used as subsequent therapy for progression of advanced or metastatic disease after at least one prior line of treatment in the advanced or metastatic disease setting; **OR**
  - Patient is not appropriate for intensive therapy; **AND**
    - Used as primary treatment for unresectable (or medically inoperable), locally advanced, or metastatic disease (excluding use as neoadjuvant therapy); **OR**
    - Used for unresectable (or medically inoperable) metastatic disease that remains unresectable after primary systemic therapy

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Head and Neck cancer**

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Therapy will not be substituted with or for ado-trastuzumab emtansine (Kadcyla) or fam-trastuzumab deruxtecan-nxki (Enhertu); **AND**
- Therapy will not be used in combination with trastuzumab and hyaluronidase-oysk (Herceptin Hylecta) or pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); **AND**
- Patient has salivary gland tumors; **AND**
  - Used as a single agent OR in combination with either docetaxel or pertuzumab; **AND**
  - Used for one of the following:
    - Recurrent disease with distant metastases; **OR**
    - Unresectable locoregional recurrence with prior radiation therapy (RT); **OR**
    - Unresectable second primary with prior RT

***HER2-positive overexpression criteria:**
• Immunohistochemistry (IHC) assay 3+; **OR** • Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number ≥ 4.0 signals/cell; **OR** • Dual-probe in situ hybridization (ISH) assay **and** concurrent IHC indicating one of the following: – HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number < 4.0 signals/cell **and** concurrent IHC 3+; **OR** – HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 6.0 signals/cell **and** concurrent IHC 2+ or 3+; **OR** – HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 4.0 and < 6.0 signals/cell **and** concurrent IHC 3+

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include cardiotoxicity (e.g., left ventricular dysfunction, cardiomyopathy), pulmonary toxicity (e.g., dyspnea, interstitial pneumonitis), neutropenia, infusion-related reactions, etc.; **AND**
  - LVEF is within the institutional normal limits and has not had an **absolute** decrease of ≥ 16% from pre-treatment baseline (LVEF results must be within the previous 3 months); **OR**
  - LVEF is below the institutional lower limits of normal and has not had an **absolute** decrease of ≥ 10% from pre-treatment baseline (LVEF results must be within the previous 3 months); **AND**
- Use for neoadjuvant and adjuvant breast cancer treatment is limited to a total of 52 weeks of therapy.

HEREDITARY ANGIOEDEMA

Length of Authorization:	• Berinert, Firazyr, Kalbitor, Ruconest: 12 weeks and is eligible for renewal • **Note:** The cumulative amount of medication(s) the patient has on-hand, indicated for the acute treatment of HAE, will be taken into account when authorizing. The authorization will provide a sufficient quantity in order for the patient to have a cumulative amount of HAE medication(s) on-hand in order to treat up to 4 acute attacks per 4 weeks for the duration of the authorization. • Cinryze, Haegarda: 12 months and is eligible for renewal • Orladeyo, Takhzyro: 6 months, may be renewed annually thereafter
Initiative:	SPC: Hereditary Angioedema (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

KALBITOR CRITERIA

Treatment of acute attacks of Hereditary Angioedema (HAE):

- Patient is at least 12 years of age; **AND**
- Must be prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Patient has a history of moderate to severe cutaneous or abdominal attacks **or** mild to severe airway swelling attacks of HAE (i.e., debilitating cutaneous/gastrointestinal symptoms **or** laryngeal/pharyngeal/tongue swelling); **AND**
- Confirmation the patient is avoiding the following possible triggers for HAE attacks:
  - Estrogen-containing oral contraceptive agents AND hormone replacement therapy **AND**
  - Antihypertensive agents containing ACE inhibitors; **AND**
  - Dipeptidyl peptidase IV (DPP-IV) inhibitors (e.g., sitagliptin); **AND**
  - Neprilysin inhibitors (e.g., sacubitril); **AND**
- Patient has one of the following clinical presentations consistent with a HAE subtype, which must be confirmed by repeat blood testing (treatment for acute attack should not be delayed for confirmatory testing):

HAE I (C1-Inhibitor deficiency)
• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND** – Patient has a family history of HAE; **OR** – Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS], etc.).
HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).
HAE with normal C1INH (formerly known as HAE III)
• Normal C1-INH antigenic level; **AND** • Normal C4 level; **AND** • Normal C1-INH functional level; **AND** • Repeat blood testing during an attack has confirmed the patient does not have abnormal lab values indicative of HAE I or HAE II; **AND** • Either of the following**:** – Patient has a known HAE-causing mutation (e.g., mutation of coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene, etc.); **OR** – Patient has a family history of HAE and documented evidence of lack of efficacy of chronic high-dose antihistamine therapy (e.g., cetirizine standard dosing at up to four times daily or an alternative equivalent, given for at least one month or an interval long enough to expect three or more angioedema attacks) **AND** corticosteroids with or without omalizumab.

BERINERT CRITERIA

For the **treatment of acute abdominal, facial, or laryngeal attacks of Hereditary Angioedema (HAE); AND**

- Must be prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Patient must be at least 6 years of age; **AND**
- Patient has a history of moderate to severe cutaneous attacks (without concomitant hives) OR abdominal attacks OR mild to severe airway swelling attacks of HAE (i.e., debilitating cutaneous/gastrointestinal symptoms OR laryngeal/pharyngeal/tongue swelling); **AND**
- Confirmation the patient is avoiding the following possible triggers for HAE attacks:
  - Estrogen-containing oral contraceptive agents **AND** hormone replacement therapy
  - Antihypertensive agents containing ACE inhibitors; **AND**
  - Dipeptidyl peptidase IV (DPP-IV) inhibitors (e.g., sitagliptin); **AND**
  - Neprilysin inhibitors (e.g., sacubitril); **AND**
- Patient has one of the following clinical presentations consistent with a HAE subtype, which must be confirmed by repeat blood testing (treatment for acute attack should not be delayed for confirmatory testing):

HAE I (C1-Inhibitor deficiency)
• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND** – Patient has a family history of HAE; **OR** – Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS], etc.)
HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).
HAE with Normal C1INH (also known as HAE III)
• Normal C1-INH antigenic level; **AND** • Normal C4 level; **AND** • Normal C1-INH functional level; **AND** • Repeat blood testing during an attack has confirmed the patient does not have abnormal lab values indicative of HAE I or HAE II; **AND** • Either of the following: – Patient has a known HAE-causing mutation (e.g., mutation of coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene); **OR** – Patient has a family history of HAE and documented evidence of lack of efficacy of chronic high-dose antihistamine therapy (e.g., cetirizine standard dosing at up to four times daily or an alternative equivalent, given for at least one month or an interval long enough to expect three or more angioedema attacks) **AND** corticosteroids with or without omalizumab

RUCONEST CRITERIA

Treatment of acute abdominal, peripheral or facial attacks of Hereditary Angioedema (HAE); AND

- Must be prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics**; AND**
- Patient does not have a history of allergy to rabbits or rabbit-derived products; **AND**
- Patient is at least 13 years of age; **AND**
- Patient has a history of moderate to severe cutaneous attacks (without concomitant hives) OR abdominal attacks OR mild to severe airway swelling attacks of HAE (i.e., debilitating cutaneous/gastrointestinal symptoms OR laryngeal/pharyngeal/tongue swelling); **AND**
- Confirmation the patient is avoiding the following possible triggers for HAE attacks:
  - Estrogen-containing oral contraceptive agents **AND** hormone replacement therapy
  - Antihypertensive agents containing ACE inhibitors; **AND**
  - Dipeptidyl peptidase IV (DPP-IV) inhibitors (e.g., sitagliptin); **AND**
  - Neprilysin inhibitors (e.g., sacubitril); **AND**
- Patient has **one** of the following clinical presentations consistent with a HAE subtype, which must be confirmed by repeat blood testing (treatment for acute attack should not be delayed for confirmatory testing):

HAE I (C1-Inhibitor deficiency)
• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND** – Patient has a family history of HAE; **OR** – Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS], etc.)
HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).
HAE with Normal C1INH (formerly known as HAE III)
• Normal C1-INH antigenic level; **AND** • Normal C4 level; **AND** • Normal C1-INH functional level; **AND** • Repeat blood testing **during an attack** has confirmed the patient does not have abnormal lab values indicative of HAE I or HAE II; **AND** • Either of the following: – Patient has a known HAE-causing mutation (e.g., mutation of coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene, etc.); **OR** – Patient has a family history of HAE and documented evidence of lack of efficacy of chronic high-dose antihistamine therapy (e.g., cetirizine standard dosing at up to four times daily or an alternative equivalent, given for at least one month or an interval long enough to expect three or more angioedema attacks) **AND** corticosteroids with or without omalizumab

CINRYZE

Prophylaxis against angioedema attacks of Hereditary Angioedema (HAE)

- Patient is at least 6 years of age; **AND**
- Must be prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Not used in combination with other prophylactic therapies targeting C1 inhibitor (i.e., Haegarda) or kallikrein (i.e., Takhzyro or Orladeyo); **AND**
- Patient has one of the clinical presentations listed in the table below consistent with an HAE subtype, which must be confirmed by repeat blood testing (treatment for acute attack should not be delayed for confirmatory testing); **AND**
  - Patient is receiving treatment as short-term HAE prophylaxis prior to a procedure (i.e., dental or medical procedure); **OR**
  - Patient has a history of one of the following criteria for long-term HAE prophylaxis:
    - History of **TWO** or more severe HAE attacks per month (i.e., airway swelling, debilitating cutaneous or gastrointestinal episodes)
    - Patient is disabled more than 5 days per month by HAE
    - History of at least one laryngeal attack caused by HAE; **AND**
- Treatment of patient with "on-demand" therapy (i.e., Kalbitor, Firazyr, Ruconest, or Berinert) did not provide satisfactory control or access to "on-demand therapy" is limited; **AND**
- Confirmation the patient is avoiding the following possible triggers of HAE attacks:
  - Estrogen-containing oral contraceptive agents AND hormone replacement therapy
  - Antihypertensive agents containing ACE inhibitors; **AND**
  - Dipeptidyl peptidase IV (DPP-IV) inhibitors (e.g., sitagliptin); **AND**
  - Neprilysin inhibitors (e.g., sacubitril)

CINRYZE *(CONTINUED)*

HAE I (C1-Inhibitor deficiency)
• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND** – Patient has a family history of HAE; **OR** – Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS])
HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).
HAE with Normal C1INH (formerly known as HAE III)
• Prophylaxis for HAE with normal C1-INH is not routinely recommended and will be evaluated on a case by case basis. – Prior to consideration of long-term prophylaxis, the patient must have demonstrated: • An inadequate response or intolerance to an adequate trial of prophylactic therapy with an antifibrinolytic agent (e.g., tranexamic acid (TXA) or aminocaproic acid) and/or a 17α-alkylated androgen (e.g., danazol) unless contraindicated. Female patients may derive additional benefit from progestins[16,17,18]; **AND** • Response to therapy from an agent indicated for the treatment of acute attacks (i.e., C1 esterase inhibitor, icatibant, ecallantide)

HAEGARDA

Prophylaxis to prevent Hereditary Angioedema (HAE) attacks

- Patient is at least 6 years of age; **AND**
- Must be prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Not used in combination with other prophylactic therapies targeting C1 inhibitor (i.e., Cinryze) or kallikrein (i.e., Takhzyro or Orladeyo); **AND**
- Patient has a history of one of the following criteria for long-term HAE prophylaxis
  - History of TWO or more severe HAE attacks per month (i.e., airway swelling, debilitating cutaneous or gastrointestinal episodes)
  - Patient is disabled more than 5 days per month by HAE
  - History of at least one laryngeal attacks caused by HAE; **AND**
- Treatment of patient with "on-demand" therapy (i.e., Kalbitor, Firazyr, Ruconest, or Berinert) did not provide satisfactory control or access to "on-demand therapy" is limited; **AND**
- Confirmation the patient is avoiding the following possible triggers of HAE attacks:
  - Estrogen-containing oral contraceptive agents AND hormone replacement therapy; **AND**
  - Antihypertensive agents containing ACE inhibitors; **AND**
  - Dipeptidyl peptidase IV (DPP-IV) inhibitors (e.g., sitagliptin); **AND**
  - Neprilysin inhibitors (e.g., sacubitril); **AND**
- Patient has one of the following clinical presentations consistent with a HAE subtype, which must be confirmed by repeat blood testing (treatment for acute attack should not be delayed for confirmatory testing):

HAE I (C1-Inhibitor deficiency)
• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND** – Patient has a family history of HAE; **OR** – Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS], etc.)
HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).
HAE with normal C1INH (formerly known as HAE III)
• Prophylaxis for HAE with normal C1-INH is not routinely recommended and will be evaluated on a case by case basis. – Prior to consideration of long-term prophylaxis, the patient must have demonstrated: • An inadequate response or intolerance to an adequate trial of prophylactic therapy with an antifibrinolytic agent (e.g., tranexamic acid [TXA] or aminocaproic acid) and/or a 17α-alkylated androgen (e.g., danazol) unless contraindicated. Female patients may derive additional benefit from progestins; **AND** • Response to therapy from an agent indicated for the treatment of acute attacks (e.g., C1 esterase inhibitor, icatibant, ecallantide)

TAKHZYRO™ (LANADELUMAB-FLYO)

Prophylaxis to prevent Hereditary Angioedema (HAE) attacks

- Patient is at least 12 years of age; **AND**
- Must be prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Not used in combination with C1 inhibitor prophylaxis (e.g., Cinryze or Haegarda) or berotralstat (Orladeyo); **AND**
- Patient has a history of **one** of the following criteria for long-term HAE prophylaxis
  - History of **two** or more severe HAE attacks per month (i.e., airway swelling, debilitating cutaneous or gastrointestinal episodes)
  - Patient is disabled more than 5 days per month by HAE
  - History of at least one laryngeal attacks caused by HAE; **AND**
- Treatment of patient with "on-demand" therapy (e.g., Kalbitor, Firazyr, Ruconest, or Berinert) did not provide satisfactory control or access to "on-demand therapy" is limited; **AND**
- Confirmation the patient is avoiding the following possible triggers of HAE attacks:
  - Estrogen-containing oral contraceptive agents **and** hormone replacement therapy; **AND**
  - Antihypertensive agents containing ACE inhibitors; **AND**
  - Dipeptidyl peptidase IV (DPP-IV) inhibitors (e.g., sitagliptin); **AND**
  - Neprilysin inhibitors (e.g., sacubitril); **AND**
- Patient has one of the following clinical presentations consistent with a HAE subtype, which must be confirmed by repeat blood testing (treatment for acute attack should not be delayed for confirmatory testing):

HAE I (C1-Inhibitor deficiency)
• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND** – Patient has a family history of HAE; **OR** – Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS], etc.)
HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).
HAE with normal C1INH (formerly known as HAE III)
• Prophylaxis for HAE with normal C1-INH is not routinely recommended and will be evaluated on a case by case basis. – Prior to consideration of long-term prophylaxis, the patient must have demonstrated: • An inadequate response or intolerance to an adequate trial of prophylactic therapy with an antifibrinolytic agent (e.g., tranexamic acid [TXA] or aminocaproic acid) and/or a 17α-alkylated androgen (e.g., danazol) unless contraindicated. Female patients may derive additional benefit from progestins; **AND** • Response to therapy from an agent indicated for the treatment of acute attacks (e.g., C1 esterase inhibitor, icatibant, ecallantide)

ORLADEYO™ (BEROTRALSTAT)

Prophylaxis to prevent Hereditary Angioedema (HAE) attacks

- Patient is at least 12 years of age; **AND**
- Must be prescribed by, or in consultation with, a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Not used in combination with C1 inhibitor prophylaxis (e.g., Cinryze or Haegarda) or lanadelumab (Takhzyro); **AND**
- Patient has a history of **one** of the following criteria for long-term HAE prophylaxis
  - History of **two** or more severe HAE attacks per month (i.e., airway swelling, debilitating cutaneous or gastrointestinal episodes)
  - Patient is disabled more than 5 days per month by HAE
  - History of at least one laryngeal attacks caused by HAE; **AND**
- Treatment of patient with "on-demand" therapy (e.g., Kalbitor, Firazyr, Ruconest, or Berinert) did not provide satisfactory control or access to "on-demand therapy" is limited; **AND**
- Confirmation the patient is avoiding the following possible triggers of HAE attacks:
  - Estrogen-containing oral contraceptive agents **and** hormone replacement therapy; **AND**
  - Antihypertensive agents containing ACE inhibitors; **AND**
  - Dipeptidyl peptidase IV (DPP-IV) inhibitors (e.g., sitagliptin); **AND**
  - Neprilysin inhibitors (e.g., sacubitril); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with P-gp or BCRP-inhibitors (e.g., cyclosporine, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with P-gp inducers (e.g., rifampin, St. John's Wort, etc.); **AND**
- Patient has one of the following clinical presentations consistent with a HAE subtype, which must be confirmed by repeat blood testing (treatment for acute attack should not be delayed for confirmatory testing):

ORLADEYO™ (BEROTRALSTAT) (*CONTINUED*)

HAE I (C1-Inhibitor deficiency)
• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND** – Patient has a family history of HAE; **OR** – Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS], etc.)
HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).
HAE with normal C1INH (formerly known as HAE III)
• Prophylaxis for HAE with normal C1-INH is not routinely recommended and will be evaluated on a case by case basis. – Prior to consideration of long-term prophylaxis, the patient must have demonstrated: • An inadequate response or intolerance to an adequate trial of prophylactic therapy with an antifibrinolytic agent (e.g., tranexamic acid [TXA] or aminocaproic acid) and/or a 17α-alkylated androgen (e.g., danazol) unless contraindicated. Female patients may derive additional benefit from progestins; **AND** • Response to therapy from an agent indicated for the treatment of acute attacks (e.g., C1 esterase inhibitor, icatibant, ecallantide)

FIRAZYR

Treatment of acute attacks of Hereditary Angioedema (HAE):

- Patient must be at least 18 years of age; **AND**
- Must be prescribed by, or in consultation with a specialist in allergy, immunology, hematology, pulmonology, or medical genetics; **AND**
- Patient has a history of moderate to severe cutaneous attacks (without concomitant hives) **or** abdominal attacks **or** mild to severe airway swelling attacks of HAE (i.e., debilitating cutaneous/gastrointestinal symptoms **or** laryngeal/pharyngeal/tongue swelling); **AND**
- Confirmation the patient is avoiding the following possible triggers for HAE attacks:
  - Estrogen-containing oral contraceptive agents **and** hormone replacement therapy; **AND**
  - Antihypertensive agents containing ACE inhibitors; **AND**
  - Dipeptidyl peptidase IV (DPP-IV) inhibitors (e.g., sitagliptin); **AND**
  - Neprilysin inhibitors (e.g., sacubitril); **AND**
- Patient has one of the following clinical presentations consistent with HAE subtype, which must be confirmed by repeat blood testing (treatment for acute attack should not be delayed for confirmatory testing):

HAE I (C1-Inhibitor deficiency)
• Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); **AND** – Patient has a family history of HAE; **OR** – Acquired angioedema has been ruled out (i.e., patient onset of symptoms occur prior to 30 years old, normal C1q levels, patient does not have underlying disease such as lymphoma or benign monoclonal gammopathy [MGUS], etc.)
HAE II (C1-Inhibitor dysfunction)
• Normal to elevated C1-INH antigenic level; **AND** • Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); **AND** • Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test).
HAE with Normal C1INH (formerly known as HAE III)
• Normal C1-INH antigenic level; **AND** • Normal C4 level; **AND** • Normal C1-INH functional level; **AND** • Repeat blood testing during an attack has confirmed the patient does not have abnormal lab • values indicative of HAE I or HAE II; **AND** • Either of the following: – Patient has a known HAE-causing mutation (e.g., mutation of coagulation factor XII gene [F12 mutation], mutation in the angiopoietin-1 gene, mutation in the plasminogen gene, etc.); **OR** – Patient has a family history of HAE and documented evidence of lack of efficacy of chronic high-dose antihistamine therapy (e.g., cetirizine standard dosing at up to four times daily or an alternative equivalent, given for at least one month or an interval long enough to expect three or more angioedema attacks) AND corticosteroids with or without omalizumab

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hypersensitivity reactions, including anaphylaxis serious thromboembolic events (arterial or venous), etc.; **AND**

BERINERT, FIRAZYR, KALBITOR, RUCONEST, TAKHZYRO

- Significant improvement in severity and duration of attacks have been achieved and sustained

HAEGARDA

- Significant improvement in severity, frequency, and/or duration of attacks have been achieved and sustained

CINRYZE

- Significant improvement in severity, frequency, and/or duration of attacks have been achieved and sustained; **OR**
- Patient requires dose titration due to an inadequate response to therapy (> 1.0 HAE attack/month, regardless of severity/duration)

BERINERT, FIRAZYR, KALBITOR, RUCONEST

- Significant improvement in severity and duration of attacks have been achieved and sustained
  - The cumulative amount of medication(s) the patient has on hand, indicated for the acute treatment of HAE, will be taken into account when authorizing. The authorization will provide a sufficient quantity in order for the patient to have a cumulative amount of HAE medication(s) on hand in order to treat up to 4 acute attacks per 4 weeks for the duration of the authorization.

ORLADEYO

- Significant improvement in severity, frequency, and/or duration of attacks have been achieved and sustained

TAKHZYRO

- Significant improvement in severity, frequency, and/or duration of attacks have been achieved and sustained; **AND**
- Patients who have demonstrated improvement/stabilization of disease and are well-controlled (e.g., attack free) for at least 6 months should attempt a trial of dosing every 4 weeks

HEREDITARY TYROSINEMIA

Length of Authorization:	1 year
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

ORFADIN, NITYR

Diagnosis of **hereditary tyrosinemia type 1 (HT-1)**

- Patient is on a tyrosine and phenylalanine restricted diet

HICON® (SODIUM IODIDE I-131)

Length of Authorization:	One administration of Hicon and cannot be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Hyperthyroidism**

- Patient is 18 years or older; **AND**
- Women of child-bearing age must have a negative pregnancy test prior to treatment; **AND**
- Lactating women should discontinue breast feeding at least 6 weeks prior to administration; **AND**
- Patient has adhered to a low-iodide diet for at least two weeks prior to therapy; **AND**
- Patient has discontinued any anti-thyroid medication (e.g., methimazole, propylthiouracil, triiodothyronine, thyroxine, etc.) for at least three days prior to therapy; **AND**
- Patients of reproductive potential must use effective contraception during treatment with therapy and for at least six months after the last dose; **AND**
- Patient is not currently experiencing vomiting and/or diarrhea; **AND**
- Patients with thyroid malignancies (e.g., medullary or anaplastic carcinomas) must demonstrate iodide uptake; **AND**
- Other causes of hyperthyroidism have been ruled out (e.g., thyroid malignancy, TSH-secreting pituitary tumors, etc.); **AND**
  - Patient has a confirmed diagnosis of hyperthyroidism related to Grave's Disease; **AND**
    - Patient has failed or has intolerance or contraindication to anti-thyroid medication therapy; **OR**
  - Patient has a confirmed diagnosis of hyperthyroidism related to toxic nodular/multinodular goiter or toxic adenoma

Diagnosis of **Thyroid Carcinoma**

- Patient is 18 years or older; **AND**
- Women of child-bearing age must have a negative pregnancy test prior to treatment; **AND**
- Lactating women should discontinue breast feeding at least 6 weeks prior to administration; **AND**
- Patient has adhered to a low-iodide diet for at least two weeks prior to therapy; **AND**
- Patient has discontinued any anti-thyroid medication (e.g., methimazole, propylthiouracil, triiodothyronine, thyroxine, etc.) for at least three days prior to therapy; **AND**
- Patients of reproductive potential must use effective contraception during treatment with therapy and for at least six months after the last dose; **AND**
- Patient is not currently experiencing vomiting and/or diarrhea; **AND**
- Patients with thyroid malignancies (e.g., medullary or anaplastic carcinomas) must demonstrate iodide uptake; **AND**
- Patient has a diagnosis of follicular, papillary, or Hürthle cell carcinoma; **AND**
  - Patient had a thyroidectomy; **OR**
  - Patient has locoregional, metastatic, or recurrent disease

CLINICAL CRITERIA FOR RENEWAL

- Cannot be renewed

HIV AGENTS

Length of Authorization:	1 year, may be renewed For Cabenuva and Vocabria: 6 months initial, 1 year on renewal
Initiative:	SPC: Antivirals (IE 2462 / NCPDP 75, 50081 and 2193)

STEP THERAPY: ATRIPLA, GENERIC EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE

For patients new to Atripla or generic efavirenz/emtricitabine/tenofovir disoproxil fumarate therapy, the patient must try and fail Symfi, Symfi Lo, OR efavirenz/lamivudine/tenofovir disoproxil fumarate.

STEP THERAPY: CIMDUO (NO GRANDFATHERING)

Patient must try Temixys

STEP THERAPY: COMPLERA

For patients new to Complera therapy, the patient must try one of the following: efavirenz/emtricitabine/tenofovir disoproxil fumarate (generic Atripla); efavirenz/lamivudine/tenofovir disoproxil fumarate (generic Symfi); efavirenz/lamivudine/tenofovir disoproxil fumarate (generic Symfi Lo); Atripla; Symfi; Symfi Lo; Delstrigo; or Odefsey

CLINICAL CRITERIA FOR INITIAL APPROVAL, PLAN MAY REQUIRE A PA

APTIVUS (TIPRANAVIR)

- Diagnosis of HIV-1; **AND**
- Patient must be ≥ 2 years of age; **AND**
- Patient must be taking ritonavir; **AND**
- Must **not** be used in treatment naïve patients; **AND**
- Patient must **not** have moderate to severe hepatic impairment; **AND**
- Patient must **not** be taking any of the following medications: alfuzosin, amiodarone, bepridil, flecainide, propafenone, quinidine, rifampin, dihydroergotamine, ergonovine, ergotamine, methylergonovine, cisapride, St, John's Wort, lovastatin, simvastatin, pimozide, lurasidone, Revatio, oral midazolam, or triazolam

BIKTARVY (BICTEGRAVIR, EMTRICITABINE, TENOFOVIR ALAFENAMIDE)

- Diagnosis of HIV-1; **AND**
- Patient has no history of antiretroviral treatment history; **OR**
- Biktarvy is replacing the current antiretroviral treatment in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 3 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy.

CLINICAL CRITERIA FOR INITIAL APPROVAL, PLAN MAY REQUIRE A PA (CONTINUED)

CABOTEGRAVIR/RILPIVIRINE (CABENUVA) AND CABOTEGRAVIR (VOCABRIA)

- Patient has a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection; **AND**
- Patient is ≥ 18 years of age; **AND**
- Patient is virologically suppressed with HIV-RNA < 50 copies/mL and is on a stable antiretroviral regimen; **AND**
- Patient has no history of treatment failure or known or suspected resistance to cabotegravir or rilpivirine; **AND**
- Patient has not had a previous hypersensitivity reaction to cabotegravir or rilpivirine; **AND**
- Patient will NOT receive concomitant therapy with ANY of the following medications that can result in significant decreases of cabotegravir and/or rilpivirine:
  - Carbamazepine
  - Oxcarbazepine
  - Phenobarbital
  - Phenytoin
  - Rifabutin
  - Rifampin
  - Rifapentine
  - Dexamethasone (more than a single-dose treatment)
  - St. John's wort; **AND**
- Patient will complete oral cabotegravir and rilpivirine ≥ 1 month prior to starting therapy with the injectable cabotegravir and rilpivirine formulations: **AND**
- Patient will contact their healthcare provider if they plan to miss a scheduled monthly injection visit to coordinate treatment with oral therapy to replace up to 2 consecutive monthly injections; **AND**
- Prescribed by or in consultation with an infectious disease specialist.

RENEWAL CRITERIA

- Patient continues to meet initial criteria; **AND**
- Patient has been adherent to their antiretroviral treatment with cabotegravir/rilpivirine; **AND**
- There is an absence of unacceptable toxicity from the drug (e.g. hypersensitivity reactions, hepatotoxicity, serious post-injection reactions, and unremitting depression); **AND**
- Patient has not experienced virologic failure of cabotegravir/rilpivirine and has documented clinical improvement and/or stabilization

CIMDUO (LAMIVUDINE, TENOFOVIR DISOPROXIL FUMARATE)

- Diagnosis of HIV-1; **AND**
- Patient is at least 35kg (adult and pediatric patients).

CRIXIVAN (INDINAVIR)

- Diagnosis of HIV-1; **AND**
- Patient must **not** be taking any of the following medications: alfuzosin, amiodarone, lurasidone, dihydroergotamine, ergotamine, methylergonovine, cisapride, lovastatin, simvastatin, oral midazolam, triazolam, alprazolam, or Revatio.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

COMBIVIR (LAMIVUDINE/ZIDOVUDINE)

- Diagnosis of HIV-1; **AND**
- Patient must be tested for Hepatitis B virus (HBV) before initiating; **AND**
- Patient must weigh ≥ 35 kg; **AND**
- Patient must not have a CrCl < 50 mL/min
- **Not** approved for the treatment of chronic Hepatitis B virus infection

DESCOVY (EMTRICITABINE/TENOFOVIR ALAFENAMIDE)

- Diagnosis of HIV-1 infection and patient weighs ≥ 25 kg; **OR**
- Requested for pre-exposure prophylaxis (PrEP) in at-risk and adolescents weighing ≥ 35 kg; **AND**
  - For PrEP: patient has a history of intolerance or contraindication to generic emtricitabine/tenofovir disoproxil fumarate (e.g., renal impairment, decreases in bone density, history of pathologic fracture or other risk factors for osteoporosis or bone loss).
  - If approved for PrEP, then it should be processed under the ACA coverage for those enrolled as $0.

    Note for PrEP approvals: when faxing the prescriber with the determination, let the MDO know that the pharmacy must submit a submission clarification code (SCC) of "10"

EDURANT (RILPIVIRINE)

- Diagnosis of HIV-1; **AND**
- Patient must be antiretroviral treatment-naïve; **AND**
- Patient must be ≥ 12 years of age; **AND**
- Patient must weigh at least 35 kg; **AND**
- Patient must **not** be taking any of the following medications: carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, proton pump inhibitors, dexamethasone, or St. John's Wort

EMTRIVA (EMTRICITABINE)

- Diagnosis of HIV-1; **AND**
- Patient must be tested for Hepatitis B (HBV) before initiating
- Medication is **not** approved for the treatment of chronic hepatitis B virus infection

EPIVIR (LAMIVUDINE)

- Diagnosis of HIV-1; **AND**
- Patient must be tested for Hepatitis B virus (HBV) before initiating
- **Not** approved for the treatment of chronic Hepatitis B virus infection

EPZICOM (ABACAVIR/LAMIVUDINE)

- Diagnosis of HIV-1; **AND**
- Patient must be screened for HLA-B*5701 allele before initiating [contraindicated in HLA-B*5701 positive patients]; **AND**
- Patient must not have moderate to severe hepatic impairment

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

EVOTAZ (ATAZANAVIR/COBICISTAT)

- Diagnosis of HIV-1; **AND**
- Patient does **not** have end stage renal disease managed with hemodialysis; **AND**
- Patient does **not** have any degree of hepatic impairment

FUZEON (ENFUVIRTIDE)

- Diagnosis of HIV-1; **AND**
- Patient must be ≥ 6 years of age

INTELENCE (ETRAVIRINE)

- Diagnosis of HIV-1; **AND**
- Patient must be ≥ 6 years of age

INVIRASE (SAQUINAVIR MESYLATE)

- Diagnosis of HIV-1; **AND**
- Patient must **not** be taking ritonavir; **AND**
- Patient is ≥ 16 years of age; **AND**
- Patient must **not** have a history of AV block or long QT syndrome; **AND**
- Patient must **not** have severe hepatic impairment; **AND**
- Patient must **not** be taking any of the following medications: alfuzosin, amiodarone, bepridil, dofetilide, flecainide, lidocaine (systemic), propafenone, quinidine, trazodone, clarithromycin, erythromycin, pentamidine, rifampin, lurasidone, chlorpromazine, clozapine, haloperidol, mesoridazine, phenothiazines, pimozide, sertindole, thioridazine, ziprasidone, dihydroergotamine, ergonovine, ergotamine, methylergonovine, cisapride, atazanavir, lovastatin, simvastatin, tacrolimus, Revatio, triazolam, oral midazolam, dapsone, disopyramide, quinine

ISENTRESS (RALTEGRAVIR)

- Diagnosis of HIV-1; **AND**
- Patient must be ≥ 4 years of age; **AND**
- Patient must weigh at least 40 kg

KALETRA AND LOPINAVIR/RITONAVIR

- Diagnosis of HIV-1 and used in combination with other antiretroviral agents for the treatment of HIV-1 infection; **AND**
- Patient must be ≥ 14 days old; **AND**
- Patient must not be taking any of the following medications: apalutamide, alfuzosin, ranolazine, dronedarone, colchicine (in patients with renal and/or hepatic impairment), rifampin, lurasidone, pimozide, dihydroergotamine, ergotamine, methylergonovine, cisapride, elbasvir/grazoprevir, St. John's Wort, lovastatin, simvastatin, lomitapide, Revatio and generic sildenafil for the treatment of pulmonary arterial-hypertension, triazolam, or orally administered midazolam

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

LEXIVA (FOSAMPRENAVIR)

- Diagnosis of HIV-1; **AND**
- Patient must be ≥ 4 weeks of age

NORVIR (RITONAVIR)

- Diagnosis of HIV-1; **AND**
- Patient must be ≥ 1 month old; **AND**
- Patient must **not** be taking any of the following medications: alfuzosin, amiodarone, dronedarone, flecainide, propafenone, quinidine, voriconazole, colchicine, lurasidone, pimozide, dihydroergotamine, ergotamine, methylergonovine, cisapride, St. John's Wort, lovastatin, simvastatin, Revatio, oral midazolam, or triazolam.

PREZCOBIX (DARUNAVIR/COBICISTAT)

- Diagnosis of HIV-1; **AND**
- Patient must be ≥ 18 years of age; **AND**
- Patient must **not** have any darunavir resistance-associated substitutions (V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V); **AND**
- Patient must **not** have an estimated CrCl below 70 mL/min (if patient is also receiving tenofovir)

PREZISTA (DARUNAVIR)

- Diagnosis of HIV-1; **AND**
- Patient must be ≥ 3 years of age; **AND**
- Medication must be co-administered with ritonavir (to exert its therapeutic effect)

RESCRIPTOR (DELAVIRDINE MESYLATE)

- Diagnosis of HIV-1; **AND**
- Patient must be at least 16 years of age

RETROVIR (ZIDOVUDINE)

- Diagnosis of HIV-1; **AND**
- Patient must be ≥ 4 weeks of age; **OR**
- Diagnosis of prevention of maternal-fetal HIV-1 transmission

REYATAZ (ATAZANAVIR)

- Diagnosis of HIV-1; **AND**
- Patient is ≥ 3 months of age; **AND**
- Patient is ≥ 5 kg; **AND**
- Patient is **not** taking any of the following medications: alfuzosin, triazolam, orally administered midazolam, ergot derivatives, rifampin, irinotecan, lurasidone, lovastatin, simvastatin, indinavir, cisapride, pimozide, St. John's Wort, nevirapine, or Revatio

SELZENTRY (MARAVIROC)

- Diagnosis of CCR5-tropic HIV-1 infection confirmed by a highly sensitive tropism assay; **AND**
- The requested medication will be used in combination with other antiretroviral agents

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

SYMFI-LO (EFAVIRENZ, LAMIVUDINE, TENOFOVIR DISOPROXIL FUMARATE)

- Diagnosis of HIV-1; **AND**
- Patient is at least 35kg (adult and pediatric patients)

SUSTIVA (EFAVIRENZ)

- Diagnosis of HIV-1; **AND**
- Patient must weigh at least 3.5 kg; **AND**
- Patient must be at least 3 months of age

TRIUMEQ (ABACAVIR/DOLUTEGRAVIR/LAMIVUDINE)

- Diagnosis of HIV-1; **AND**
- Patient has been screened for HLA-B*5701 prior to starting any regimen with Abacavir; **AND**
- Anti-Retroviral resistance testing for each component has been completed; **AND**
- Patient does not have integrase strand transfer inhibitor resistance
- DENY if patient is resistant to any component. Resistance will cause insufficient dosing in the dose of dolutegravir and be subtherapeutic for this population

TIVICAY (DOLUTEGRAVIR)

- Diagnosis of HIV-1; **AND**
- Patient must weigh at least 30 kg

TRIZIVIR (ABACAVIR/LAMIVUDINE/ZIDOVUDINE)

- Diagnosis of HIV-1; **AND**
- Patient weighs at least 40 kg (adult and pediatric patients); **AND**
- Patient must be screened for HLA-B*5701 allele before initiating [contraindicated in HLA-B*5701 positive patients]; **AND**
- Must not have moderate to severe hepatic impairment

TROGARZO (IBALIZUMAB-UIYK)

- Diagnosis of **Human Immunodeficiency Virus Type-1 (HIV-1)**; **AND**
- Patient is at least 18 years old; **AND**
- Patient has heavily treated multi-drug resistant disease, confirmed by resistance testing, to at least one drug in at least three classes (see table below); **AND**
- Patient has a baseline viral load > 1,000 copies/mL; **AND**
- Patient is failing on their current anti-retroviral regimen; **AND**
- Used in combination with highly active antiretroviral therapy (HAART) for which, via resistance testing, the patient's disease is known to be sensitive/susceptible

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

TROGARZO (IBALIZUMAB-UIYK) *(CONTINUED)*

Class	Examples (not all-inclusive)
Nucleoside reverse transcription inhibitor (NRTI)	Abacavir, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, zidovudine
Non-nucleoside reverse transcription inhibitor (NNRTI)	Delavirdine, efavirenz, rilpivirine, nevirapine, etravirine, doravirine
Protease inhibitor (PI)	Atazanavir, darunavir, fosamprenavir, nelfinavir, ritonavir, tipranavir

RENEWAL INFO

- Absence of unacceptable toxicity from the drug (e.g., immune reconstitution inflammatory syndrome [IRIS]); **AND**
- Disease response as indicated by a decrease in viral load from pretreatment baseline
- **Note:** increases in viral load from nadir and/or less than anticipated reduction from baseline should prompt resistance testing for susceptibility and optimization of the background regimen

TRUVADA (EMTRICITABINE/TENOFOVIR)

- Diagnosis of HIV-1 and patient weighs ≥ 17 kg; **OR**
- Requested for pre-exposure prophylaxis (PrEP) in at-risk adults and adolescents weighing ≥ 35 kg

VIDEX OR VIDEX EC (DIDANOSINE)

- Diagnosis of HIV-1; **AND**
- Patient must be at least 2 weeks of age

VIRACEPT (NELFINAVIR)

- Diagnosis of HIV-1; **AND**
- Patient must be ≥ 2 years of age; **AND**
- Patient must not have moderate to severe hepatic impairment; **AND**
- Patient must not be taking any of the following medications: alfuzosin, amiodarone, quinidine, rifampin, lurasidone, pimozide, dihydroergotamine, ergotamine, methylergonovine, cisapride, St. John's Wort, lovastatin, simvastatin, Revatio, triazolam, or orally administered midazolam

VIRAMUNE (NEVIRAPINE)

- Diagnosis of HIV-1; **AND**
- Patient must be ≥ 15 days of old; **AND**
- Patient must **not** have moderate to severe hepatic impairment
- **Not** approved for occupational and non-occupational post-exposure prophylaxis (PEP) regimens

VIRAMUNE XR (NEVIRAPINE ER)

- Diagnosis of HIV-1; **AND**
- Patient must be ≥ 6 years of age; **AND**
- Patient must **not** have moderate to severe hepatic impairment
- **Not** approved for occupational and non-occupational post-exposure prophylaxis (PEP) regimens

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

VIREAD (TENOFOVIR)

- Diagnosis of HIV-1; **AND**
- Patient must be ≥ 2 years of age; **OR**
- Diagnosis of chronic Hepatitis B infection; **AND**
- Patient must be ≥ 12 years of age

VITEKTA (ELVITEGRAVIR)

- Diagnosis of HIV-1; **AND**
- Patient must be at least 18 years of age; **AND**
- Medication must be taken with ritonavir **and** another protease inhibitor (atazanavir, lopinavir, darunavir, fosamprenavir, tipranavir)

ZERIT/ZERIT XR (STAVUDINE)

- Diagnosis of HIV-1; **AND**
- Patient must not have severe hepatic impairment

ZIAGEN (ABACAVIR)

- Diagnosis of HIV-1; **AND**
- Patient must be screened for HLA-B*5701 allele before initiating [contraindicated in HLA-B*5701 positive patients]; **AND**
- Patient must not have moderate to severe hepatic impairment

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above.

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **moderate to severe vasomotor symptoms (i.e., hot flashes) associated with menopause in post-menopausal women**

- Trial and failure of estrogen replacement therapy

HUNTINGTONS DISEASE CHOREA

Length of Authorization:	6 months, may be renewed [Xenazine] 1 year, may be renewed [Austedo]
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

XENAZINE (TETRABENAZINE)

Diagnosis of **Chorea associated with Huntington's Disease**

- Patient is ≥ 18 years old; **AND**
- Patient has been diagnosed with Huntington's disease; **AND**
- Patient is not pregnant; **AND**
- Patient has normal hepatic function (ALT < 3 times ULN); **AND**
- Patient is not receiving concomitant monoamine oxidase inhibitor (MAOI) therapy or MAOI therapy was discontinued at least 14 days prior to starting tetrabenazine; **AND**
- Patient is not receiving concomitant reserpine therapy or reserpine was discontinued at least 20 days prior to starting tetrabenazine; **AND**
- Patient is not receiving concomitant therapy with another vesicular monoamine transporter 2 (VMAT2)-inhibitor (e.g., deutetrabenazine, valbenazine, etc.); **AND**
- Patient will not be on concomitant therapy with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented:
  - Drugs that prolong the QT-interval (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone, moxifloxacin, quinidine, procainamide, amiodarone, sotalol, etc.)
  - Strong CYP2D6 inhibitors (e.g., fluoxetine, paroxetine, quinidine); **AND**
- If patient's dose is above 50 mg per day, then the patient must be genotyped for CYP2D6 enzyme to confirm the patient is not a poor metabolizer (PM) or extensive metabolizer (EM); **AND**
- Patient is not actively suicidal; **AND**
- Patient does not have uncontrolled or untreated depression; **AND**
- The patient has had an inadequate response to at least a 3 month trial with one of the following conventional treatments for chorea: amantadine or antipsychotics (i.e., risperidone, olanzapine, haloperidol, quetiapine, aripiprazole); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., Total Chorea Score, Unified Huntington's Disease Rating Scale (UHDRS) or Physician-rated Clinical Global Impression (CGI)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

AUSTEDO (DEUTETRABENAZINE)

Diagnosis of **Huntington's Disease chorea**

- Patient has been diagnosed with chorea related to Huntington's disease; **AND**
- Patient is able to swallow; **AND**
- Patient is ≥ 18 years; **AND**
- Patient should **not** meet the following:
  - History of untreated or inadequately controlled depression
  - Suicidal ideation
  - Concurrent therapy with another VMAT2 inhibitor (i.e., tetrabenazine, valbenazine), reserpine (within 20 days), or monoamine oxidase (MAO) inhibitors (i.e., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc., within 14 days)
  - Pregnancy
  - Hepatic impairment

Diagnosis of **Tardive Dyskinesia**

- Patient has been diagnosed with tardive dyskinesia; **AND**
- Patient is ≥ 18 years; **AND**
- Patient is able to swallow; **AND**
- Documentation that AIMS test has been completed (i.e., score or copy of AIMS assessment); **AND**
- Prescribed by or in consultation with a neurologist or psychiatrist (or other mental health provider), provided patient has reasonable access; **AND**
- Documentation or claims history of current or former chronic patient use of a dopamine antagonist (i.e., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.); **AND**
- Patient should **not** meet the following:
  - Concurrent therapy with another VMAT2 inhibitor (i.e., tetrabenazine, valbenazine), reserpine (within 20 days), or monoamine oxidase (MAO) inhibitors (i.e., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc. within 14 days)
  - Pregnancy
  - Hepatic impairment

CLINICAL CRITERIA FOR RENEWAL

AUSTEDO

- Disease response with improvement of symptoms with respective condition (i.e., tardive dyskinesia or Huntington's Chorea; **AND**
- Absence of unacceptable toxicity from the drug (e.g., increased depression or suicidality in patients with Huntington's disease, clinical worsening of Huntington's disease, significant QTc prolongation, neuroleptic malignant syndrome [NMS], significant hyperprolactinemia, severe akathisia)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

XENAZINE

- Disease response as indicated by improvement of symptoms per one of the following: Total Chorea Score, Unified Huntington's Disease Rating Scale (UHDRS) or Physician-rated Clinical Global Impression (CGI); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: neuroleptic malignant syndrome, restlessness, agitation, akathisia, parkinsonism, sedation/somnolence and QT prolongation, suicidal thinking and behaviors and symptomatic hyperprolactinemia, etc.

HYCAMTIN® (TOPOTECAN)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

CRITERIA FOR **ORAL** HYCAMTIN

Diagnosis of **small cell lung cancer (oral)**

- Must be used as a single agent; **AND**
- Patient will avoid concomitant therapy with P-gp or BCRP-inhibitors (e.g., cyclosporine, etc.); **AND**
- Patient must have a performance status of 0-2; **AND**
- Patient has contraindication to intravenous administration of topotecan; **AND**
- One of the following:
  - Patient has relapse within 6 months following complete or partial response or stable disease with initial treatment; **OR**
  - Patient has primary progressive disease.

Diagnosis of **Merkel cell carcinoma (oral)**

- Must be used as a single agent; **AND**
- Patient will avoid concomitant therapy with P-gp or BCRP-inhibitors (e.g., cyclosporine, etc.); **AND**
- Patient has disseminated metastatic disease; **AND**
- Patient has contraindication to intravenous administration of topotecan; **AND**
- Patient is unable to receive or not a candidate for checkpoint immunotherapy (e.g., avelumab, pembrolizumab, nivolumab, etc.)

CRITERIA FOR **IV** HYCAMTIN:

- Diagnosis of Cervical Cancer (IV)
- Diagnosis of Ovarian Cancer (Epithelial, Primary Peritoneal and Fallopian Tube cancers) (IV)
- Diagnosis of Small Cell Lung Cancer (IV)
- Diagnosis of Bone Cancer – (Ewing's sarcoma and Osteosarcoma) (IV)
- Diagnosis of CNS Cancers – **Leptomeningeal Metastases** (IV)
- Diagnosis of Merkel Cell Carcinoma (IV)
- Diagnosis of Soft Tissue Sarcoma – Non-pleomorphic Rhabdomyosarcoma (IV)
- Diagnosis of Uterine Neoplasms –Endometrial Carcinoma (IV)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hematologic toxicities [neutropenia, thrombocytopenia, anemia], interstitial lung disease [monitor for new or progressive respiratory symptoms])

HYPOGLYCEMICS: AMYLIN ANALOG

Length of Authorization:	1 Year
Initiative:	MNC: Hypoglycemics (IE 2462 / NCPDP 75)

SYMLIN INITIAL CRITERIA

Diagnosis of **type 1 or type 2 diabetes mellitus**

- The patient has been receiving Symlin for at least 3 months **and** has demonstrated a reduction in A1c since starting therapy; **OR**
- The patient does **not** have any of the following:
  - Gastroparesis
  - Hypoglycemia unawareness (i.e., inability to detect and act upon the signs or symptoms of hypoglycemia)

SYMLIN CLINICAL CRITERIA FOR RENEWAL

- The patient is stable on medication; **AND**
- Patient still meets initial criteria

HYPOGLYCEMICS: BIGUANIDE

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Hypoglycemics (IE 2462 / NCPDP 75)

BRAND RIOMET®/RIOMET® ER (METFORMIN SUSPENSION)

- Patient age is 10 years or older; **AND**
- Patient has had a trial of generic metformin (tablets or solution) or the dosage needed is not available in another formulation

CLINICAL CRITERIA FOR RENEWAL

- Continue to meet above criteria; **AND**
- No contraindications to continuation of therapy; **AND**
- Documentation of positive clinical response to therapy

HYPOGLYCEMICS: DIPEPTIDYL PEPTIDASE IV (DPP4) INHIBITORS

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

Length of Authorization:	6 months for initial approval, Renewals: 1 year
Initiative:	MNC: Hypoglycemics (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

Diagnosis of **Type 2 Diabetes**

- Patient has failed to achieve adequate glycemic control with metformin or metformin ER; **OR**
- Patient has failed to achieve adequate glycemic control with glipizide/metformin or glyburide/metformin; **OR**
- Patient has failed to achieve adequate glycemic control with pioglitazone/metformin

ALOGLIPTIN, ALOGLIPTIN/METFORMIN, ALOGLIPTIN/PIOGLITAZONE, KAZANO, KOMBIGLYZE XR, NESINA, ONGLYZA AND OSENI (NO GRANDFATHERING)

- **Standard and Enhanced Formularies:** In addition to clinical criteria above, the patient has tried one agent from each of the following groups ***for at least 90 days***:
  - Januvia, Janumet or Janumet XR; **AND**
  - Jentadueto, Jentadueto XR, Tradjenta

HYPOGLYCEMICS: INCRETIN MIMETICS

STANDARD FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Hypoglycemics (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL (PA, NO GRANDFATHERING)

ADLYXIN

- Patient has failed to achieve adequate glycemic control with metformin, metformin ER, glipizide/metformin, glyburide/metformin, or pioglitazone/metformin; **AND**
- Patient has tried the following medications:
  - Victoza **OR** Trulicity **OR** Ozempic **OR** Rybelsus; **AND**
  - Byetta **OR** Bydureon **OR** Bydureon BCise.

RYBELSUS

Patient has failed to achieve adequate glycemic control with metformin, metformin ER, glipizide/metformin, glyburide/metformin, or pioglitazone/metformin

PRECISION/PLUS FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Hypoglycemics (IE 2462 / NCPDP 75)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

Summary of Drug Preferencing:

- Patient has tried and failed metformin, metformin ER, glipizide/metformin, glyburide/metformin, or pioglitazone/metformin; **THEN**
  - Once the above parameters are met, a member can have: Victoza, Trulicity, Rybelsus, Ozempic, Byetta, Bydureon, Bydureon BCise.
- Adlyxin is excluded on Precision Formulary

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

BYETTA, BYDUREON, BYDUREON BCISE, OZEMPIC, RYBELSUS, TRULICITY, AND VICTOZA

- Patient has failed to achieve adequate glycemic control with metformin, metformin ER, glipizide/metformin, glyburide/metformin, or pioglitazone/metformin

CORE FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Hypoglycemics (IE 2462 / NCPDP 75 – HICL)

CLINICAL CRITERIA FOR INITIAL APPROVAL (PA, NO GRANDFATHERING)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

ADLYXIN, VICTOZA, OZEMPIC, RYBELSUS

Patient has failed to achieve adequate glycemic control with metformin, metformin ER, glipizide/metformin, glyburide/metformin, or pioglitazone/metformin.

HYPOGLYCEMICS: INCRETIN MIMETICS/INSULIN

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Hypoglycemics: GLP1 Agonists (IE 2462 / NCPDP 75)

XULTOPHY® (NO GRANDFATHERING)

- Patient has failed to achieve adequate glycemic control with metformin/ER, glipizide/metformin, glyburide/metformin, or pioglitazone/metformin.

PRECISION FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Hypoglycemics: GLP1 Agonists (IE 2462 / NCPDP 75)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

SOLIQUA®, XULTOPHY® (NO GRANDFATHERING)

- Patient has failed to achieve adequate glycemic control with metformin/ER, glipizide/metformin, glyburide/metformin, or pioglitazone/metformin;.

HYPOGLYCEMICS: INSULINS

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Hypoglycemics (IE 2462 / NCPDP 75)

CLINCAL CRITERIA FOR INITIAL APPROVAL

AFREZZA®

- No history of smoking in the previous 6 months
- No history of chronic lung disease, such as asthma or COPD
- For patients with Type 1 DM must be used with a long acting insulin

APIDRA® SOLOSTAR®, APIDRA®, FIASP® FLEXTOUCH®, GENERIC INSULIN LISPRO, GENERIC INSULIN ASPART, GENERIC INSULIN LISPRO JUNIOR, GENERIC INSULIN LISPRO PROTAMINE/INSULIN LISPRO,GENERIC INSULIN ASPART PROTAMINE/INSULIN ASPART, AND ADMELOG® (NO GRANDFATHERING)

- Patient has tried and failed both TWO of the following: Humalog®, Novolog®, or Lyumjev®

BASAGLAR® AND SEMGLEE (NO GRANDFATHERING)

- The patient has tried and failed **two** of the following: Lantus®, Levemir®, Toujeo®, or Tresiba®

PRECISION/PLUS FORMULARY CRITERIA

CORE FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Hypoglycemics (IE 2462 / NCPDP 75)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

CLINCAL CRITERIA FOR INITIAL APPROVAL

AFREZZA

- No history of smoking in the previous 6 months
- No history of chronic lung disease, such as asthma or COPD
- For patients with Type 1 DM must be used with a long acting insulin

ENHANCED FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Hypoglycemics (IE 2462 / NCPDP 75 – HICL)

CLINCAL CRITERIA FOR INITIAL APPROVAL

AFREZZA®

- No history of smoking in the previous 6 months
- No history of chronic lung disease, such as asthma or COPD
- For patients with Type 1 DM must be used with a long acting insulin

APIDRA® SOLOSTAR®, APIDRA®, GENERIC INSULIN LISPRO, GENERIC INSULIN ASPART, GENERIC INSULIN LISPRO JUNIOR, GENERIC INSULIN LISPRO PROTAMINE/INSULIN LISPRO, GENERIC INSULIN ASPART PROTAMINE/INSULIN ASPART, AND ADMELOG® (NO GRANDFATHERING)

- Patient has tried one agent from each of the following groups:
  - Humalog OR Lyumjev; **AND**
  - Novolog OR Fiasp

BASAGLAR® AND SEMGLEE (NO GRANDFATHERING)

The patient has tried and failed **two** of the following: Lantus®, Levemir®, Toujeo®, or Tresiba®

HYPOGLYCEMICS: SODIUM GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITOR

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

Length of Authorization:	6 months, Renewals one year
Initiative:	MNC: Hypoglycemics (IE 2462 / NCPDP 75)

CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

Diagnosis of **chronic kidney disease WITHOUT type 2 diabetes (Farxiga® only)**

- Must be ≥ 18 years of age; **AND**
- Patient must have appropriate kidney function as per product label (see below under drug specific criteria); **AND**
- Patient does not have polycystic kidney disease, **OR**
- Patient does not require or have a recent history of immunosuppressive therapy for the treatment of kidney disease.

Diagnosis of **Heart Failure (NYHA class II-IV) with reduced ejection fraction WITHOUT type 2 diabetes (Farxiga® and Jardiance only)**

- Must be ≥ 18 years of age; **AND**
- Patient must have appropriate kidney function as per product label (see below under drug specific criteria).

Diagnosis of **Diabetes Mellitus type 2**

- Must be ≥ 18 years of age; **AND**
- Patient has failed to achieve adequate glycemic control with metformin, metformin ER, glipizide/metformin, glyburide/metformin, or pioglitazone/metformin**; AND**
- Patient must have appropriate kidney function as per product label (see below under drug specific criteria).
- **Drug specific criteria for Invokana®, Invokamet® IR/XR, Farxiga®, and Xigduo®:** If a patient has any of the following: chronic kidney insufficiency; congestive heart failure; and taking other medications such as diuretics, blood pressure medicines called angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs), and nonsteroidal anti-inflammatory drugs (NSAIDs), then provider must confirm appropriate kidney function as per product label (per FDA warning: 6/15/2016).
  - Steglatro™, Steglujan™, and Segluromet™: Must have eGFR ≥ 60 mL/min/1.73m^2 in order to receive
  - Invokana®: Must have eGFR ≥ 30 mL/min/1.73 m^2 to initiate
  - Invokamet® IR/XR: Must have eGFR ≥ 45 mL/min/1.73 m^2 to initiate.
  - Qtern®, Xigduo® XR, Synjardy® IR/XR, Trijardy® XR: Must have eGFR ≥ 45 mL/min/1.73 m^2.
  - Farxiga® (to improve glycemic control): Must have eGFR ≥ 45 mL/min/1.73 m^2. Contraindicated in patients on dialysis.
  - Farxiga® (to reduce the risk of eGFR decline, ESKD, CV death, and hospitalization for heart failure [hHF]): Must have eGFR ≥ 25 mL/min/1.73 m^2 to initiate; may continue therapy if eGFR <25 mL/min/1.73 m^2. Contraindicated in patients on dialysis.
  - Jardiance® (to improve glycemic control), Glyxambi: Must have eGFR ≥ 30 mL/min/1.73 m^2. Contraindicated in patients on dialysis.
  - Jardiance® (for heart failure): Must have eGFR ≥ 20 mL/min/1.73 m^2. Contraindicated in patients on dialysis.

INVOKANA®, INVOKAMET® IR/XR, QTERN®, STEGLATRO®, STEGLUJAN®, SEGLUROMET® (NO GRANDFATHERING)

- **For Standard and Enhanced Formularies:** In addition to clinical criteria above, the patient has tried one agent from each of the following groups **for at least 90 days**:
  - Farxiga® or Xigduo® XR; **AND**
  - Jardiance®, Synjardy® IR/XR, Trijardy® XR or Glyxambi®

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria identified above (for type 2 diabetes, patient must have failed preferred agents); **AND**
- Disease response; **AND**
- Patient has appropriate kidney function; **AND**
- Absence of unacceptable toxicity from the drug

HYPOGLYCEMICS: THIAZOLIDINEDIONES (TZDS)

Length of Authorization:	1 Year
Initiative:	MNC: Hypoglycemics (IE 31001 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

ACTOPLUS MET XR – BRAND ONLY

- History of ONE of the following:
  - Metformin; **OR**
  - A thiazolidinedione (i.e., pioglitazone, etc.)

AVANDAMET OR AVANDIA

Diagnosis of **Type II Diabetes Mellitus**

- **One** of the following:
  - History of failure, contraindication, or intolerance to **FOUR** of the following:
    - A biguanide
    - A sulfonylurea
    - Insulin
    - An incretin mimetic
    - A meglitinide
    - A dipeptidyl peptidase-4 inhibitor
    - A pioglitazone; **OR**
- Patient is already taking Avandia or Avandamet

Deny Avandamet or Avandia if patient has any of the following:

- Symptomatic heart failure
- New York Heart Association class III or IV heart failure
- Active bladder cancer or history of bladder cancer
- History of fracture or at high risk for fracture (e.g., postmenopausal women with low bone mass)
- Active liver disease (liver enzymes >2.5 times above the upper reference limit)
- Type 1 diabetes
- Pregnant

IBRANCE® (PALBOCICLIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a cyclin-dependent kinase (CDK) 4 and 6 inhibitor (e.g., ribociclib, abemaciclib, etc.); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, clarithromycin, nefazodone, grapefruit, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has hormone receptor (HR)-positive disease; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
- Used for recurrent, unresectable, advanced, or metastatic disease OR patient has inflammatory disease with no response to pre-operative systemic therapy; **AND**
- Patient does not have visceral crisis; **AND**
- Patient is postmenopausal, premenopausal with ovarian ablation/suppression, or male with suppression of testicular steroidogenesis; **AND**
  - Used as initial therapy in combination with a non-steroidal aromatase inhibitor (i.e., anastrozole, letrozole, etc.) or fulvestrant; **OR**
  - Used as subsequent therapy in combination with fulvestrant

Diagnosis of **Soft Tissue Sarcoma**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a cyclin-dependent kinase (CDK) 4 and 6 inhibitor (e.g., ribociclib, abemaciclib); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, clarithromycin, nefazodone, grapefruit, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has unresectable well-differentiated/dedifferentiated liposarcoma (WD-DDLS) of the retroperitoneum; **AND**
- Used as single agent therapy

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., neutropenia, severe interstitial lung disease/pneumonitis)

ICLUSIG® (PONATINIB)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of Chronic Myelogenous Leukemia (CML)

- *For Standard and Precision* ***for CML, for new starts only: patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic imatinib OR Bosulif®**** *(***following the NCCN guidelines surrounding genetic mutations)*

- Patient is at least 18 years of age; AND
- Patient has had a comprehensive baseline eye exam prior to initiating treatment and will receive periodic monitoring while on treatment; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient's disease is confirmed by a *BCR-ABL1* positive laboratory test result; AND
- Patient does not have newly diagnosed chronic phase CML; **AND**
  - Patient has chronic, accelerated, or blast phase disease; **AND**
    - Disease is T315I mutation positive; OR
  - Patient has chronic phase disease that is resistant or intolerant to prior therapy with at least two prior tyrosine kinase inhibitors (TKI) (e.g., imatinib, dasatinib, bosutinib, nilotinib, etc.); **OR**
  - Patient has accelerated or blast phase disease in which no other TKI is indicated

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 18 years of age unless otherwise specified; **AND**
- Patient has had a comprehensive baseline eye exam prior to initiating treatment and will receive periodic monitoring while on treatment; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has Philadelphia chromosome-positive (Ph+) disease; AND
  - Disease is T315I mutation positive; **OR**
  - Used in patients for whom no other tyrosine kinase inhibitor (TKI) is indicated; **OR**
  - Used as maintenance therapy; **AND**
    - Used in combination with vincristine and prednisone with or without methotrexate and mercaptopurine; **OR**
    - Used post-hematopoietic stem cell transplant; **OR**
  - Patient is at least 15 years of age and < 65 years of age; **AND**
    - Used in a multiagent chemotherapy regimen for induction or consolidation therapy; **OR**
    - Used in combination with a corticosteroid for induction or consolidation therapy; **OR**
    - Used in combination with blinatumomab as consolidation therapy for persistent/rising minimal residual disease following a complete response (CR) to induction therapy; **OR**
  - Patient is ≥ 65 years of age or with substantial comorbidities; **AND**
    - Used as induction therapy as part of one of the following regimens:
      - As a single agent or in combination with a corticosteroid; **OR**
      - In combination with vincristine and dexamethasone; **OR**
      - In combination with a multiagent chemotherapy regimen; **OR**
    - Used as consolidation therapy; **AND**
      - Patient has persistent/rising minimal residual disease (MRD) following a complete response (CR) to induction therapy; **AND**
      - Used in combination with blinatumomab

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**

- Patient is at least 18 years of age; **AND**
- Patient has had a comprehensive baseline eye exam prior to initiating treatment and will receive periodic monitoring while on treatment; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has eosinophilia and FGFR1 or ABL1 rearrangements; **AND**
  - Patient has chronic phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: arterial occlusive events, venous thromboembolic events, hepatotoxicity, ocular toxicity, serious or severe hypertension, hypertensive crisis, heart failure, pancreatitis, serious hemorrhage, fluid retention (peripheral edema, pleural effusion, and pericardial effusion), cardiac arrhythmias, Grade 3 or 4 myelosuppression, tumor lysis syndrome (TLS), gastrointestinal perforation, impaired wound healing, neuropathy, reversible posterior leukoencephalopathy syndrome (RLPS), etc.; **AND**
- Patient has been adherent to therapy; **AND**

Acute lymphoblastic leukemia (ALL) only:

- Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH

Chronic Myelogenous Leukemia (CML) only:

- Re-escalating treatment due to loss of response on a reduced dose (CP-CML or AP-CML only); **OR**
- Treatment response as indicated by one of the following BCR-ALB1 (IS) transcript levels:
  - > 0.1% to 10% at 3 months or 6 months; **OR**
  - > 0.1% to 1% at 12 months and beyond (if treatment goal is long-term survival); **OR**
  - ≤ 0.1% at 12 months and beyond (if treatment goal is treatment-free remission)

Note: cytogenetic assessment of response may be used if quantitative PT=PCR (QPCR) using International Scale (IS) for *BCR-ABL1* is not available

Myeloid/Lymphoid Neoplasms with Eosinophilia only:

- Disease response as evidenced by at least one of the following:
  - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
  - Stabilization or improvement as evidenced by a complete response [CR] (i.e. morphologic, cytogenetic or molecular complete response CR), complete hematologic response, or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

ENHANCED FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myelogenous Leukemia (CML)**

- *For Enhanced Formulary **for CML, for new starts only: patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic imatinib OR Bosulif® OR Sprycel**** (***following the NCCN guidelines surrounding genetic mutations)*
- Patient is at least 18 years of age; AND
- Patient has had a comprehensive baseline eye exam prior to initiating treatment and will receive periodic monitoring while on treatment; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient's disease is confirmed by a *BCR-ABL1* positive laboratory test result; AND
- Patient does not have newly diagnosed chronic phase CML; **AND**
  - Patient has chronic, accelerated, or blast phase disease; **AND**
    - Disease is T315I mutation positive; OR
  - Patient chronic phase disease that is resistant or intolerant to prior therapy with at least two prior tyrosine kinase inhibitors (TKI) (e.g., imatinib, dasatinib, bosutinib, nilotinib, etc.); **OR**
  - Patient has accelerated or blast phase disease in which no other TKI is indicated

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 18 years of age unless otherwise specified; **AND**
- Patient has had a comprehensive baseline eye exam prior to initiating treatment and will receive periodic monitoring while on treatment; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has Philadelphia chromosome-positive (Ph+) disease; AND
  - Disease is T315I mutation positive; **OR**
  - Used in patients for whom no other tyrosine kinase inhibitor (TKI) is indicated; **OR**
  - Used as maintenance therapy; **AND**
    - Used in combination with vincristine and prednisone with or without methotrexate and mercaptopurine; **OR**
    - Used post-hematopoietic stem cell transplant; **OR**
  - Patient is at least 15 years of age and < 65 years of age; **AND**
    - Used in a multiagent chemotherapy regimen for induction or consolidation therapy; **OR**
    - Used in combination with a corticosteroid for induction or consolidation therapy; **OR**
    - Used in combination with blinatumomab as consolidation therapy for persistent/rising minimal residual disease following a complete response (CR) to induction therapy; **OR**
  - Patient is ≥ 65 years of age or with substantial comorbidities; **AND**
    - Used as induction therapy as part of one of the following regimens:
      - As a single agent or in combination with a corticosteroid; **OR**
      - In combination with vincristine and dexamethasone; **OR**
      - In combination with a multiagent chemotherapy regimen; **OR**
    - Used as consolidation therapy; **AND**
      - Patient has persistent/rising minimal residual disease (MRD) following a complete response (CR) to induction therapy; **AND**
      - Used in combination with blinatumomab

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia**

- Patient is at least 18 years of age; **AND**
- Patient has had a comprehensive baseline eye exam prior to initiating treatment and will receive periodic monitoring while on treatment; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has eosinophilia and FGFR1 or ABL1 rearrangements; **AND**
  - Patient has chronic phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: arterial occlusive events, venous thromboembolic events, hepatotoxicity, ocular toxicity, serious or severe hypertension, hypertensive crisis, heart failure, pancreatitis, serious hemorrhage, fluid retention (peripheral edema, pleural effusion, and pericardial effusion), cardiac arrhythmias, Grade 3 or 4 myelosuppression, tumor lysis syndrome (TLS), gastrointestinal perforation, impaired wound healing, neuropathy, reversible posterior leukoencephalopathy syndrome (RLPS), etc.; **AND**
- Patient has been adherent to therapy; **AND**

Acute lymphoblastic leukemia (ALL) only:

- Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH

Chronic Myelogenous Leukemia (CML) only:

- Re-escalating treatment due to loss of response on a reduced dose (CP-CML or AP-CML only); **OR**
- Treatment response as indicated by one of the following BCR-ALB1 (IS) transcript levels:
  - > 0.1% to 10% at 3 months or 6 months; **OR**
  - > 0.1% to 1% at 12 months and beyond (if treatment goal is long-term survival); **OR**
  - ≤ 0.1% at 12 months and beyond (if treatment goal is treatment-free remission)

Note: cytogenetic assessment of response may be used if quantitative PT=PCR (QPCR) using International Scale (IS) for *BCR-ABL1* is not available

CLINICAL CRITERIA FOR RENEWAL (CONTINUED)

Myeloid/Lymphoid Neoplasms with Eosinophilia only:

- Disease response as evidenced by at least one of the following:
  - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
  - Stabilization or improvement as evidenced by a complete response [CR] (i.e. morphologic, cytogenetic or molecular complete response CR), complete hematologic response, or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

CORE FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myelogenous Leukemia (CML)**

- ***For Core Formulary for CML, for new starts only: patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic imatinib****** *(***following the NCCN guidelines surrounding genetic mutations)*
- Patient is at least 18 years of age; AND
- Patient has had a comprehensive baseline eye exam prior to initiating treatment and will receive periodic monitoring while on treatment; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient's disease is confirmed by a *BCR-ABL1* positive laboratory test result; AND
- Patient does not have newly diagnosed chronic phase CML; **AND**
  - Patient has chronic, accelerated, or blast phase disease; **AND**
    - Disease is T315I mutation positive; OR
  - Patient chronic phase disease that is resistant or intolerant to prior therapy with at least two prior tyrosine kinase inhibitors (TKI) (e.g., imatinib, dasatinib, bosutinib, nilotinib, etc.) ; **OR**
  - Patient has accelerated or blast phase disease in which no other TKI is indicated

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 18 years of age unless otherwise specified; **AND**
- Patient has had a comprehensive baseline eye exam prior to initiating treatment and will receive periodic monitoring while on treatment; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has Philadelphia chromosome-positive (Ph+) disease; AND
  - Disease is T315I mutation positive; **OR**
  - Used in patients for whom no other tyrosine kinase inhibitor (TKI) is indicated; **OR**
  - Used as maintenance therapy; **AND**
    - Used in combination with vincristine and prednisone with or without methotrexate and mercaptopurine; **OR**
    - Used post-hematopoietic stem cell transplant; **OR**
  - Patient is at least 15 years of age and < 65 years of age; **AND**
    - Used in a multiagent chemotherapy regimen for induction or consolidation therapy; **OR**
    - Used in combination with a corticosteroid for induction or consolidation therapy; **OR**
    - Used in combination with blinatumomab as consolidation therapy for persistent/rising minimal residual disease following a complete response (CR) to induction therapy; **OR**
  - Patient is ≥ 65 years of age or with substantial comorbidities; **AND**
    - Used as induction therapy as part of one of the following regimens:
      - As a single agent or in combination with a corticosteroid; **OR**
      - In combination with vincristine and dexamethasone; **OR**
      - In combination with a multiagent chemotherapy regimen; **OR**
    - Used as consolidation therapy; **AND**
      - Patient has persistent/rising minimal residual disease (MRD) following a complete response (CR) to induction therapy; **AND**
      - Used in combination with blinatumomab
      - Used in combination with blinatumomab

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia**

- Patient is at least 18 years of age; **AND**
- Patient has had a comprehensive baseline eye exam prior to initiating treatment and will receive periodic monitoring while on treatment; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has eosinophilia and FGFR1 or ABL1 rearrangements; **AND**
  - Patient has chronic phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: arterial occlusive events, venous thromboembolic events, hepatotoxicity, ocular toxicity, serious or severe hypertension, hypertensive crisis, heart failure, pancreatitis, serious hemorrhage, fluid retention (peripheral edema, pleural effusion, and pericardial effusion), cardiac arrhythmias, Grade 3 or 4 myelosuppression, tumor lysis syndrome (TLS), gastrointestinal perforation, impaired wound healing, neuropathy, reversible posterior leukoencephalopathy syndrome (RLPS), etc.; **AND**
- Patient has been adherent to therapy; **AND**

Acute lymphoblastic leukemia (ALL) only:

- Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH

Chronic Myelogenous Leukemia (CML) only:

- Re-escalating treatment due to loss of response on a reduced dose (CP-CML or AP-CML only); **OR**
- Treatment response as indicated by one of the following BCR-ALB1 (IS) transcript levels:
  - > 0.1% to 10% at 3 months or 6 months ; **OR**
  - > 0.1% to 1% at 12 months and beyond (if treatment goal is long-term survival); **OR**
  - ≤ 0.1% at 12 months and beyond (if treatment goal is treatment-free remission)

Note: cytogenetic assessment of response may be used if quantitative PT=PCR (QPCR) using International Scale (IS) for *BCR-ABL1* is not available

CLINICAL CRITERIA FOR RENEWAL (CONTINUED)

Myeloid/Lymphoid Neoplasms with Eosinophilia only:

- Disease response as evidenced by at least one of the following:
  - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
  - Stabilization or improvement as evidenced by a complete response [CR] (i.e. morphologic, cytogenetic or molecular complete response CR), complete hematologic response, or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

IDHIFA® (ENASIDENIB)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of Acute Myeloid Leukemia (AML)

- Patient is at least 18 years of age; AND
- Patient does not have active CNS leukemia; **AND**
- Patients has an isocitrate dehydrogenase-2 (IDH2) mutation, as detected by an FDA-approved or clia-compliant test; AND
  - Patient has relapsed or refractory disease; OR
  - Used as a single agent; AND
    - Used as induction therapy in patients ≥ 60 years of age who are not candidates for or decline intensive therapy; **OR**
    - Used as post-induction therapy following response to previous lower intensity therapy with the same regimen in patients ≥ 60 years of age

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., symptoms of differentiation syndrome [e.g., fever, dyspnea, acute respiratory distress, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, lymphadenopathy, bone pain, and hepatic, renal, or multi-organ dysfunction]); **AND**
- Disease response with treatment as defined by stabilization or improvement of as evidenced by a complete response (CR) (i.e., morphologic, cytogenetic or molecular complete response [CR], complete hematologic response, or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

ILARIS® (CANAKINUMAB)

Length of Authorization:	1 Year
Initiative:	SPC: Immunomodulators: Systemic (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cryopyrin-Associated Periodic Syndromes (CAPS)**

- Patient is at least 4 years of age; **AND**
- Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., anakinra, rilonacept); **AND**
- Patient is not on concurrent treatment with a TNF inhibitor, biologic response modifier, or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib); **AND**
- Used as a single agent; **AND**
- Patient has documented baseline serum levels of inflammatory proteins (C-Reactive Protein [CRP] and Serum Amyloid A [SAA]); **AND**
- Patient has documented laboratory evidence of a genetic mutation in the Cold-Induced Auto-inflammatory Syndrome 1 (CIAS1), also known as NLRP3; **AND**
  - Diagnosis of Familial Cold Autoinflammatory Syndrome (FCAS); **OR**
  - Diagnosis of Muckle-Wells Syndrome (MWS)
- Patient has two or more of any of the CAPS-typical symptoms:
  - Urticaria-like rash
  - Cold-triggered episodes
  - Sensorineural hearing loss
  - Musculoskeletal symptoms
  - Chronic aseptic meningitis
  - Skeletal abnormalities

Diagnosis of **Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)**

- Patient is at least 2 years of age; **AND**
- Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., anakinra, rilonacept); **AND**
- Patient is not on concurrent treatment with a TNF inhibitor, biologic response modifier, or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib); **AND**
- Used as a single agent; **AND**
- Patient has the presence of the TNFRSF1A mutation; **AND**
- Patient has chronic or recurrent disease (defined as > 6 flares per year); **AND**
- Patient has a documented baseline serum levels of C-Reactive Protein (CRP)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)**

- Patient is at least 2 years of age; **AND**
- Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., anakinra, rilonacept); **AND**
- Patient is not on concurrent treatment with a TNF inhibitor, biologic response modifier, or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib); **AND**
- Used as a single agent; **AND**
- Patient has a confirmed diagnosis based on genetic/enzymatic laboratory findings; **AND**
- Patient has a documented history of at least three (3) febrile episodes within a 6 month period; **AND**
- Patient has documented baseline serum levels of C-Reactive Protein (CRP)

Diagnosis of **Familial Mediterranean Fever (FMF)**

- Patient is at least 2 years of age; **AND**
- Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., anakinra, rilonacept); **AND**
- Patient is not on concurrent treatment with a TNF inhibitor, biologic response modifier, or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib); **AND**
- Used as a single agent; **AND**
- Patient has a confirmed diagnosis based on at least one known MEFV exon 10 mutation; **AND**
- Patient has failed on colchicine therapy or has a documented allergy or intolerance; **AND**
- Patient has active disease defined as at least one febrile episode per month; **AND**
- Patient has documented baseline serum levels of C-Reactive Protein (CRP)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Still's Disease (Adult-Onset Still's Disease [AOSD] and Systemic Juvenile Idiopathic Arthritis [SJIA])**

- Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., anakinra, rilonacept); **AND**
- Patient is not on concurrent treatment with a TNF inhibitor, biologic response modifier, or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib); **AND**
- Patient has active disease; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Patient has had at least a 1-month trial and failure (unless contraindicated or intolerant) of previous therapy with either oral non-steroidal anti-inflammatory drugs (NSAIDs) **or** a systemic glucocorticoid (e.g., prednisone, methylprednisolone); **AND**
  - Patient is at least 18 years of age and has active Adult-Onset Still's Disease; **OR**
  - Patient is at least 2 years of age and has active Systemic Juvenile Idiopathic Arthritis

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, serious infections [including but not limited to tuberculosis], and macrophage activation syndrome [MAS]); **AND**
- **Cryopyrin-Associated Periodic Syndromes**: Disease response as indicated by improvement in patient's symptoms from baseline **and** improvement in serum levels of inflammatory proteins (e.g., C-Reactive Protein [CRP] and/or Serum Amyloid A [SAA]) from baseline
- **Adult-Onset Still's Disease/Systemic Juvenile Idiopathic Arthritis**: Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool (e.g., an improvement on a composite scoring index such as Juvenile Arthritis Disease Activity Score [JADAS] or the American College of Rheumatology [ACR] Pediatric [ACR-Pedi 30] of at least 30% improvement from baseline in three of six variables)
- **Tumor Necrosis Factor Receptor Associated Periodic Syndrome; Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency; Familial Mediterranean Fever:** Disease response as indicated by improvement in patient's symptoms from baseline **and** improvement of serum levels of C-Reactive Protein (CRP)

ILUVIEN® (FLUOCINONIDE ACETONIDE IMPLANT)

Length of Authorization:	Coverage will be provided for 1 implant per eye every 36 months and may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of Diabetic Macular Edema (DME)

- Patient is at least 18 years of age; **AND**
- Patient is free of ocular and periocular infections; **AND**
- Must not be used in combination with other sustained-release intravitreal corticosteroids (e.g., dexamethasone implant); **AND**
- Patient does not have glaucoma with a cup to disk ratio greater than 0.8; **AND**
- Patient does not have a torn or ruptured posterior lens capsule; **AND**
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Patient's intraocular pressure is measured at baseline and periodically throughout therapy; **AND**
- Patient has been previously treated with a course of corticosteroids; AND
- Patient did not have a clinically significant rise in intraocular pressure from prior corticosteroid treatment

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., endophthalmitis and retinal detachments, increase in intraocular pressure, eye inflammation, posterior subcapsular cataracts, glaucoma); **AND**
- Disease response as indicated by stabilization of visual acuity or improvement in best-corrected visual acuity (BCVA) score when compared to baseline

IMBRUVICA® (IBRUTINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

For Imbruvica 140 mg TABLETS for all diagnoses, the patient must have a trial of Imbruvica 140 mg CAPSULES

Diagnosis of **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Used as a single agent; **OR**
- Used in combination with rituximab and bendamustine for relapsed or refractory disease; **OR**
- Used in combination with rituximab or obinutuzumab as initial therapy

Diagnosis of **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Used as a single agent or in combination with rituximab

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Chronic Graft versus Host Disease (cGvHD)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Used as a single agent or in conjunction with systemic steroids; **AND**
- Patient is post-allogeneic stem cell transplant (generally 3 or more months); **AND**
- Patient has failed one or more previous lines of systemic therapy for the treatment of cGvHD (i.e., corticosteroids or immunosuppressants such as cyclosporine)

Diagnosis of **B-Cell Lymphomas**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Used as single-agent subsequent therapy for **one** of the following:
  - Marginal zone lymphoma (MZL) (including Nodal and Splenic); **AND**
    - Patient has received at least one prior anti-CD20-based therapy (e.g., rituximab)
  - Follicular lymphoma; **AND**
    - Used for grade 1-2 refractory or progressive disease (if not previously given as first-line therapy)
  - Nongastric MALT lymphoma; **AND**
    - Used for recurrent or progressive disease
  - Gastric MALT lymphoma; **AND**
    - Used for relapsed or progressive disease
  - High-Grade B-Cell Lymphoma**; AND**
    - Used for partial response, no response, relapsed, progressive, or refractory disease in non-candidates for transplant
  - AIDS-related non-germinal center diffuse large B-Cell lymphoma; **AND**
    - Used for relapsed disease; **AND**
    - Patient is not a candidate for transplant

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

*Diagnosis of **B-Cell Lymphomas***

- Diffuse Large B-Cell Lymphoma**; AND**
  - Used for partial response, no response, relapsed, progressive, or refractory non-germinal center disease in non-candidates for transplant; **OR**
    - Used in patients with histologic transformation of FL or MZL to non-germinal center Diffuse Large B-cell Lymphoma as subsequent therapy after multiple lines of chemoimmunotherapy for indolent or transformed disease
- Post-Transplant Lymphoproliferative Disorders (PTLD)**; AND**
    - Used for patients with partial response, persistent or progressive disease after receiving first-line chemoimmunotherapy for monomorphic PTLD (non-germinal center B-cell type disease); **OR**
- Mantle Cell Lymphoma (MCL); **AND**
    - Used as subsequent therapy as a single agent or in combination with rituximab; **OR**
    - Used in combination with rituximab as pre-treatment to limit the number of aggressive induction therapy cycles with RHyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen

Diagnosis of **Primary CNS Lymphoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Used for relapsed or refractory disease; **AND**
  - Used as a single agent; **AND**
    - Patient has received previous whole brain radiation therapy; **OR**
    - Used in combination with radiation therapy in patients who had either no response or a short response (< 12-month duration) to a high-dose methotrexate-based regimen without previous radiation therapy; **OR**
    - Patient had a long response (≥ 12 months) to prior high-dose methotrexate-based regimen without prior radiation therapy OR to prior high-dose chemotherapy with stem cell rescue; **OR**
  - Used in combination with high-dose methotrexate and rituximab; **AND**
    - Patient has received previous whole brain radiation therapy; **OR**
    - Patient has received previous treatment with a high-dose methotrexate-based regimen without prior radiation therapy; **OR**
- Used as induction therapy as a single agent; **AND**
  - Patient is unsuitable for or intolerant to high-dose methotrexate

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Hairy Cell Leukemia**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with voriconazole, posaconazole, and moderate CYP3A inhibitors (e.g., aprepitant, ciprofloxacin, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with other strong CYP3A inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, grapefruit, Seville oranges, etc.); **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Used as a single agent as subsequent therapy for relapsed/refractory or progressive disease

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., hemorrhage, severe infections, myelosuppression [neutropenia, thrombocytopenia, and anemia], ventricular tachyarrhythmia, atrial fibrillation/flutter, tumor lysis syndrome, hypertension, and second primary malignancies); **AND**
- Oncology indications: Disease response with treatment defined as stabilization of disease or decrease in size of tumor or tumor spread
- cGvHD:
  - Response to therapy with an improvement in one or more of the following:
    - Clinical assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score); **OR**
    - Patient-reported symptoms (e.g., Lee Symptoms Scale).

IMCIVREE™ (SETMELANOTIDE)

Length of Authorization:	Initial: 16 weeks Renewal: 12 weeks
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is ≥ 6 years of age; **AND**
- Patient meets criteria for obesity (body mass index [BMI] ≥ 30 kg/m^2 or ≥ 95th percentile on pediatric growth chart); **AND**
- Patient has proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency, as confirmed by a genetic test; **AND**
- Patient's genetic variants are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS); **AND**
- Initial dosing is per approved labeling (2 mg/day in patients ≥ 12 years of age; 1 mg/day in patients 6 to 12 years of age); **AND**
- Prescriber attestation that patient or caregiver has been instructed on appropriate administration technique; **AND**
- Prescribed by or in consultation with an endocrinologist or geneticist.

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet above criteria; **AND**
- Patient has experienced ≥ 5% reduction in body weight (or ≥ 5% of baseline body mass index [BMI] in those with continued growth potential); **AND**
- Patient has not experienced any treatment-limiting adverse reactions (e.g., gastrointestinal intolerability below labeled dosing for age, sexual adverse effects, depression or suicidal ideation).

IMFINZI® (DURVALUMAB)

Length of Authorization:	Non-Small Cell Lung Cancer: Coverage will be provided for six months and may be renewed up to a maximum of 12 months of therapy. Small Cell Lung Cancer: Coverage will be provided for six months and may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, cemiplimab) unless otherwise specified; **AND**
- Used as consolidation therapy; **AND**
- Patient has unresectable stage II-III disease; **AND**
- Disease did not progress after 2 or more cycles of definitive chemoradiation; **AND**
- Patient has a performance status (PS) of 0-1

Diagnosis of **Small Cell Lung Cancer (SCLC)**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, cemiplimab) unless otherwise specified; **AND**
- Patient has extensive stage disease (ES-SCLC); **AND**
  - Used as first-line therapy in combination with etoposide and either carboplatin or cisplatin; **OR**
  - Used as single-agent maintenance therapy after initial therapy with etoposide and either carboplatin or cisplatin

CLINICAL CRITERIA FOR RENEWAL

Coverage can be renewed based upon the following criteria:

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, skin reactions, etc.), etc.; **AND**
- For Bladder Cancer/Urothelial Carcinoma and NSCLC: Patient has not exceeded a maximum of 12 months of therapy

NSCLC

- Patient has not exceeded a maximum of 12 months of therapy

Continuation Maintenance Therapy for SCLC

- Refer to initial criteria

IMLYGIC® (TALIMOGENE LAHERPAREPVEC)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Melanoma**

- Patient is 18 years of age or older; **AND**
- Patient is not pregnant (**Note**: Women of childbearing potential should be advised to use an effective method of contraception to prevent pregnancy during treatment); **AND**
- Patient is not immunocompromised (i.e., patients with a history of primary or acquired immunodeficient states, leukemia, lymphoma, AIDS or other clinical manifestations of infection with human immunodeficiency viruses, and those on immunosuppressive therapy); **AND**
- Treatment (i.e., talimogene laherparepvec) will only be administered via intralesional injection; **AND**
- Patient has one of the following:
  - Unresectable, distant metastatic disease; **OR**
  - Unresectable or incomplete resection of nodal recurrence: **OR**
  - Limited resectable or unresectable stage III disease with clinical satellite or in-transit metastases; **OR**
  - Limited resectable or unresectable disease with local satellite and/or in-transit recurrence

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: herpetic infection, injection site complications (necrosis, ulceration, cellulitis and systemic bacterial infection), immune-mediated events, plasmacytoma at injection site, obstructive airway disorder, etc.; **AND**
- Patient continues to have injectable lesions to treat; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

IMMUNE GLOBULINS

Length of Authorization:	6 months, unless noted, renewable for one year
Initiative:	SPC: Immune Globulins (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

SCIG (IMMUNE GLOBULIN SQ): HIZENTRA®, GAMMAGARD LIQUID®, GAMUNEX®-C, GAMMAKED®, HYQVIA®, CUVITRU®, CUTAQUIG®, XEMBIFY®

Diagnosis of **Primary immunodeficiency (PID)/Wiskott-Aldrich syndrome**

Note: For SC administered IG (IMMUNE GLOBULIN SQ): HIZENTRA®, GAMMAGARD LIQUID®, GAMUNEX®-C, GAMMAKED®, HYQVIA®, CUVITRU®, XEMBIFY®: *Patients ≥ 2 years of age must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Cutaquig® (NO GRANDFATHERING)*

Note*: Examples of PID include x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, IgG subclass deficiency with or without IgA deficiency, antibody deficiency with near normal immunoglobulin levels and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome). This list is not all inclusive.*

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient is ≥ 2 years old (Exception: HyQvia – patient must be ≥ 18 years old
- Patient's IgG level is < 200 **or both** of the following:
  - Patient has a history of multiple hard to treat infections as indicated by at least **one** of the following:
    - Four or more ear infections within 1 year
    - Two or more serious sinus infections within 1 year
    - Two or more months of antibiotics with little effect
    - Two or more pneumonias within 1 year
    - Recurrent or deep skin abscesses
    - Need for intravenous antibiotics to clear infections
    - Two or more deep-seated infections including septicemia; **AND**
  - The patient has a deficiency in producing antibodies in response to vaccination; **AND**
    - Titers were drawn before challenging with vaccination; **AND**
    - Titers were drawn between 4 and 8 weeks of vaccination.

Note: Initial authorization is valid for 6 months; subsequent authorizations will be approved for 1 year.

RENEWAL

Coverage can be renewed for 1 year based upon the following criteria:

- Absence of unacceptable toxicity from the drug (e.g., acute kidney injury, thrombosis, hemolysis, hypersensitivity, pulmonary adverse reactions, volume overload); **AND**
- BUN and serum creatinine obtained within the last 6 months and the concentration and rate of infusion adjusted accordingly; **AND**
- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency or infection
  - Decrease in the severity of infection

Diagnosis of **chronic inflammatory demyelinating polyneuropathy (CIDP)—Hizentra® only**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient must be ≥ 18 years old; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.); **AND**
  - Used as initial maintenance therapy for prevention of disease relapses after treatment and stabilization with intravenous immunoglobulin (IVIG); **OR**
  - Used for re-initiation of maintenance therapy after experiencing a relapse and requiring re-induction therapy with IVIG (see clinical criteria for renewal)

RENEWAL

Coverage can be renewed for 1 year based upon the following criteria:

- Absence of unacceptable toxicity from the drug (e.g., acute kidney injury, thrombosis, hemolysis, hypersensitivity, pulmonary adverse reactions, volume overload); **AND**
- BUN and serum creatinine obtained within the last 6 months and the concentration and rate of infusion adjusted accordingly; **AND**
  - Renewals will be authorized for patients that have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength,6 MWT, Rankin, Modified Rankin, etc.); **OR**
  - Patient is re-initiating maintenance therapy after experiencing a relapse while on Hizentra**; AND**
- Patient improved and stabilized on IVIG treatment: **AND**
- Patient was **not** receiving maximum dosing of Hizentra prior to relapse

Diagnosis of **Acquired Immune Deficiency secondary to Chronic Lymphocytic Leukemia**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient's IgG level is < 200 **or both** of the following:
  - Patient has a history of multiple hard to treat infections as indicated by at least **one** of the following:
    - Four or more ear infections within 1 year
    - Two or more serious sinus infections within 1 year
    - Two or more months of antibiotics with little effect
    - Two or more pneumonias within 1 year
    - Recurrent or deep skin abscesses
    - Need for intravenous antibiotics to clear infections
    - Two or more deep-seated infections including septicemia; **AND**
  - The patient has a deficiency in producing antibodies in response to vaccination; **AND**
    - Titers were drawn before challenging with vaccination; **AND**
    - Titers were drawn between 4 and 8 weeks of vaccination.

***Note**: Other secondary immunodeficiencies resulting in hypogammaglobulinemia and/or B-cell aplasia will be evaluated on a case-by-case basis*

RENEWAL

Coverage can be renewed for 1 year based upon the following criteria:

- Absence of unacceptable toxicity from the drug (e.g., acute kidney injury, thrombosis, hemolysis, hypersensitivity, pulmonary adverse reactions, volume overload); **AND**
- BUN and serum creatinine obtained within the last 6 months and the concentration and rate of infusion adjusted accordingly; **AND**
- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency or infection
  - Decrease in the severity of infection; **AND**
- Patient is at a decreased risk of infection as a result of treatment necessitating continued therapy

IMMUNE GLOBLULINS (INTRAVENOUS) (IVIG): ASCENIV, BIVIGAM, CARIMUNE NF, FLEBOGAMMA, GAMUNEX-C, GAMMAGARD LIQUID, GAMMAGARD S/D, GAMMAKED, GAMMAPLEX, OCTAGAM, PRIVIGEN, PANZYGA

Diagnosis of **Primary immunodeficiency (PID)/Wiskott-Aldrich syndrome**

Note: For IVIG (IV administered IMMUNE GLOBULIN): Asceniv, Flebogamma, Gammagard, Gammaplex, Gammaked, Gamunex-C, Panzyga, Privigen: *Patients ≥ 6 years of age must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Octagam (NO GRANDFATHERING)*

Note*: E.g., x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, IgG subclass deficiency with or without IgA deficiency, antibody deficiency with near normal immunoglobulin levels and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome) (list is not all inclusive)*

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient's IgG level is < 200 **or both** of the following:
  - Patient has a history of multiple hard to treat infections as indicated by at least **one** of the following:
    - Four or more ear infections within 1 year
    - Two or more serious sinus infections within 1 year
    - Two or more months of antibiotics with little effect
    - Two or more pneumonias within 1 year
    - Recurrent or deep skin abscesses
    - Need for intravenous antibiotics to clear infections
    - Two or more deep-seated infections including septicemia; **AND**
  - The patient has a deficiency in producing antibodies in response to vaccination; **AND**
    - Titers were drawn before challenging with vaccination; **AND**
    - Titers were drawn between 4 and 8 weeks of vaccination.

Note: Initial authorization is valid for 6 months, Subsequent authorizations will be approved for 1 year

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Immune thrombocytopenia/Idiopathic thrombocytopenia purpura (ITP) (For Gammaplex):**

- For acute disease state:
  - Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
  - To manage acute bleeding due to severe thrombocytopenia (platelet counts less than 30 X 10^9/L); **OR**
  - To increase platelet counts prior to invasive surgical procedures such as splenectomy. (Platelets less than 100 X 10^9/L); **OR**
  - Patient has severe thrombocytopenia (platelet counts ≤ 20 X 10^9/L)
  - Authorization is valid for 1 month only and cannot be renewed
- For chronic disease state (Chronic Immune Thrombocytopenia- CIT):
  - ***Note: For IVIG (IV administered IMMUNE GLOBULIN): Flebogamma, Gammagard, Gammaplex, Gammaked, Gamunex-C, Panzyga, Privigen:*** *Patients ≥ 18 years of age must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Octagam*
  - Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
  - The patient is at increased risk for bleeding as indicated by a platelet count ≤ 30 X 10^9/L; **AND**
  - History of failure, contraindication, or intolerance with corticosteroids; **AND**
  - Duration of illness > 6 months

Diagnosis of **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (for Gamunex-C)**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient's disease course is progressive or relapsing and remitting for ≥ 2 months; **AND**
- Patient has abnormal or absent deep tendon reflexes in upper or lower limbs; **AND**
- Electrodiagnostic testing indicating demyelination:
  - Partial motor conduction block in at least 2 motor nerves or in 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
  - Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
  - Abnormal temporal dispersion conduction must be present in at least 2 motor nerves; **OR**
  - Reduced motor conduction velocity in at least 2 motor nerves; **OR**
  - Prolonged distal motor latency in at least 2 motor nerves; **OR**
  - Absent F wave in at least 2 motor nerves plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
  - Prolonged F wave latency in at least 2 motor nerves; **AND**
- Patient is refractory or intolerant to corticosteroids (e.g., prednisolone, prednisone) given in therapeutic doses over at least three months; **AND**
- Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., INCAT, Medical Research Council [MRC] muscle strength, 6-MWT, Rankin, Modified Rankin)

  Note: Initial authorization is valid for 3 months; subsequent authorizations will be approved for 1 year

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Guillain-Barre Syndrome (Acute inflammatory polyneuropathy)**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has severe disease (e.g., patient requires assistance to ambulate); **AND**
- Onset of symptoms are recent (less than 1 month); **AND**
- Patient has abnormal or absent deep tendon reflexes in upper or lower limbs**; AND**
- Patient diagnosis is confirmed using a cerebrospinal fluid (CSF) analysis; **AND**
- Approval will be granted for a maximum of 2 rounds of therapy within 6 weeks on onset; **AND**
- Authorization is valid for 2 months only and cannot be renewed

Diagnosis of **Multifocal Motor Neuropathy**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has progressive focal, asymmetric limb weakness (without sensory symptoms) for > 1 month; **OR**
- Patient has complete or partial conduction block or abnormal temporal dispersion conduction in at least 2 motor nerves; **AND**
- Patient has normal sensory nerve conduction on all nerves tested; **AND**
- Baseline in strength/weakness has been documented using objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6 MWT, Rankin, Modified Rankin) and renewals will require current results; AND
- Initial authorization length is valid for 3 months
- Renewals will be authorized for patients that have demonstrated an improvement of 1 or better on the INCAT scale; **AND**
- Improvement over baseline in strength/weakness

Diagnosis of **HIV infected children: bacterial control or prevention**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient age does not exceed 13 years of age; **AND**
- Patient's IgG level is < 400 mg/dL

Diagnosis of **Myasthenia Gravis**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies; **AND**
- Patient has an acute exacerbation resulting in impending myasthenic crisis (i.e., respiratory compromise, acute respiratory failure, and/or bulbar compromise); **AND**
- Patient is failing on conventional immunosuppressant therapy alone (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate, methotrexate, tacrolimus, cyclophosphamide, etc.); **AND**
- Patient will be on combination therapy with corticosteroids or other immunosuppressant (e.g., azathioprine, mycophenolate, cyclosporine, methotrexate, tacrolimus, cyclophosphamide, etc.)

Note: *Authorization length is 1 course (1 month) and cannot be renewed*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Dermatomyositis or Polymyositis**

***Note**: **For IVIG (IV administered IMMUNE GLOBULIN):** Octagam 10% is the only immunoglobulin product FDA approved for dermatomyositis in adults.*

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has severe active disease; **AND**
- Patient has proximal weakness in all upper and/or lower limbs; **AND**
- Diagnosis has been confirmed by muscle biopsy; **AND**
- Patient has failed a trial of corticosteroids (e.g., prednisone); **AND**
- Patient has failed a trial of immunosuppressants (e.g., MTX, azathioprine, etc.); **AND**
- Must be used as part of combination therapy with other agents; **AND**
- Patient has a documented baseline physical exam and muscular strength/function; **AND**
- Initial approval will be valid for 3 months; **AND**
- Renewals will require current CPK lab and physical exam

Diagnosis of **complications of transplanted organ (kidney, liver, lung, heart, pancreas) and bone marrow transplant**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Coverage is provided for one or more of the following (list not all-inclusive):
- Suppression of panel-reactive anti-HLA antibodies prior to transplantation; **OR**
- Treatment of antibody mediated rejection of solid organ transplantation; **OR**
- Prevention or treatment of viral infections (e.g., cytomegalovirus, Parvo B-19 virus, and Polyoma BK virus)

Diagnosis of **Stiff person syndrome**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has anti-glutamic acid decarboxylase (GAD) antibodies; **AND**
- Patient has failed at least 2 of the following treatments: benzodiazepines, baclofen, gabapentin, valproate, tiagabine, or levetiracetam; **AND**
- Patient has a documented baseline on physical exam

Diagnosis of **Allogeneic Bone Marrow Transplant Or stem cell transplant**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Used for prevention of acute Graft-Versus-Host-Disease (aGvHD) or infection; **AND**
- Patient's bone marrow (BMT) or hematopoietic stem cell (HSCT) transplant was allogeneic; **AND**
- Patient's IgG level is less than 400 mg/dL

***Note:** Initial authorization is valid for 3 months*

Diagnosis of **Kawasaki's disease (pediatric)**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**

***Note:** Authorization is valid for 1 course (1 month) only and cannot be renewed*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Fetal Alloimmune Thrombocytopenia (FAIT)**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has a history of one or more of the following:
  - Previous FAIT pregnancy
  - Family history of the disease
  - Screening reveals platelet alloantibodies

Note: *Authorization is valid through the delivery date only and cannot be renewed*

Diagnosis of **Neonatal Alloimmune Thrombocytopenia (NAIT)**

- Baseline values for BUN and serum creatinine obtained within 30 days of request

Note: *Authorization is valid for 1 course (1 month) only and cannot be renewed*

Diagnosis of **Auto-immune Mucocutaneous Blistering Diseases**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has been diagnosed with one of the following:
  - Pemphigus vulgaris
  - Pemphigus foliaceus
  - Bullous Pemphigoid
  - Mucous Membrane Pemphigoid (AKA Cicatricial Pemphigoid)
  - Epidermolysis bullosa acquisita
  - Pemphigus gestationis (Herpes gestationis)
  - Linear IgA dermatosis; **AND**
- Patient has severe disease that is extensive and debilitating; **AND**
- Diagnosis has been confirmed by biopsy; **AND**
- Patient's disease is progressive; **AND**
- Disease is refractory to a trial of conventional therapy with corticosteroids and concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil, etc.); **AND**
- Patient has a documented baseline on physical exam

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Acquired Immune Deficiency secondary to Chronic Lymphocytic Leukemia † or Multiple Myeloma**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patients IgG level is < 200 **OR BOTH** of the following:
  - Patient has a history of multiple hard to treat infections as indicated by at least **ONE** of the following:
    - Four or more ear infections within 1 year
    - Two or more serious sinus infections within 1 year
    - Two or more months of antibiotics with little effect
    - Two or more pneumonias within 1 year
    - Recurrent or deep skin abscesses
    - Need for intravenous antibiotics to clear infections
    - Two or more deep-seated infections including septicemia; **AND**
  - The patient has a deficiency in producing antibodies in response to vaccination; **AND**
    - Titers were drawn before challenging with vaccination; **AND**
    - Titers were drawn between 4 and 8 weeks of vaccination.

***Note**: Other secondary immunodeficiencies resulting in hypogammaglobulinemia and/or B-cell aplasia will be evaluated on a case-by-case basis*

Diagnosis of **Acquired Immune Deficiency secondary to Acute Lymphoblastic Leukemia (ALL)**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Used for prevention of infection; **AND**
- Patient age is less than 18 years old; **AND**
- Patient's IgG level is less than 400 mg/dL

Diagnosis of **Toxic Shock Syndrome**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**

***Note**: Authorization is valid for 1 course (1 month) only and cannot be renewed.*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Management of Immune Checkpoint Inhibitor-Related Toxicity**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, dostarlimab, etc.); **AND**
- Patient has one of the following toxicities related to their immunotherapy:
  - Severe (G3) or life-threatening (G4) bullous dermatitis
  - Stevens-Johnson syndrome (SJS)
  - Toxic epidermal necrolysis (TEN)
  - Severe (G3-4)myasthenia gravis
  - Transverse myelitis
  - Suspected myocarditis if no improvement within 24 hours of starting pulse-dose methylprednisolone
  - Moderate (G2) or severe (G3-4) Guillain-Barre Syndrome or severe (G3-4) peripheral neuropathy used in combination with pulse-dose methylprednisolone
  - Severe (G3-4) pneumonitis if no improvement after 48 hours of methylprednisolone
  - Encephalitis used in combination with pulse-dose methylprednisolone for severe or progressing symptoms or if oligoclonal bands are present
  - Moderate, severe, or life-threatening steroid-refractory myalgias or myositis

Diagnosis of **Management of CAR T-Cell-Related Toxicity**

- Baseline values for BUN and serum creatinine obtained within 30 days of request; **AND**
- Patient has been receiving treatment with anti-CD19 chimeric antigen receptor (CAR) T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, lisocabtagene maraleucel, tisagenlecleucel, etc.); **AND**
- Patient has hypogammaglobulinemia as confirmed by serum IgG levels <600 mg/dL; **AND**
- Patient has serious or recurrent infections

Note: *May **not** be renewed.*

CLINICAL CRITERIA FOR RENEWAL OF IVIG

Note: *Unless otherwise specified, the renewal authorization is provided for 1 year*

Coverage can be renewed based on the following criteria:

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: renal dysfunction and acute kidney renal failure, thrombosis, hemolysis, severe hypersensitivity reactions, pulmonary adverse reactions, hyperproteinemia, increased serum viscosity, hyponatremia, aseptic meningitis syndrome, hypertension, volume overload, etc.; **AND**
- BUN and serum creatinine obtained within the last 6 months and the concentration and rate of infusion adjusted accordingly; **AND**
- Patient meets the disease-specific criteria identified below:

Primary immunodeficiency (PID)/Wiskott-Aldrich syndrome

- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency or infection
  - Decrease in the severity of infection

CLINICAL CRITERIA FOR RENEWAL (*CONTINUED*)

Chronic Immune Thrombocytopenia/ITP

- Disease response as indicated by the achievement and maintenance of a platelet count of ≥ 30 X 10^9/L and at least doubling the baseline platelet count

Chronic Inflammatory Demyelinating Polyneuropathy

- Renewals will be authorized for patients who have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6 MWT, Rankin, Modified Rankin, etc.)

Guillain-Barre Syndrome (Acute inflammatory polyneuropathy)

- May not be renewed.

Multifocal Motor Neuropathy

- Renewals will be authorized for patients who have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6 MWT, Rankin, Modified Rankin, etc.)

HIV-infected children: Bacterial control or prevention

- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency of infection
  - Decrease in the severity of infection; **AND**
- Patient continues to be at an increased risk of infection necessitating continued therapy, as evidenced by an IgG level < 400 mg/dL

Myasthenia Gravis

- May not be renewed

Dermatomyositis/polymyositis

- Patient had an improvement from baseline on physical exam and/or muscular strength and function

Note: *Renewal authorization is for 6 months*

Complications of transplanted solid organ (kidney, liver, lung, heart, pancreas) and bone marrow transplant

- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency of infection
  - Decrease in the severity of infection; **AND**
- Patient is at a decreased risk of infection as a result of treatment necessitating continued therapy .

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

Stiff person disease

- Documented improvement over baseline per physical exam

Allogeneic Bone Marrow or Stem Cell Transplant

- Patient's IgG is less than or equal to 400 mg/dL; **AND**

***Note**: Renewal authorizations are provided for 3 months*

Kawasaki's Disease

- May not be renewed.

Fetal Alloimmune Thrombocytopenia (FAIT)

- Authorization is valid through the delivery date only and cannot be renewed

Neonatal Alloimmune Thrombocytopenia

- May not be renewed.

Autoimmune mucocutaneous blistering diseases

- Documented improvement over baseline per physical exam

***Note:** Renewals will be approved for 6 months*

Acquired Immune Deficiency secondary to Acute Lymphoblastic Leukemia (ALL), Chronic Lymphocytic Leukemia (CLL), or Multiple Myeloma

- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency of infection
  - Decrease in the severity of infection; **AND**
- Patient is at a decreased risk of infection as a result of treatment necessitating continued therapy

Toxic Shock Syndrome

- May not be renewed.

Management of Immune Checkpoint Inhibitor-related Toxicity

- May not be renewed.

IMMUNOMODULATORS

Length of Authorization:	Varies
Initiative:	SPC: Immunomodulators: Systemic (IE 2462 / NCPDP 75) **For initial start, the patient must meet screening questions, initial approval criteria, and drug specific criteria**.

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

SCREENING QUESTIONS FOR ALL AGENTS [UNLESS NOTED]

- Patient has been evaluated and screened to rule out the presence of latent TB infection prior to initiating treatment **[Except Otezla]; AND**
- Patient has been evaluated for the presence of hepatitis B virus (HBV) prior to initiating treatment **[For Enbrel, Cimzia, Humira, Infliximab, Orencia, Rinvoq, Rituxan, Simponi]**; **AND**
- Patient does not have an active infection, including clinically important localized infections **[Except Otezla]; AND**
- Patient will not receive any live vaccines while on therapy **[Except Otezla]; AND**
- Patient is not on concurrent treatment with another TNF inhibitor, biologic response modifier, or other non-biologic agent (e.g., apremilast, tofacitinib, baricitinib, upadacitinib); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool

Note: patient use of free goods or samples does not qualify as an established patient or guarantee coverage. All policy criteria must be met in order to obtain coverage

ACTEMRA (TOCILIZUMAB) (EFFECTIVE DATE 06/01/2021)

ACTEMRA (TOCILIZUMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Drug Name: Actemra (tocilizumab IV), Actemra (tocilizumab SC)

- INDICATIONS
  - **Rheumatoid arthritis** Indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs).
  - **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for the treatment of active polyarticular juvenile idiopathic arthritis in patients ages 2 and older.
  - **Systemic Juvenile Idiopathic Arthritis (SJIA)** Indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older.

Drug Name: Actemra (tocilizumab IV)

- INDICATIONS
  - **Cytokine Release Syndrome** Indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older.

ACTEMRA (TOCILIZUMAB) *(CONTINUED)*

Drug Name: Actemra (tocilizumab SC)

- INDICATIONS
  - **Giant Cell Arteritis (GCA)** Indicated for the treatment of giant cell arteritis (GCA) in adult patients.
  - **Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)** Indicated for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

Drug Name:	Actemra (tocilizumab IV), Actemra (tocilizumab SC)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active rheumatoid arthritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **one** nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate [Rheumatrex/Trexall], Arava [leflunomide], Azulfidine [sulfasalazine]) [2]; **AND**
- One of the following:
  - Trial and failure, contraindication, or intolerance to **two** of the following, or attestation demonstrating a trial may be inappropriate*
    - Cimzia (certolizumab pegol)
    - Humira (adalimumab)
    - Rinvoq (upadacitinib)
    - Simponi (golimumab)
    - Xeljanz(tofacitinib) or Xeljanz XR(tofacitinib ER); **OR**
  - For continuation of prior Actemra therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Notes:

*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

Drug Name:	Actemra (tocilizumab IV), Actemra (tocilizumab SC)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Actemra therapy

ACTEMRA (TOCILIZUMAB) *(CONTINUED)*

Drug Name:	Actemra (tocilizumab IV), Actemra (tocilizumab SC)
Diagnosis:	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active systemic juvenile idiopathic arthritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **one** of the following [3]:
  - Non-steroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
  - Systemic glucocorticoid (e.g., prednisone)
  - methotrexate

Drug Name:	Actemra (tocilizumab IV), Actemra (tocilizumab SC)
Diagnosis:	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Actemra therapy;

Drug Name:	Actemra (tocilizumab IV), Actemra (tocilizumab SC)
Diagnosis:	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active polyarticular juvenile idiopathic arthritis; **AND**
- Trial and failure, contraindication, or intolerance to **one** of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs) [4]:
  - Arava (leflunomide)
  - methotrexate (Rheumatrex/Trexall); **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- One of the following:
  - Trial and failure, contraindication, or intolerance to Humira (adalimumab), or attestation demonstrating that a trial may be inappropriate*; **OR**
  - For continuation of Actemra therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Notes: * Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

ACTEMRA (TOCILIZUMAB) *(CONTINUED)*

Drug Name:	Actemra (tocilizumab IV), Actemra (tocilizumab SC)
Diagnosis:	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Actemra therapy

Drug Name:	Actemra (tocilizumab SC)
Diagnosis:	Giant Cell Arteritis (GCA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of giant cell arteritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to a glucocorticoid

Drug Name:	Actemra (tocilizumab SC)
Diagnosis:	Giant Cell Arteritis (GCA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Actemra therapy

Drug Name:	Actemra (tocilizumab SC)
Diagnosis:	Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by the following [5-7]:
  - Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity); **AND**
  - **One** of the following:
    - In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (e.g., fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD, **OR**
    - In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD

AND

- Prescribed by or in consultation with a pulmonologist or rheumatologist

ACTEMRA (TOCILIZUMAB) *(CONTINUED)*

Drug Name:	Actemra (tocilizumab SC)
Diagnosis:	Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Actemra therapy

Drug Name:	Actemra (tocilizumab IV)
Diagnosis:	Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy
Approval Length:	2 months [A]
Guideline Type:	Prior Authorization

Criteria:

- Patient will receive or is receiving chimeric antigen receptor (CAR) T-cell immunotherapy (i.e., Kymriah [tisagenlecleucel], Yescarta [axicabtagene ciloleucel]); **AND**
- Prescribed by or in consultation with an oncologist or hematologist

CIMZIA (CERTOLIZUMAB PEGOL) (EFFECTIVE DATE 06/01/2021)

CIMZIA (CERTOLIZUMAB PEGOL) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Drug Name: Cimzia (certolizumab pegol)
INDICATIONS

- **Crohn's Disease** Indicated for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
- **Rheumatoid Arthritis** Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis.
- **Psoriatic Arthritis** Indicated for the treatment of adult patients with active psoriatic arthritis (PsA).
- **Ankylosing Spondylitis** Indicated for the treatment of adults with active ankylosing spondylitis.
- **Plaque Psoriasis** Indicated for the treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.
- **Non-radiographic Axial Spondyloarthritis** Indicated for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

Drug Name:	Cimzia (certolizumab pegol)
Diagnosis:	Crohn's disease
Approval Length:	16 weeks [A]
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active Crohn's disease; **AND**
- Trial and failure, contraindication, or intolerance to one of the following conventional therapies: [2]
  - 6-mercaptopurine (Purinethol)
  - Azathioprine (Imuran)
  - Corticosteroids (e.g., prednisone, methylprednisolone)
  - Methotrexate (Rheumatrex, Trexall); **AND**
- Prescribed by or in consultation with a gastroenterologist

Drug Name:	Cimzia (certolizumab pegol)
Diagnosis:	Crohn's disease
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Cimzia therapy

CIMZIA (CERTOLIZUMAB PEGOL) *(CONTINUED)*

Drug Name:	Cimzia (certolizumab pegol)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active RA; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication or intolerance to one non-biologic DMARDs [e.g., Rheumatrex/Trexall (methotrexate), Arava (leflunomide), Azulfidine (sulfasalazine)] [3]

Drug Name:	Cimzia (certolizumab pegol)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Cimzia therapy

Drug Name:	Cimzia (certolizumab pegol)
Diagnosis:	Psoriatic Arthritis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active psoriatic arthritis [1,4]; **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist

Drug Name:	Cimzia (certolizumab pegol)
Diagnosis:	Psoriatic Arthritis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Cimzia therapy

CIMZIA (CERTOLIZUMAB PEGOL) *(CONTINUED)*

Drug Name:	Cimzia (certolizumab pegol)
Diagnosis:	Ankylosing Spondylitis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active ankylosing spondylitis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to two NSAIDs [5]

Drug Name:	Cimzia (certolizumab pegol)
Diagnosis:	Ankylosing Spondylitis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Cimzia therapy

Drug Name:	Cimzia (certolizumab pegol)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderate to severe plaque psoriasis [1,6]; **AND**
- Prescribed by or in consultation with a dermatologist

Drug Name:	Cimzia (certolizumab pegol)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Cimzia therapy as evidenced by **ONE** of the following [1,6]:
  - Reduction in body surface area (BSA) involvement from baseline
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline

CIMZIA (CERTOLIZUMAB PEGOL) *(CONTINUED)*

Drug Name:	Cimzia (certolizumab pegol)
Diagnosis:	Non-radiographic Axial Spondyloarthritis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of non-radiographic axial spondyloarthritis; **AND**
- Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1,5]; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to two NSAIDs [5]

Drug Name:	Cimzia (certolizumab pegol)
Diagnosis:	Non-radiographic Axial Spondyloarthritis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Cimzia therapy

COSENTYX (SECUKINUMAB) (EFFECTIVE DATE 09/24/2021)

COSENTYX (SECUKINUMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Drug Name: Cosentyx (secukinumab)

INDICATIONS

- **Plaque Psoriasis** Indicated for the treatment of moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy.
- **Psoriatic Arthritis** Indicated for the treatment of adult patients with active psoriatic arthritis.
- **Ankylosing Spondylitis** Indicated for the treatment of adult patients with active ankylosing spondylitis.
- **Non-radiographic Axial Spondyloarthritis** Indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

Drug Name:	Cosentyx (secukinumab)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderate to severe plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist; **AND**
- **ONE** of the following
  - Both of the following:
    - Trial and failure, contraindication, or intolerance to **THREE** of the following:
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Skyrizi (risankizumab)
      - Stelara (ustekinumab)
      - Tremfya (guselkumab)

    AND
    - Trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

  OR
  - For continuation of prior Cosentyx therapy**

**Notes:

- Cosentyx is non-preferred for STANDARD and ENHANCED.
- Cosentyx is excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Cosentyx is allowed for STANDARD, ENHANCED, and PRECISION only.
- Grandfathering of Cosentyx is not allowed for PRECISION PLUS and CORE.

COSENTYX (SECUKINUMAB) *(CONTINUED)*

Drug Name:	Cosentyx (secukinumab)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Cosentyx therapy as evidenced by **ONE** of the following [2]:
  - Reduction in body surface area (BSA) involvement from baseline
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline.

Drug Name:	Cosentyx (secukinumab)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Non-Formulary

Criteria:

- Diagnosis of moderate to severe plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist; **AND**
- **ONE** of the following
  - Both of the following:
    - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **THREE** of the following:
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Skyrizi (risankizumab)
      - Stelara (ustekinumab)
      - Tremfya (guselkumab)

    AND
    - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

  OR
  - Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy**

**Notes:

- Cosentyx is non-preferred for STANDARD and ENHANCED.
- Cosentyx is excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Cosentyx is allowed for STANDARD and ENHANCED.
- Grandfathering of Cosentyx is allowed for PRECISION (continuation of prior therapy is defined as no more than a 45-day gap in therapy).
- Grandfathering of Cosentyx is not allowed for PRECISION PLUS and CORE.

COSENTYX (SECUKINUMAB) *(CONTINUED)*

Drug Name:	Cosentyx (secukinumab)
Diagnosis:	Ankylosing Spondylitis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active ankylosing spondylitis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **two** non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen); **AND**
- **ONE** of the following:
  - Both of the following:
    - Trial and failure, contraindication, or intolerance to **two** of the following, or attestation demonstrating a trial may be inappropriate*
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Simponi (golimumab)**;**

    AND
    - Trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

  OR
  - For continuation of prior Cosentyx therapy**

*Notes:

- Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

**Notes:

- Cosentyx is non-preferred for STANDARD and ENHANCED.
- Cosentyx is excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Cosentyx is allowed for STANDARD, ENHANCED, and PRECISION only.
- Grandfathering of Cosentyx is not allowed for PRECISION PLUS and CORE

COSENTYX (SECUKINUMAB) *(CONTINUED)*

Drug Name:	Cosentyx (secukinumab)
Diagnosis:	Ankylosing Spondylitis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Cosentyx therapy.

Drug Name:	Cosentyx (secukinumab)
Diagnosis:	Ankylosing Spondylitis
Approval Length:	12 months
Therapy Stage:	Non-Formulary

Criteria:

- Diagnosis of active ankylosing spondylitis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **TWO** non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen); **AND**
- **ONE** of the following:
  - Both of the following:
    - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **TWO** of the following, or attestation demonstrating a trial may be inappropriate*
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Simponi (golimumab)**;**

    AND
    - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

  OR
  - Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy **

*Notes:

- Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

**Notes:

- Cosentyx is non-preferred for STANDARD and ENHANCED.
- Cosentyx is excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Cosentyx is allowed for STANDARD and ENHANCED.
- Grandfathering of Cosentyx is allowed for PRECISION (continuation of prior therapy is defined as no more than a 45-day gap in therapy).
- Grandfathering of Cosentyx is not allowed for PRECISION PLUS and CORE.

COSENTYX (SECUKINUMAB) *(CONTINUED)*

Drug Name:	Cosentyx (secukinumab)
Diagnosis:	Psoriatic Arthritis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active psoriatic arthritis; **AND**
- Prescribed by or in consultation with **one** of the following:
  - Dermatologist
  - Rheumatologist**; AND**
- **ONE** of the following:
  - All of the following:
    - Trial and failure, contraindication, or intolerance to **TWO** of the following:
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Simponi (golimumab)
      - Stelara (ustekinumab)
      - Tremfya (guselkumab)

    AND
    - Trial and failure, contraindication, or intolerance to **one** of the following:
      - Orencia (abatacept)
      - Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

    AND
    - Trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

  OR
  - For continuation of prior Cosentyx therapy**

**Notes:
- Cosentyx is non-preferred for STANDARD and ENHANCED.
- Cosentyx is excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Cosentyx is allowed for STANDARD, ENHANCED, and PRECISION only.
- Grandfathering of Cosentyx is not allowed for PRECISION PLUS and CORE

COSENTYX (SECUKINUMAB) *(CONTINUED)*

Drug Name:	Cosentyx (secukinumab)
Diagnosis:	Psoriatic Arthritis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Cosentyx therapy.

Drug Name:	Cosentyx (secukinumab)
Diagnosis:	Psoriatic Arthritis
Approval Length:	12 months
Therapy Stage:	Non-Formulary

Criteria:

- Diagnosis of active psoriatic arthritis; **AND**
- Prescribed by or in consultation with **one** of the following:
  - Dermatologist
  - Rheumatologist**; AND**
- **ONE** of the following:
  - All of the following:
    - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **TWO** of the following:
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Simponi (golimumab)
      - Stelara (ustekinumab)
      - Tremfya (guselkumab)

    AND
    - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **ONE** of the following:
      - Orencia (abatacept)
      - Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

    AND
    - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

  OR
  - Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy **

**Notes:
- Cosentyx is non-preferred for STANDARD and ENHANCED.
- Cosentyx is excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Cosentyx is allowed for STANDARD and ENHANCED.
- Grandfathering of Cosentyx is allowed for PRECISION (continuation of prior therapy is defined as no more than a 45-day gap in therapy).
- Grandfathering of Cosentyx is not allowed for PRECISION PLUS and CORE.

COSENTYX (SECUKINUMAB) *(CONTINUED)*

Drug Name:	Cosentyx (secukinumab)
Diagnosis:	Non-radiographic Axial Spondyloarthritis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active non-radiographic axial spondyloarthritis; **AND**
- Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 3]; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to TWO non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, meloxicam, naproxen) [2]; **AND**
- **One** of the following:
  - Trial and failure, contraindication, or intolerance to both of the following:
    - Cimzia (certolizumab pegol)
    - Taltz (ixekizumab)

  OR
  - For continuation of prior Cosentyx therapy**

**Notes:
- Cosentyx is non-preferred for STANDARD and ENHANCED.
- Cosentyx is excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Cosentyx is allowed for STANDARD, ENHANCED, and PRECISION only.
- Grandfathering of Cosentyx is not allowed for PRECISION PLUS and CORE

COSENTYX (SECUKINUMAB) *(CONTINUED)*

Drug Name:	Cosentyx (secukinumab)
Diagnosis:	Non-radiographic Axial Spondyloarthritis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

. Documentation of positive clinical response to therapy

Drug Name:	Cosentyx (secukinumab)
Diagnosis:	Non-radiographic Axial Spondyloarthritis
Approval Length:	12 months
Therapy Stage:	Non-Formulary

Criteria:

- Diagnosis of active non-radiographic axial spondyloarthritis; **AND**
- Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 3]; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **TWO** non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, meloxicam, naproxen) [2]; **AND**
- **One** of the following:
  - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to both of the following:
    - Cimzia (certolizumab pegol)
    - Taltz (ixekizumab)

  OR
  - Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy **

**Notes:
- Cosentyx is non-preferred for STANDARD and ENHANCED.
- Cosentyx is excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Cosentyx is allowed for STANDARD and ENHANCED.
- Grandfathering of Cosentyx is allowed for PRECISION (continuation of prior therapy is defined as no more than a 45-day gap in therapy).
- Grandfathering of Cosentyx is not allowed for PRECISION PLUS and CORE.

ENBREL (ETANERCEPT) (EFFECTIVE DATE 06/01/2021)

ENBREL (ETANERCEPT) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Drug Name: Enbrel (etanercept)

INDICATIONS

- **Rheumatoid Arthritis (RA)** Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. Enbrel can be initiated in combination with methotrexate (MTX) or used alone.
- **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 and older.
- **Psoriatic Arthritis (PsA)** Indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis. Enbrel can be used with or without MTX.
- **Ankylosing Spondylitis (AS)** Indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.
- **Plaque Psoriasis (PsO)** Indicated for the treatment of patients 4 years of age and older with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Drug Name:	Enbrel (etanercept)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active rheumatoid arthritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to one nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate [Rheumatrex/Trexall], Arava [leflunomide], Azulfidine [sulfasalazine]) [2]; **AND**
- **ONE** of the following:
  - **ALL** of the following:
    - Trial and failure, contraindication, or intolerance to **TWO** of the following, or attestation demonstrating a trial may be inappropriate*
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Rinvoq (upadacitinib)
      - Simponi (golimumab)
      - Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER); **AND**
    - Trial and failure, contraindication, or intolerance to **BOTH** of the following:
      - Actemra (tocilizumab)
      - Orencia (abatacept); **OR**

– For continuation of prior Enbrel therapy STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Notes:

* Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

ENBREL (ETANERCEPT) *(CONTINUED)*

Drug Name:	Enbrel (etanercept)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Enbrel therapy

Drug Name:	Enbrel (etanercept)
Diagnosis:	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to one of the following nonbiologic disease-modifying antirheumatic drugs (DMARDs): [3]
  - Arava (leflunomide)
  - methotrexate (Rheumatrex/Trexall); **AND**
- One of the following:
  - Both of the following:
    - Trial and failure, contraindication, or intolerance to Humira (adalimumab), or attestation demonstrating that a trial may be inappropriate*

    AND
    - Trial and failure, contraindication, or intolerance to ALL of the following: :
      - Actemra (tocilizumab)
      - Orencia (abatacept)
      - Xeljanz (tofacitinib)

  OR

  - For continuation of prior Enbrel therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Notes: * Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

Drug Name:	Enbrel (etanercept)
Diagnosis:	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Enbrel therapy

ENBREL (ETANERCEPT) *(CONTINUED)*

Drug Name:	Enbrel (etanercept)
Diagnosis:	Psoriatic Arthritis (PsA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active psoriatic arthritis ; **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist**; AND**
- **ONE** of the following:
  - **ALL** of the following:
    - Trial and failure, contraindication, or intolerance to **TWO** of the following [4]:
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Simponi (golimumab)
      - Stelara (ustekinumab)
      - Tremfya (guselkumab)**; AND**
    - Trial and failure, contraindication, or intolerance to **TWO** of the following:
      - Taltz (ixekizumab)
      - Orencia (abatacept)
      - Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)**; OR**
  - For continuation of prior Enbrel therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Drug Name:	Enbrel (etanercept)
Diagnosis:	Psoriatic Arthritis (PsA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Enbrel therapy

ENBREL (ETANERCEPT) *(CONTINUED)*

Drug Name:	Enbrel (etanercept)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderate to severe chronic plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist; **AND**
- **ONE** of the following:
  - **BOTH** of the following:
    - Trial and failure, contraindication, or intolerance to **THREE** of the following [5]:
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Skyrizi (risankizumab)
      - Stelara (ustekinumab)
      - Tremfya (guselkumab); **AND**
    - Trial and failure, contraindication, or intolerance to Taltz (ixekizumab); **OR**
  - For continuation of prior Enbrel therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Drug Name:	Enbrel (etanercept)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 Months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Enbrel therapy as evidenced by ONE of the following:
  - Reduction in body surface area (BSA) involvement from baseline
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline

ENBREL (ETANERCEPT) *(CONTINUED)*

Drug Name:	Enbrel (etanercept)
Diagnosis:	Ankylosing Spondylitis (AS)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active ankylosing spondylitis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to two NSAIDs (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen) [6]; **AND**
- **ONE** of the following:
  - All of the following:
    - Trial and failure, contraindication, or intolerance to **two** of the following, or attestation demonstrating a trial may be inappropriate*
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Simponi (golimumab)

    AND
    - Trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

OR

- For continuation of prior Enbrel therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Notes:
*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

Drug Name:	Enbrel (etanercept)
Diagnosis:	Ankylosing Spondylitis (AS)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Enbrel therapy

HUMIRA (ADALIMUMAB) (EFFECTIVE DATE 06/01/2021)

HUMIRA (ADALIMUMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Drug Name: Humira (adalimumab)

INDICATIONS

- **Rheumatoid arthritis (RA)** Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severe active rheumatoid arthritis (RA). Humira can be used alone or in combination with methotrexate (MTX) or other non-biologic disease-modifying antirheumatic drugs (DMARDs).
- **Polyarticular Juvenile idiopathic arthritis (PJIA)** Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 years of age and older. Humira can be used alone or in combination with MTX.
- **Psoriatic arthritis (PsA)** Indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. Humira can be used alone or in combination with non-biologic DMARDs.
- **Ankylosing spondylitis (AS)** Indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.
- **Crohn's disease (CD)** Indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.
- **Ulcerative Colitis** Indicated for the treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older. Limitations of use: The effectiveness of Humira has not been established in patients who have lost response to or were intolerant to TNF blockers.
- **Plaque psoriasis** Indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. Humira should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.
- **Hidradenitis Suppurativa** Indicated for the treatment of moderate to severe hidradenitis suppurativa.
- **Uveitis (UV)** Indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients.

HUMIRA (ADALIMUMAB) *(CONTINUED)*

Drug Name:	Humira (adalimumab)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active RA; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to one non-biologic disease-modifying antirheumatic drug (DMARD) [e.g., methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)] [2]

Drug Name:	Humira (adalimumab)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Humira therapy

Drug Name:	Humira (adalimumab)
Diagnosis:	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderate to severely active polyarticular JIA; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to one of the following non-biologic disease-modifying antirheumatic drugs (DMARDs): [3]
  - Arava (leflunomide)
  - methotrexate (Rheumatrex/Trexall)

HUMIRA (ADALIMUMAB) *(CONTINUED)*

Drug Name:	Humira (adalimumab)
Diagnosis:	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Humira therapy

Drug Name:	Humira (adalimumab)
Diagnosis:	Psoriatic Arthritis (PsA)
Approval Length:	12 months [9]
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active PsA; **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist

Drug Name:	Humira (adalimumab)
Diagnosis:	Psoriatic Arthritis (PsA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Humira therapy

Drug Name:	Humira (adalimumab)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderate to severe chronic plaque psoriasis [A]; **AND**
- Prescribed by or in consultation with a dermatologist

HUMIRA (ADALIMUMAB) *(CONTINUED)*

Drug Name:	Humira (adalimumab)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to therapy as evidenced by ONE of the following:
  - Reduction in the body surface area (BSA) involvement from baseline
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Drug Name:	Humira (adalimumab)
Diagnosis:	Ankylosing Spondylitis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active ankylosing spondylitis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to two NSAIDs (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen) [6]

Drug Name:	Humira (adalimumab)
Diagnosis:	Ankylosing Spondylitis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Humira therapy

HUMIRA (ADALIMUMAB) *(CONTINUED)*

Drug Name:	Humira (adalimumab)
Diagnosis:	Crohn's disease
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active Crohn's disease [7, 8, B]; **AND**
- **ONE** of the following:
  - Trial and failure, contraindication, or intolerance to one of the following conventional therapies: [7]
    - 6-mercaptopurine (Purinethol)
    - Azathioprine (Imuran)
    - Corticosteroids (e.g., prednisone, methylprednisolone)
    - Methotrexate (Rheumatrex, Trexall); **AND**
- Prescribed by or in consultation with a gastroenterologist

Drug Name:	Humira (adalimumab)
Diagnosis:	Crohn's disease [1-4]
Approval Length:	12 Months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Humira therapy

Drug Name:	Humira (adalimumab)
Diagnosis:	Ulcerative Colitis
Approval Length:	12 Weeks
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active ulcerative colitis; **AND**
- Trial and failure, contraindication, or intolerance to one of the following conventional therapies: [9, 10]
  - 6-mercaptopurine (Purinethol)
  - Aminosalicylate [e.g., mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)]
  - Azathioprine (Imuran)
  - Corticosteroids (e.g., prednisone, methylprednisolone)
- Prescribed by or in consultation with a gastroenterologist

HUMIRA (ADALIMUMAB) *(CONTINUED)*

Drug Name:	Humira (adalimumab)
Diagnosis:	Ulcerative Colitis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- **ONE** of the following:
  - For patients who initiated Humira therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy; **OR**
  - For patients who have been maintained on Humira therapy for longer than 12 weeks: Documentation of positive clinical response to Humira therapy

Drug Name:	Humira (adalimumab)
Diagnosis:	Hidradenitis Suppurativa
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III); **AND**
- Prescribed by or in consultation with a dermatologist

Drug Name:	Humira (adalimumab)
Diagnosis:	Hidradenitis Suppurativa
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Humira therapy

HUMIRA (ADALIMUMAB) *(CONTINUED)*

Drug Name:	Humira (adalimumab)
Diagnosis:	Uveitis (UV)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of non-infectious uveitis; **AND**
- Uveitis is classified as one of the following:
  - Intermediate
  - Posterior
  - Panuveitis**; AND**
- Prescribed by or in consultation with one of the following:
  - Ophthalmologist
  - Rheumatologist

Drug Name:	Humira (adalimumab)
Diagnosis:	Uveitis (UV)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Humira therapy

ILUMYA (TILDRAKIZUMAB-ASMN) (EFFECTIVE DATE 09/01/2021)

ILUMYA (TILDRAKIZUMAB-ASMN) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

INDICATIONS

- **Plaque Psoriasis** Indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Drug Name:	Ilumya (tildrakizumab-asmn)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderate-to-severe plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist; **AND**
- **ONE** of the following:
  - **BOTH** of the following:
    - Trial and failure, contraindication, or intolerance to **THREE** of the following:
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Skyrizi (risankizumab)
      - Stelara (ustekinumab)
      - Tremfya (guselkumab)**; AND**
    - Trial and failure, contraindication, or intolerance to Taltz (ixekizumab)**; OR**
  - For continuation of prior Ilumya therapy**

**Notes:

- Ilumya is non-preferred for STANDARD and ENHANCED.
- Ilumya is excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Ilumya is allowed for STANDARD, ENHANCED, and PRECISION only.
- Grandfathering of Ilumya is not allowed for PRECISION PLUS and CORE.

Drug Name:	Ilumya (tildrakizumab-asmn)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Ilumya therapy as evidenced by ONE of the following [2]:
  - Reduction in body surface area (BSA) involvement from baseline
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline

INFLIXIMAB (EFFECTIVE DATE 09/01/2021)

INFLIXIMAB INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Drug Name: Remicade® (infliximab), Avsola™ (infliximab-axxq), Inflectra® (infliximab-dyyb), Renflexis® (Infliximab-abda)

INDICATIONS

- **Crohn's Disease** Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Also, indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease.
- **Pediatric Crohn's Disease** Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.
- **Ulcerative Colitis** Indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.
- **Pediatric Ulcerative Colitis** Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.
- **Rheumatoid Arthritis** Indicated in combination with methotrexate, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis.
- **Ankylosing Spondylitis** Indicated for reducing signs and symptoms in patients with active ankylosing spondylitis
- **Psoriatic Arthritis** Indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis.
- **Plaque Psoriasis** Indicated for the treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. Therapy should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

Off Label Uses: **Sarcoidosis** Has been used for the treatment of refractory sarcoidosis. [5-7]

INFLIXIMAB *(CONTINUED)*

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Crohn's Disease or Fistulizing Crohn's Disease [A]
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- **One** of the following diagnoses:
  - Moderately to severely active Crohn's disease [B]
  - Fistulizing Crohn's disease; **AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Trial and failure, contraindication, or intolerance to one of the following conventional therapies: [4]
  - 6-mercaptopurine (Purinethol)
  - Azathioprine (Imuran)
  - Corticosteroids (e.g., prednisone, methylprednisolone)
  - Methotrexate (Rheumatrex, Trexall); **AND**
- Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Remicade® and Renflexis only)
  - Avsola
  - Inflectra

Notes:

* Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

- Avsola and Inflectra® are preferred for all formularies.
- Remicade® and Renflexis are non-preferred for STANDARD and ENHANCED.
- Remicade® and Renflexis are excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Remicade® and Renflexis is allowed for STANDARD, ENHANCED, and PRECISION only.
- Grandfathering of Remicade® and Renflexis is not allowed for PRECISION PLUS and CORE.

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Crohn's Disease or Fistulizing Crohn's Disease [A]
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to infliximab therapy.

INFLIXIMAB *(CONTINUED)*

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Crohn's Disease or Fistulizing Crohn's Disease [A]
Approval Length:	12 months
Therapy Stage:	Non-Formulary

Criteria:

- **One** of the following diagnoses:
  - Moderately to severely active Crohn's disease [B]
  - Fistulizing Crohn's disease; **AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following conventional therapies: [2]
  - 6-mercaptopurine (Purinethol)
  - Azathioprine (Imuran)
  - Corticosteroids (e.g., prednisone, methylprednisolone)
  - Methotrexate (Rheumatrex, Trexall); **AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Remicade® and Renflexis only)
  - Avsola
  - Inflectra

Notes:

* Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

- Avsola and Inflectra® are preferred for all formularies.
- Remicade® and Renflexis are non-preferred for STANDARD and ENHANCED.
- Remicade® and Renflexis are excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Remicade® and Renflexis is allowed for STANDARD, ENHANCED, and PRECISION only.
- Grandfathering of Remicade® and Renflexis is not allowed for PRECISION PLUS and CORE.

INFLIXIMAB *(CONTINUED)*

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Ulcerative Colitis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active ulcerative colitis; **AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Trial and failure, contraindication, or intolerance to one of the following conventional therapies: [3]
  - 6-mercaptopurine (Purinethol®)
  - Aminosalicylate (e.g., mesalamine [Asacol®, Pentasa®, Rowasa®], olsalazine [Dipentum®], sulfasalazine [Azulfidine®, Sulfazine])
  - Azathioprine (Imuran®)
  - Corticosteroids (e.g., prednisone, methylprednisolone)**; AND**
- Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Remicade® and Renflexis only)
  - Avsola
  - Inflectra

Notes:

*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product. Avsola and Inflectra® are preferred for all formularies.

- Remicade® and Renflexis are non-preferred for STANDARD and ENHANCED.
- Remicade® and Renflexis are excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Remicade® and Renflexis is allowed for STANDARD, ENHANCED, and PRECISION only.
- Grandfathering of Remicade® and Renflexis is not allowed for PRECISION PLUS and CORE

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Ulcerative Colitis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to infliximab therapy.

INFLIXIMAB *(CONTINUED)*

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Ulcerative Colitis
Approval Length:	12 months
Therapy Stage:	Non-Formulary

Criteria:

- Diagnosis of moderately to severely active ulcerative colitis; **AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following conventional therapies: [3]
  - 6-mercaptopurine (Purinethol®)
  - Aminosalicylate (e.g., mesalamine [Asacol®, Pentasa®, Rowasa®], olsalazine [Dipentum®], sulfasalazine [Azulfidine®, Sulfazine])
  - Azathioprine (Imuran®)
  - Corticosteroids (e.g., prednisone, methylprednisolone)**; AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Remicade® and Renflexis only)
  - Avsola
  - Inflectra

Notes:

*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product. Avsola and Inflectra® are preferred for all formularies.

- Remicade® and Renflexis are non-preferred for STANDARD and ENHANCED.
- Remicade® and Renflexis are excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Remicade® and Renflexis is allowed for STANDARD, ENHANCED, and PRECISION only.
- Grandfathering of Remicade® and Renflexis is not allowed for PRECISION PLUS and CORE

INFLIXIMAB *(CONTINUED)*

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active RA; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- **One** of the following:
  - Patient is receiving concurrent therapy with methotrexate (Rheumatrex®, Trexall®); **OR**
  - Trial and failure, contraindication, or intolerance to methotrexate (Rheumatrex®, Trexall®)**; AND**
- Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Remicade® and Renflexis only)
  - Avsola
  - Inflectra

Notes:

* Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

- Avsola and Inflectra® are preferred for all formularies.
- Remicade® and Renflexis are non-preferred for STANDARD and ENHANCED.
- Remicade® and Renflexis are excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Remicade® and Renflexis is allowed for STANDARD, ENHANCED, and PRECISION only.
- Grandfathering of Remicade® and Renflexis is not allowed for PRECISION PLUS and CORE.

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to infliximab therapy.

INFLIXIMAB *(CONTINUED)*

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Non-Formulary

Criteria:

- Diagnosis of moderately to severely active RA; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- **One** of the following:
  - Patient is receiving concurrent therapy with methotrexate (Rheumatrex®, Trexall®); **OR**
  - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to methotrexate (Rheumatrex®, Trexall®)**; AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Remicade® and Renflexis only)
  - Avsola
  - Inflectra

Notes:

* Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

- Avsola and Inflectra® are preferred for all formularies.
- Remicade® and Renflexis are non-preferred for STANDARD and ENHANCED.
- Remicade® and Renflexis are excluded for PRECISION, PRECISION PLUS, and CORE.
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- Grandfathering of Remicade® and Renflexis is not allowed for PRECISION PLUS and CORE.

INFLIXIMAB *(CONTINUED)*

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Ankylosing Spondylitis (AS)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active ankylosing spondylitis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to two NSAIDs (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen) [4]; **AND**
- Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Remicade® and Renflexis only)
  - Avsola
  - Inflectra

Notes:

* Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product. Avsola and Inflectra® are preferred for all formularies.

- Remicade® and Renflexis are non-preferred for STANDARD and ENHANCED.
- Remicade® and Renflexis are excluded for PRECISION, PRECISION PLUS, and CORE.
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- Grandfathering of Remicade® and Renflexis is not allowed for PRECISION PLUS and CORE

INFLIXIMAB *(CONTINUED)*

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Ankylosing Spondylitis (AS)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to infliximab therapy

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Ankylosing Spondylitis (AS)
Approval Length:	12 months
Therapy Stage:	Non-Formulary

Criteria:

- Diagnosis of active ankylosing spondylitis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two NSAIDs (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen) [4]; **AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Remicade® and Renflexis only)
  - Avsola
  - Inflectra

Notes:

* Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product. Avsola and Inflectra® are preferred for all formularies.

- Remicade® and Renflexis are non-preferred for STANDARD and ENHANCED.
- Remicade® and Renflexis are excluded for PRECISION, PRECISION PLUS, and CORE.
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- Grandfathering of Remicade® and Renflexis is not allowed for PRECISION PLUS and CORE

INFLIXIMAB *(CONTINUED)*

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Psoriatic Arthritis (PsA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active PsA; **AND**
- Prescribed by or in consultation with **one** of the following:
  - Dermatologist
  - Rheumatologist**; AND**
- Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Remicade® and Renflexis only)
  - Avsola
  - Inflectra

Notes:

* Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

- Avsola and Inflectra® are preferred for all formularies.
- Remicade® and Renflexis are non-preferred for STANDARD and ENHANCED.
- Remicade® and Renflexis are excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Remicade® and Renflexis is allowed for STANDARD, ENHANCED, and PRECISION only.
- Grandfathering of Remicade® and Renflexis is not allowed for PRECISION PLUS and CORE

INFLIXIMAB *(CONTINUED)*

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Psoriatic Arthritis (PsA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to infliximab therapy

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Psoriatic Arthritis (PsA)
Approval Length:	12 months
Therapy Stage:	Non-Formulary

Criteria:

- Diagnosis of active PsA; **AND**
- Prescribed by or in consultation with **one** of the following:
  - Dermatologist
  - Rheumatologist**; AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Remicade® and Renflexis only)
  - Avsola
  - Inflectra

Notes:

* Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

- Avsola and Inflectra® are preferred for all formularies.
- Remicade® and Renflexis are non-preferred for STANDARD and ENHANCED.
- Remicade® and Renflexis are excluded for PRECISION, PRECISION PLUS, and CORE.
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- Grandfathering of Remicade® and Renflexis is not allowed for PRECISION PLUS and CORE

INFLIXIMAB *(CONTINUED)*

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist; **AND**
- Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Remicade® and Renflexis only):
  - Avsola
  - Inflectra

Notes:

* Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product. Avsola and Inflectra® are preferred for all formularies.

- Remicade® and Renflexis are non-preferred for STANDARD and ENHANCED.
- Remicade® and Renflexis are excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Remicade® and Renflexis is allowed for STANDARD, ENHANCED, and PRECISION only.
- Grandfathering of Remicade® and Renflexis is not allowed for PRECISION PLUS and CORE

Drug Name:	Avsola Inflectra, Remicade, Renflexis
Diagnosis:	Plaque Psoriasis
Approval Length:	12 Months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to infliximab therapy as evidenced by **one** of the following: [8]
  - Reduction the body surface area (BSA) involvement from baseline
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline

INFLIXIMAB *(CONTINUED)*

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Non-Formulary

Criteria:

- Diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist; **AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Remicade® and Renflexis only):
  - Avsola
  - Inflectra

Notes:

* Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product. Avsola and Inflectra® are preferred for all formularies.

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- Remicade® and Renflexis are excluded for PRECISION, PRECISION PLUS, and CORE.
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- Grandfathering of Remicade® and Renflexis is not allowed for PRECISION PLUS and CORE

INFLIXIMAB *(CONTINUED)*

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Sarcoidosis [Off-label] [5-7]
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of sarcoidosis; **AND**
- Prescribed by or in consultation with **one** of the following:
  - Pulmonologist
  - Dermatologist
  - Ophthalmologist
- Trial and failure, contraindication, or intolerance to one corticosteroid (e.g., prednisone); **AND**
- Trial and failure, contraindication, or intolerance to one immunosuppressant [e.g., methotrexate (Rheumatrex, Trexall), Cytoxan (cyclophosphamide), or Imuran (azathioprine)]; **AND**
- Trial and failure or intolerance to **ONE** of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Remicade® and Renflexis only)
  - Avsola
  - Inflectra

Notes:

* Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

- Avsola and Inflectra® are preferred for all formularies.
- Remicade® and Renflexis are non-preferred for STANDARD and ENHANCED.
- Remicade® and Renflexis are excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Remicade® and Renflexis is allowed for STANDARD, ENHANCED, and PRECISION only.
- Grandfathering of Remicade® and Renflexis is not allowed for PRECISION PLUS and CORE

INFLIXIMAB *(CONTINUED)*

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Sarcoidosis [Off-label] [5-7]
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to infliximab therapy.

Drug Name:	Avsola™, Inflectra®, Remicade®, Renflexis®
Diagnosis:	Sarcoidosis [Off-label] [5-7]
Approval Length:	12 months
Therapy Stage:	Non-Formulary

Criteria:

- Diagnosis of sarcoidosis; **AND**
- Prescribed by or in consultation with **one** of the following:
  - Pulmonologist
  - Dermatologist
  - Ophthalmologist
- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one corticosteroid (e.g., prednisone); **AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one immunosuppressant [e.g., methotrexate (Rheumatrex, Trexall), Cytoxan (cyclophosphamide), or Imuran (azathioprine)]; **AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **ONE** of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Remicade® and Renflexis only)
  - Avsola
  - Inflectra

Notes:

* Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

- Avsola and Inflectra® are preferred for all formularies.
- Remicade® and Renflexis are non-preferred for STANDARD and ENHANCED.
- Remicade® and Renflexis are excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Remicade® and Renflexis is allowed for STANDARD, ENHANCED, and PRECISION only.
- Grandfathering of Remicade® and Renflexis is not allowed for PRECISION PLUS and CORE

KEVZARA (SARILUMAB) (EFFECTIVE DATE 05/01/2021)

KEVZARA (SARILUMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

INDICATIONS

- **Rheumatoid arthritis** Indicated for treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).

Drug Name:	Kevzara (sarilumab)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active rheumatoid arthritis (RA); **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **ONE** nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., Rheumatrex/Trexall [methotrexate], Arava [leflunomide], Azulfidine [sulfasalazine]) [1-2]; **AND**
- **ONE** of the following:
  - **BOTH** of the following:
    - Trial and failure, contraindication, or intolerance to **TWO** of the following, or attestation demonstrating a trial may be inappropriate*:
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Rinvoq (upadacitinib)
      - Simponi (golimumab)
      - Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)**; AND**
    - Trial and failure, contraindication, or intolerance to **BOTH** of the following:
      - Actemra (tocilizumab)
      - Orencia (abatacept); **OR**

– For continuation of prior Kevzara therapy STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Notes: *Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

Drug Name:	Kevzara (sarilumab)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to therapy

KINERET (ANAKINRA) (EFFECTIVE DATE 04/01/2021)

KINERET (ANAKINRA) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Indications

- **Rheumatoid arthritis** Indicated for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs). Kineret can be used alone or in combination with DMARDs other than tumor necrosis factor (TNF) blocking agents.
- Cryopyrin-associated periodic syndromes (CAPS): Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [A] Indicated for the treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID).
- **Deficiency of Interleukin-1 Receptor Antagonist (DIRA)** Indicated for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA).

Off Label Uses

Systemic Juvenile Idiopathic Arthritis Has been used for the treatment of systemic juvenile idiopathic arthritis. [3,4]

Drug Name:	Kineret (anakinra)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active rheumatoid arthritis (RA); **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **ONE** nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate [Rheumatrex/Trexall], Arava [leflunomide], Azulfidine [sulfasalazine]) [1, 2,5]; **AND**
- **ONE** of the following:
  - **ALL** of the following:
    - Trial and failure, contraindication, or intolerance to **TWO** of the following, or attestation demonstrating a trial may be inappropriate*
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Rinvoq (upadacitinib)
      - Simponi (golimumab)
      - Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)**; AND**
    - Trial and failure, contraindication, or intolerance to BOTH of the following:
      - Actemra (tocilizumab)
      - Orencia (abatacept); **OR**

- For continuation of prior Kineret therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Notes:

*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

KINERET (ANAKINRA) (EFFECTIVE DATE 04/01/2020) *(CONTINUED)*

Drug Name:	Kineret (anakinra)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Kineret therapy

Drug Name:	Kineret (anakinra)
Diagnosis:	Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [1, B]
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of neonatal-onset multisystem inflammatory disease (NOMID); **AND**
- Diagnosis of NOMID has been confirmed by one of the following: [7-8.B]
  - NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3-gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation; **OR**
  - **BOTH** of the following:
    - Two of the following clinical symptoms
      - Urticaria-like rash
      - Cold/stress triggered episodes
      - Sensorineural hearing loss
      - Musculoskeletal symptoms (e.g., arthralgia, arthritis, myalgia)
      - Chronic aseptic meningitis
      - Skeletal abnormalities (e.g., epiphyseal overgrowth, frontal bossing)**; AND**
    - Elevated acute phase reactants (e.g., erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], serum amyloid A [SAA])**; AND**
- Prescribed by or in consultation with one of the following
  - Allergist/Immunologist
  - Rheumatologist
  - Pediatrician

Drug Name:	Kineret (anakinra)
Diagnosis:	Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [1, B]
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Kineret therapy;

Drug Name:	Kineret (anakinra)
Diagnosis:	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Approval Length:	12 months

Criteria:

- Diagnosis of deficiency of Interleukin-1 Receptor Antagonist (DIRA)

Drug Name:	Kineret (anakinra)
Diagnosis:	Systemic Juvenile Idiopathic Arthritis (SJIA) (off-label)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active systemic juvenile idiopathic arthritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **ONE** of the following [3]:
  - Non-steroidal anti-inflammatory drug (NSAID) (e.g., Motrin [ibuprofen], Naprosyn [naproxen])
  - Systemic glucocorticoid (e.g., prednisone)

Drug Name:	Kineret (anakinra)
Diagnosis:	Systemic Juvenile Idiopathic Arthritis (SJIA) (off-label)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Kineret therapy

OLUMIANT (BARICITINIB) (EFFECTIVE DATE 09/24/2021)

OLUMIANT (BARICITINIB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Indications

- **Rheumatoid arthritis** Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies. Limitation of Use: Use of Olumiant in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Drug Name:	Olumiant (baricitinib)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active rheumatoid arthritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **one** nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate [Rheumatrex/Trexall], Arava [leflunomide], Azulfidine [sulfasalazine]) [2]; **AND**
- **One** of the following:
  - **All** of the following:
    - Trial and failure, contraindication, or intolerance to **two** of the following, or attestation demonstrating a trial may be inappropriate
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Rinvoq (upadacitinib)
      - Simponi (golimumab)
      - Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER); **AND**
    - Trial and failure, contraindication, or intolerance to **both** of the following:
      - Actemra (tocilizumab)
      - Orencia (abatacept); **OR**
  - For continuation of prior Olumiant therapy*; **AND**

***Notes:**

- Olumiant is non-preferred for STANDARD and ENHANCED.
- Olumiant is excluded for PRECISION, PRECISION PLUS, and CORE
- Grandfathering of Olumiant is allowed for STANDARD, ENHANCED, and PRECISION only
- Grandfathering of Olumiant is not allowed for PRECISION PLUS and CORE; **AND**

- Patient is not receiving Olumiant in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine) ** [1,3] .

Notes:

*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

**Olumiant® may be used with concomitant methotrexate and/or low stable dosages of corticosteroids (equivalent to 10 mg or less of prednisone daily).

OLUMIANT (BARICITINIB) *(CONTINUED)*

Drug Name:	Olumiant (baricitinib)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Olumiant therapy; **AND**
- Patient is not receiving Olumiant in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)** [1, 3].

Notes:

**Olumiant® may be used with concomitant methotrexate and/or low stable dosages of corticosteroids (equivalent to 10 mg or less of prednisone daily).

Drug Name:	Olumiant (baricitinib)
Approval Length:	12 months
Therapy Stage:	Non-Formulary

Criteria:

- Diagnosis of moderately to severely active rheumatoid arthritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **ONE** nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate [Rheumatrex/Trexall], Arava [leflunomide], Azulfidine [sulfasalazine]) [2]; **AND**
- **One** of the following:
  - **All** of the following:
    - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **TWO** of the following, or attestation demonstrating a trial may be inappropriate
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Rinvoq (upadacitinib)
      - Simponi (golimumab)
      - Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER); **AND**
    - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **BOTH** of the following:
      - Actemra (tocilizumab)
      - Orencia (abatacept); **OR**
  - Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Olumiant therapy, defined as no more than a 45-day gap in therapy*; **AND**

OLUMIANT (BARICITINIB) *(CONTINUED)*

***Notes:**

- Olumiant is non-preferred for STANDARD and ENHANCED.
- Olumiant is excluded for PRECISION, PRECISION PLUS, and CORE.
- Grandfathering of Olumiant is allowed for STANDARD and ENHANCED.
- Grandfathering of Olumiant is allowed for PRECISION (continuation of prior therapy is defined as no more than a 45-day gap in therapy).
- Grandfathering of Olumiant is not allowed for PRECISION PLUS and CORE; **AND**

- Patient is not receiving Olumiant in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine) ** [1,3].

OLUMIANT (BARICITINIB) (CONTINUED)

Notes:

*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

**Olumiant® may be used with concomitant methotrexate and/or low stable dosages of corticosteroids (equivalent to 10 mg or less of prednisone daily).

ORENCIA (ABATACEPT) (EFFECTIVE DATE 06/01/2021)

ORENCIA (ABATACEPT) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Indications

- **Adult Rheumatoid Arthritis (RA)** Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis. Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic disease modifying antirheumatic drugs, Janus kinase [JAK] inhibitors) is not recommended.
- **Polyarticular Juvenile Idiopathic Arthritis** Indicated for the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis. Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic disease modifying antirheumatic drugs, Janus kinase [JAK] inhibitors) is not recommended.
- **Adult Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis (PsA). Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic disease modifying antirheumatic drugs, Janus kinase [JAK] inhibitors) is not recommended.

Drug Name:	Orencia (abatacept SC), Orencia (abatacept IV)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active rheumatoid arthritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **ONE** nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate [Rheumatrex/Trexall], Arava [leflunomide], Azulfidine [sulfasalazine]) [2]; **AND**
- **ONE** of the following:
  - Trial and failure, contraindication, or intolerance to **TWO** of the following, or attestation demonstrating a trial may be inappropriate*
    - Cimzia (certolizumab pegol)
    - Humira (adalimumab)
    - Rinvoq (upadacitinib)
    - Simponi (golimumab)
    - Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

OR

- For continuation of prior Orencia therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Notes:

*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

ORENCIA (ABATACEPT) *(CONTINUED)*

Drug Name:	Orencia (abatacept SC), Orencia (abatacept IV)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Orencia therapy;

Drug Name:	Orencia (abatacept IV), Orencia (abatacept SC)
Diagnosis:	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **ONE** of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs)[3]:
  - Arava (leflunomide)
  - Methotrexate (Rheumatrex/Trexall); **AND**
- **ONE** of the following:
  - Trial and failure, contraindication, or intolerance to Humira (adalimumab), or attestation demonstrating a trial may be inappropriate*; **OR**
  - For continuation of prior Orencia therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Notes: * Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

Drug Name:	Orencia (abatacept IV), Orencia (abatacept SC)
Diagnosis:	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Orencia therapy;

ORENCIA (ABATACEPT) *(CONTINUED)*

Drug Name:	Orencia (abatacept IV), Orencia (abatacept SC)
Diagnosis:	Psoriatic Arthritis (PsA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active psoriatic arthritis (PsA); **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist; **AND**
- **ONE** of the following:
  - Trial and failure, contraindication, or intolerance to TWO of the following [4]
    - Cimzia (certolizumab pegol)
    - Humira (adalimumab)
    - Simponi (golimumab)
    - Stelara (ustekinumab)
    - Tremfya (guselkumab); **OR**
  - For continuation of prior Orencia therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Drug Name:	Orencia (abatacept IV), Orencia (abatacept SC)
Diagnosis:	Psoriatic Arthritis (PsA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Orencia therapy;

OTEZLA® (APREMILAST) (EFFECTIVE DATE 12/01/2021)

OTEZLA (APREMILAST) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Indications

- **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis.
- **Plaque Psoriasis** Indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- **Oral Ulcers Associated with Behcet's Disease** Indicated for the treatment of adult patients with oral ulcers associated with Behcet's Disease

Drug Name:	Otezla (apremilast)
Diagnosis:	Psoriatic Arthritis (PsA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active psoriatic arthritis; **AND**
- Prescribed by or in consultation with **one** of the following:
  - Dermatologist
  - Rheumatologist

Drug Name:	Otezla (apremilast)
Diagnosis:	Psoriatic Arthritis (PsA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Otezla therapy (e.g., improvement in number of swollen/tender joints, pain, or stiffness)

Drug Name:	Otezla (apremilast)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderate-to-severe plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist

OTEZLA® (APREMILAST) *(CONTINUED)*

Drug Name:	Otezla (apremilast)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Otezla therapy as evidenced by **ONE** of the following [2, 4]:
  - Reduction in body surface area (BSA) involvement from baseline
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline.

Drug Name:	Otezla (apremilast)
Diagnosis:	Oral Ulcers Associated with Behcet's Disease
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of Behcet's Disease; **AND**
- Patient has active oral ulcers

Drug Name:	Otezla (apremilast)
Diagnosis:	Oral Ulcers Associated with Behcet's Disease
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Otezla therapy (e.g., reduction in pain from oral ulcers or reduction in number of oral ulcers).

RINVOQ (UPADACITINIB) (EFFECTIVE DATE 10/01/2021)

RINVOQ (UPADACITINIB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

INDICATIONS

- **Rheumatoid Arthritis** Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. Limitation of Use: Use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended.

Drug Name:	Rinvoq (upadacitinib)
Diagnosis:	Rheumatoid Arthritis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active rheumatoid arthritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **one** nonbiologic disease-modifying antirheumatic drug (DMARD), methotrexate [Rheumatrex/Trexall], Arava [leflunomide], Azulfidine [sulfasalazine]); **AND**
- Patient is not receiving Rinvoq in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)* [1,2].

Notes: *Rinvoq may be used with concomitant methotrexate and/or low stable dosages of corticosteroids (equivalent to 10 mg or less of prednisone daily).

Drug Name:	Rinvoq (upadacitinib)
Diagnosis:	Rheumatoid Arthritis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Rinvoq therapy; **AND**
- Patient is not receiving Rinvoq in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)* [1,2].

Notes: *Rinvoq may be used with concomitant methotrexate and/or low stable dosages of corticosteroids (equivalent to 10 mg or less of prednisone daily).

RITUXAN (RITUXIMAB) (EFFECTIVE DATE 09/24/2021)

RITUXAN (RITUXIMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Indications

- **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with: a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma as a single agent. b. Previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens. c. Previously untreated follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy. d. Non-progressing (including stable disease) low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma, as a single agent, after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy. Limitations of Use: Rituxan is not recommended for use in patients with severe, active infections.
- **Rheumatoid Arthritis (RA)** In combination with methotrexate, is indicated for the treatment of adult patients with moderately- to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies. Limitation of Use: Rituxan is not recommended for use in patients with severe, active infections.
- **Chronic Lymphocytic Leukemia (CLL)** Indicated for the treatment of patients with previously untreated and previously treated CD20-positive CLL in combination fludarabine and cyclophosphamide (FC). Limitations of Use: Rituxan is not recommended for use in patients with severe, active infections.
- **Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)** Indicated for the treatment of adult patients with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in combination with glucocorticoids. Limitations of Use: Rituxan is not recommended for use in patients with severe, active infections.
- **Pemphigus Vulgaris** Indicated for the treatment of moderate to severe Pemphigus Vulgaris (PV) in adult patients.

Off Label Uses

- **Immune Thrombocytopenic Purpura (ITP)** Has been used for the treatment of immune or idiopathic thrombocytopenic purpura. [1,2] Overall response rates of 35% to 52% in patients with refractory idiopathic thrombocytopenic purpura. [3,4]
- **Waldenström's Macroglobulinemia** Has been used for the treatment of relapsed/refractory Waldenström's macroglobulinemia. Rituximab monotherapy (1 to 8 cycles) has shown efficacy in limited studies. [5-8]

RITUXAN (RITUXIMAB) *(CONTINUED)*

Drug Name:	Rituxan (rituximab)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	1 month
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately- to severely active rheumatoid arthritis; **AND**
- **ONE** of the following:
  - Patient is concurrently on methotrexate [A]; **OR**
  - History of contraindication or intolerance to methotrexate**; AND**
- **ONE** of the following:
  - BOTH of the following:
    - Trial and failure, contraindication, or intolerance to **TWO** of the following, or attestation demonstrating a trial may be inappropriate*
      - Cimzia (certolizumab)
      - Humira (adalimumab)
      - Rinvoq (upadacitinib)
      - Simponi (golimumab)
      - Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER); **AND**
    - Trial and failure, contraindication, or intolerance to **BOTH** of the following:
      - Actemra (tocilizumab)
      - Orencia (abatacept); **OR**
  - Continuation of prior Rituxan therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE; **AND**
- Prescribed by or in consultation with a rheumatologist

Notes: *Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

Drug Name:	Rituxan (rituximab)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	1 month
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Rituxan therapy; **AND**
- At least 16 weeks have elapsed since last course of therapy [B]

RITUXAN (RITUXIMAB) *(CONTINUED)*

Drug Name:	Rituxan (rituximab)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	1 month
Therapy Stage:	Non-Formulary

Criteria:

- Diagnosis of moderately- to severely active rheumatoid arthritis; **AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming **ONE** of the following:
  - Patient is concurrently on methotrexate [A]; **OR**
  - History of contraindication or intolerance to methotrexate**; AND**
- **ONE** of the following:
  - All of the following:
    - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **TWO** of the following, or attestation demonstrating a trial may be inappropriate*
      - Cimzia (certolizumab)
      - Humira (adalimumab)
      - Rinvoq (upadacitinib)
      - Simponi (golimumab)
      - Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER); **AND**
    - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **BOTH** of the following:
      - Actemra (tocilizumab)
      - Orencia (abatacept); **OR**
  - Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Rituxan therapy, defined as no more than a 45-day gap in therapy, for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE; **AND**
- Prescribed by or in consultation with a rheumatologist

Notes: *Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

RITUXAN (RITUXIMAB) *(CONTINUED)*

Drug Name:	Rituxan (rituximab)
Diagnosis:	Non-Hodgkin Lymphoma
Approval Length:	12 months
Guideline Type:	Prior Authorization

Criteria:

- **ONE** of the following:
  - **BOTH** of the following: [10]
    - Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma
    - Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens**; OR**
  - **BOTH** of the following:
    - Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
    - Used as first-line treatment in combination with chemotherapy**; OR**
  - **ALL** of the following:
    - Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
    - Patient achieved a complete or partial response to Rituxan in combination with chemotherapy
    - Followed by Rituxan used as monotherapy for maintenance therapy**; OR**
  - **BOTH** of the following: [1]
    - Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma; **AND**
    - **ONE** of the following:
      - Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy
      - Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy**; OR**
  - Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma; **AND**
- Prescribed by or in consultation with an oncologist/hematologist; **AND**

For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Ruxience

Drug Name:	Rituxan (rituximab)
Diagnosis:	Chronic Lymphocytic Leukemia
Approval Length:	12 months
Guideline Type:	Prior Authorization

Criteria:

- Diagnosis of chronic lymphocytic leukemia [2,12,15-19]; **AND**
- Used in combination with fludarabine and cyclophosphamide; **AND**
- Prescribed by or in consultation with an oncologist/hematologist; **AND**

For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Ruxience

RITUXAN (RITUXIMAB) *(CONTINUED)*

Drug Name:	Rituxan (rituximab)
Diagnosis:	Immune or Idiopathic Thrombocytopenic Purpura [1,2] (Off-Label)
Approval Length:	12 months
Guideline Type:	Prior Authorization

Criteria:

- Diagnosis of immune or idiopathic thrombocytopenic purpura (off-label) [3,4,11]; **AND**
- Prescribed by or in consultation with a hematologist/oncologist; **AND**
- Trial and failure, contraindication, or intolerance to at least **ONE** of the following: [12]
  - Glucocorticoids (e.g., prednisone, methylprednisolone)
  - Immunoglobulins (e.g., IVIG)
  - Splenectomy**; AND**
- Documented platelet count of less than 50 x 10^9 / L [11].

Drug Name:	Rituxan (rituximab)
Diagnosis:	Pemphigus Vulgaris
Approval Length:	12 months
Guideline Type:	Initial Authorization

Criteria:

- Diagnosis of moderate to severe Pemphigus Vulgaris; **AND**
- Prescribed by or in consultation with a dermatologist.

Drug Name:	Rituxan (rituximab)
Diagnosis:	Pemphigus Vulgaris
Approval Length:	12 months
Guideline Type:	Reauthorization

Criteria:

- Documentation of positive clinical response to Rituxan therapy.

Drug Name:	Rituxan (rituximab)
Diagnosis:	Waldenström's Macroglobulinemia
Approval Length:	12 months
Guideline Type:	Prior Authorization

Criteria:

- Diagnosis of relapsed/refractory Waldenström's macroglobulinemia (off-label) [1,2,5-8].

RITUXAN (RITUXIMAB) *(CONTINUED)*

Drug Name:	Rituxan (rituximab)
Diagnosis:	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length:	3 months
Guideline Type:	Prior Authorization

Criteria:

- One of the following diagnoses:
  - Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)
  - Microscopic Polyangiitis**; AND**
- One of the following:
  - Patient is concurrently on glucocorticoids (e.g., prednisone) **; OR**
  - History of contraindication or intolerance to glucocorticoids (e.g., prednisone) **; AND**
- Prescribed by or in consultation with one of the following:
  - Nephrologist
  - Pulmonologist
  - Rheumatologist

For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Ruxience.

SILIQ (BRODALUMAB) (EFFECTIVE DATE 07/01/2021)

SILIQ (BRODALUMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

INDICATIONS

- **Plaque Psoriasis** Indicated for the treatment of adults with moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

Drug Name:	Siliq (brodalumab)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderate to severe plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist; **AND**
- **ONE** of the following:
  - **BOTH** of the following:
    - Trial and failure, contraindication, or intolerance to **THREE** of the following:
      - Cimzia (certolizumab pegol)
      - Humira (adalimumab)
      - Skyrizi (risankizumab)
      - Stelara (ustekinumab)
      - Tremfya (guselkumab)**; AND**
    - Trial and failure, contraindication, or intolerance to Taltz (ixekizumab)**; OR**
  - For continuation of prior Siliq therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Drug Name:	Siliq (brodalumab)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Siliq therapy as evidenced by **ONE** of the following [2]:
  - Reduction in body surface area (BSA) involvement from baseline
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline

SIMPONI, SIMPONI ARIA (GOLIMUMAB) (EFFECTIVE DATE 02/01/2021)

SIMPONI, SIMPONI ARIA (GOLIMUMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Drug Name: Simponi (golimumab) – for *subcutaneous* use
INDICATIONS

- **Rheumatoid Arthritis (RA)** In combination with methotrexate, indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis.
- **Psoriatic Arthritis (PsA)** Alone or in combination with methotrexate, indicated for the treatment of adult patients with active psoriatic arthritis.
- **Ankylosing Spondylitis (AS)** Indicated for the treatment of adult patients with active ankylosing spondylitis.
- **Ulcerative Colitis (UC)** Indicated in adult patients with moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine or 6-mercaptopurine for: (1) inducing and maintaining clinical response, (2) improving endoscopic appearance of the mucosa during induction, (3) inducing clinical remission, and (4) achieving and sustaining clinical remission in induction responders.

Drug Name: Simponi Aria (golimumab) – for *intravenous* use
INDICATIONS

- **Rheumatoid Arthritis (RA)** In combination with methotrexate, indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis.
- **Psoriatic Arthritis (PsA)** Indicated for the treatment of active psoriatic arthritis in patients 2 years of age and older.
- **Ankylosing Spondylitis (AS)** Indicated for the treatment of adult patients with active ankylosing spondylitis.
- **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for the treatment of active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older

Drug Name:	Simponi, Simponi Aria (golimumab)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active RA; **AND**
- **ONE** of the following:
  - Patient is receiving concurrent therapy with methotrexate (Rheumatrex, Trexall)**; OR**
  - Trial and failure, contraindication or intolerance to methotrexate (Rheumatrex, Trexall)**; AND**
- Prescribed by or in consultation with a rheumatologist

SIMPONI, SIMPONI ARIA (GOLIMUMAB) (EFFECTIVE DATE 01/01/2020) *(CONTINUED)*

Drug Name:	Simponi, Simponi Aria (golimumab)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to therapy

Drug Name:	Simponi Aria
Diagnosis:	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active PJIA; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to one of the following nonbiologic disease-modifying antirheumatic drugs (DMARDs): [6]
  - Arava (leflunomide)
  - methotrexate (Rheumatrex/Trexall)

Drug Name:	Simponi Aria
Diagnosis:	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to therapy

Drug Name:	Simponi, Simponi Aria (golimumab)
Diagnosis:	Psoriatic Arthritis (PsA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active PsA; **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist

SIMPONI, SIMPONI ARIA (GOLIMUMAB) (EFFECTIVE DATE 01/01/2020) *(CONTINUED)*

Drug Name:	Simponi, Simponi Aria (golimumab)
Diagnosis:	Psoriatic Arthritis (PsA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to therapy

Drug Name:	Simponi, Simponi Aria (golimumab)
Diagnosis:	Ankylosing Spondylitis (AS)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active ankylosing spondylitis; **AND**
- Trial and failure, contraindication, or intolerance to two NSAIDs (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen) [3]; **AND**
- Prescribed by or in consultation with a rheumatologist

SIMPONI, SIMPONI ARIA (GOLIMUMAB) (EFFECTIVE DATE 01/01/2020) *(CONTINUED)*

Drug Name:	Simponi, Simponi Aria (golimumab)
Diagnosis:	Ankylosing Spondylitis (AS)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to therapy

Drug Name:	Simponi
Diagnosis:	Ulcerative Colitis (UC)
Approval Length:	10 weeks
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active ulcerative colitis; **AND**
- **ONE** of the following:
  - Patient is corticosteroid dependent (i.e., an inability to successfully taper corticosteroids without a return of the symptoms of UC)**; OR**
  - Trial and failure, contraindication, or intolerance to one of the following conventional therapies: [4,5]
    - 6-mercaptopurine (Purinethol)
    - Aminosalicylate [e.g., mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)]
    - Azathioprine (Imuran)
    - Corticosteroids (e.g., prednisone, methylprednisolone)
- Prescribed by or in consultation with a gastroenterologist

Drug Name:	Simponi
Diagnosis:	Ulcerative Colitis (UC)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to therapy

SKYRIZI (RISANKIZUMAB-RZAA) (EFFECTIVE DATE 08/01/2021)

SKYRIZI (RISANKIZUMAB-RZAA) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

INDICATIONS

- **Plaque Psoriasis** Indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Drug Name:	Skyrizi (risankizumab-rzaa)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderate-to-severe plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist.

Drug Name:	Skyrizi (risankizumab-rzaa)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Skyrizi therapy as evidenced by ONE of the following [2]:
  - Reduction in body surface area (BSA) involvement from baseline
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline

DOSAGE AND ADMINISTRATION

Indication	Dose
Plaque Psoriasis	• 150mg at Week 0, Week 4 and every 12 weeks thereafter

**** Single dose vial must be prepared and administered by a healthcare professional**

Max ML (per dose and over time):

Indication	# mL to build in FirstTrax℠	Per # days*
Plaque Psoriasis	**Loading Dose**: 2 syringes entered as 1 kit	28
	Maintenance Dose: 1 syringe or pen	84

STELARA (USTEKINUMAB) (EFFECTIVE DATE 11/1/2021)

STELARA (USTEKINUMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Drug Name: Stelara SC (ustekinumab)
INDICATIONS

- **Psoriasis (Ps)** Indicated for the treatment of patients 6 years of age or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients (18 years or older) with active psoriatic arthritis. Stelara can be used alone or in combination with methotrexate (MTX).
- **Crohn's Disease (CD)** Indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have: (1) failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed treatment with a tumor necrosis factor (TNF) blocker or (2) failed or were intolerant to treatment with one or more TNF blockers.
- **Ulcerative Colitis (UC)** Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

Drug Name: Stelara IV (ustekinumab)
INDICATIONS

- **Crohn's Disease (CD)** Indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have: (1) failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed treatment with a tumor necrosis factor (TNF) blocker or (2) failed or were intolerant to treatment with one or more TNF blockers.
- **Ulcerative Colitis (UC)** Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis

Product Name:	Stelara SC (USTEKINUMAB) 45 mg/0.5 mL
Diagnosis:	Psoriasis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderate to severe plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist.

Product Name:	Stelara SC (ustekinumab) 90 mg/1 mL
Diagnosis:	Psoriasis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderate to severe plaque psoriasis; **AND**
- Patient's weight is greater than 100 kg (220 lb.); **AND**
- Prescribed by or in consultation with a dermatologist.

STELARA (USTEKINUMAB) *(CONTINUED)*

Drug Name:	Stelara SC (ustekinumab)
Diagnosis:	Psoriasis [1-4]
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Stelara therapy as evidenced by **ONE** of the following [2]:
  - Reduction in body surface area (BSA) involvement from baseline
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name:	Stelara SC (ustekinumab) 45 mg/0.5 mL
Diagnosis:	Psoriatic Arthritis [1, 3]
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active psoriatic arthritis; **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist

Product Name:	Stelara SC (ustekinumab) 90 mg/1 mL
Diagnosis:	Psoriatic Arthritis [1, 3]
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active psoriatic arthritis; **AND**
- Diagnosis of co-existent moderate to severe psoriasis [1,3]; **AND**
- Patient's weight is greater than 100 kg (220 lb.); **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist

Drug Name:	Stelara SC (ustekinumab)
Diagnosis:	Psoriatic Arthritis [1, 3]
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Stelara therapy

STELARA (USTEKINUMAB) *(CONTINUED)*

Product Name:	Stelara (ustekinumab) IV
Diagnosis:	Crohn's Disease
Approval Length:	1 time
Guideline Type:	Prior Authorization

Criteria:

- Diagnosis of moderately to severely active Crohn's disease; **AND**
- Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies; [4]
  - 6-mercaptopurine (Purinethol)
  - azathioprine (Imuran)
  - corticosteroids (e.g., prednisone, methylprednisolone)
  - methotrexate (Rheumatrex, Trexall); **AND**
- Stelara is to be administered as an intravenous induction dose; **AND**
- Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's disease:
  - 260 mg for patients weighing 55 kg or less
  - 390 mg for patients weighing more than 55 kg to 85 kg
  - 520 mg for patients weighing more than 85 kg; **AND**
- Prescribed by or in consultation with a gastroenterologist.

Product Name:	Stelara (ustekinumab) SC
Diagnosis:	Crohn's disease
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active Crohn's disease; **AND**
- Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies; [4]
  - 6-mercaptopurine (Purinethol)
  - azathioprine (Imuran(
  - corticosteroids (e.g., prednisone, methylprednisolone)
  - methotrexate (Rheumatrex, Trexall); **AND**
- Prescribed by or in consultation with a gastroenterologist.

STELARA (USTEKINUMAB) *(CONTINUED)*

Product Name:	Stelara (ustekinumab) IV
Diagnosis:	Ulcerative Colitis
Approval Length:	1 Time
Therapy Stage:	Prior Authorization

Criteria:

- Diagnosis of moderately to severely active ulcerative colitis; **AND**
- Trial and failure, contraindication, or intolerance to at least ONE of the following [5]:
  - Corticosteroid (e.g., prednisone)
  - Purinethol (6-mercaptopurine)
  - Imuran (azathioprine)
  - Aminosalicylates (e.g., mesalamine [Asacol, Pentasa, Rowasa], olsalazine [Dipentum], sulfasalazine [Azulfidine, Sulfazine])

AND

- Stelara is to be administered as an intravenous induction dose; **AND**
- Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for ulcerative colitis:
  - 260 mg for patients weighing 55 kg or less
  - 390 mg for patients weighing more than 55 kg to 85 kg
  - 520 mg for patients weighing more than 85 kg

AND

- Prescribed by or in consultation with a gastroenterologist

STELARA (USTEKINUMAB) *(CONTINUED)*

Product Name:	Stelara (ustekinumab) SC
Diagnosis:	Ulcerative Colitis
Approval Length:	12 Months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active ulcerative colitis; **AND**
- Trial and failure, contraindication, or intolerance to at least ONE of the following [5]:
  - Corticosteroid (e.g., prednisone)
  - Purinethol (6-mercaptopurine)
  - Imuran (azathioprine)
  - Aminosalicylates (e.g., mesalamine [Asacol, Pentasa, Rowasa], olsalazine [Dipentum], sulfasalazine [Azulfidine, Sulfazine])

AND

- Prescribed by or in consultation with a gastroenterologist.

Drug Name:	Stelara (ustekinumab) SC
Diagnosis:	Crohn's disease and Ulcerative Colitis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Stelara therapy

Indication	Dose
Plaque Psoriasis & Psoriatic Arthritis with co-existent moderate-severe Plaque Psoriasis	**Adult Subcutaneous Loading Dose:** • < 100 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later • > 100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later **Adult Subcutaneous Maintenance Dose:** • < 100 kg: 45 mg every 12 weeks • > 100 kg: 90 mg every 12 weeks **Pediatric Subcutaneous Loading Dose:** • < 60 kg: 0.75 mg/kg at weeks 0 & 4, then begin maintenance dosing 12 weeks later • 60–100 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later • > 100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later **Pediatric Subcutaneous Maintenance Dose:** • < 60 kg: 0.75 mg/kg every 12 weeks • 60–100 kg: 45 mg every 12 weeks • > 100 kg: 90 mg every 12 weeks
Psoriatic Arthritis	**Subcutaneous Loading Dose:** • 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later **Subcutaneous Maintenance Dose:** • 45 mg every 12 weeks
Crohn's Disease & Ulcerative Colitis	**Intravenous Induction Dose (one-time only):** • ≤ 55 kg: 260 mg • > 55 kg to 85 kg: 390 mg • > 85 kg: 520 mg **Subcutaneous Maintenance Dose:** • 90 mg given 8 weeks after the initial IV dose, then every 8 weeks thereafter

Max syringes (per dose and over time):

Indication	Max # syringes to build in FirstTrax℠	Per # days*
Plaque Psoriasis & Psoriatic Arthritis with co-existent moderate-severe Plaque Psoriasis	**Loading Dose**: 2 syringes entered as 1 ml (select dose based on weight above)	28
	Maintenance Dose: 1 syringe (0.5 mL) (select dose based on weight above)	84
Psoriatic Arthritis	**Loading Dose**: 2 syringes of 45mg entered as 1 mL	28
	Maintenance Dose: 1 syringe of the 45 mg, entered as 0.5 mL	84
Crohn's Disease & Ulcerative Colitis	**One-time IV dose** Enter in number of vials based on weight above (billed in mL, 26 mL per vial)	28
	Maintenance Dose: 1 syringe of the 90 mg (0.5 mL)	56

TALTZ (IXEKIZUMAB) (EFFECTIVE DATE 9/01/2021)

TALTZ (IXEKIZUMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

INDICATIONS

- **Plaque Psoriasis** Indicated for the treatment of patients 6 years of age and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis.
- **Ankylosing Spondylitis** Indicated for the treatment of adult patients with active ankylosing spondylitis.
- **Non-radiographic Axial Spondyloarthritis** Indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

Drug Name:	Taltz (ixekizumab)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

TALTZ (IXEKIZUMAB) *(CONTINUED)*

Criteria:

- Diagnosis of moderate to severe plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist; **AND**
- **ONE** of the following:
  - Trial and failure, contraindication, or intolerance to **ONE** of the following:
    - Cimzia (certolizumab pegol)
    - Humira (adalimumab)
    - Skyrizi (risankizumab)
    - Stelara (ustekinumab)
    - Tremfya (guselkumab)

OR

- For continuation of prior Taltz therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Drug Name:	Taltz (ixekizumab)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to therapy as evidenced by **ONE** of the following [2]:
  - Reduction in body surface area (BSA) involvement from baseline
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline

TALTZ (IXEKIZUMAB) *(CONTINUED)*

Drug Name:	Taltz (ixekizumab)
Diagnosis:	Psoriatic Arthritis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active psoriatic arthritis; **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist
- **ONE** of the following:
  - Trial and failure, contraindication, or intolerance to **ONE** of the following:
    - Cimzia (certolizumab pegol)
    - Humira (adalimumab)
    - Simponi (golimumab)
    - Stelara (ustekinumab)
    - Tremfya (guselkumab); **OR**
  - For continuation of prior Taltz therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Drug Name:	Taltz (ixekizumab)
Diagnosis:	Psoriatic Arthritis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to therapy.

TALTZ (IXEKIZUMAB) *(CONTINUED)*

Drug Name:	Taltz (ixekizumab)
Diagnosis:	Ankylosing Spondylitis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active ankylosing spondylitis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **two** non-steroidal anti-inflammatory drugs (NSAIDs) (e.g. diclofenac, ibuprofen, indomethacin, meloxicam, naproxen); **AND**
- **One** of the following:
  - Trial and failure, contraindication, intolerance to **ONE** of the following, or attestation demonstrating a trial may be inappropriate*:
    - Cimzia (certolizumab pegol)
    - Humira (adalimumab)
    - Simponi (golimumab); **AND**

OR

- For continuation of prior Taltz therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Notes:

*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

Drug Name:	Taltz (ixekizumab)
Diagnosis:	Ankylosing Spondylitis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to therapy.

TALTZ (IXEKIZUMAB) *(CONTINUED)*

Drug Name:	Taltz (ixekizumab)
Diagnosis:	Non-radiographic Axial Spondyloarthritis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active non-radiographic axial spondyloarthritis; **AND**
- Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1-2]; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **two** non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen) [2]; **AND**
- **One** of the following:
  - Trial and failure, contraindication, intolerance to Cimzia (certolizumab pegol); **OR**
  - For continuation of prior Taltz therapy for STANDARD, ENHANCED, and PRECISION only. No grandfathering allowed for PRECISION PLUS and CORE.

Drug Name:	Taltz (ixekizumab)
Diagnosis:	Non-radiographic Axial Spondyloarthritis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to therapy

DOSAGE AND ADMINISTRATION FOR ALL FORMULARIES

Indication	Dose
Plaque Psoriasis	**Adults:** Administer 160 mg (two 80 mg injections) subcutaneously at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks thereafter **Pediatrics age 6 to <18 years of age:** • Weight > 50 kg: Administer 160 mg (two 80 mg injections) subcutaneously at Week 0, followed by 80 mg every 4 weeks thereafter • Weight 25 to 50 kg: Administer 80 mg subcutaneously at Week 0, followed by 40 mg every 4 weeks thereafter • Weight < 25 kg: Administer 40 mg subcutaneously at Week 0, followed by 20 mg every 4 weeks thereafter
Psoriatic Arthritis	Administer 160 mg (two 80 mg injections) subcutaneously at Week 0, followed by 80 mg every 4 weeks • *Note: For psoriatic arthritis patients, with coexistent moderate-to-severe plaque psoriasis, use the dosing regimen for plaque psoriasis.*
Ankylosing Spondylitis	• Administer 160 mg (two 80 mg injections) subcutaneously at Week 0, followed by 80 mg every 4 weeks thereafter
Non-Radiographic Axial Spondyloarthritis	• Administer 80 mg subcutaneously every 4 weeks

Max syringes (per dose and over time):

Indication	Max # syringes to build in FirstTrax℠	Per # days*
Plaque Psoriasis	**Loading Dose ADULTS**: 8 syringes entered as 8 syringes	84
	Maintenance Dose ADULTS: 1 syringe	28
	Loading Dose PEDIATRICS: (Based on weight above) Weight > 50kg: 2 syringes Weight 25 to 50 kg: 1 syringe Weight < 25 kg: 1 syringe	28
	Maintenance Dose PEDIATRICS: 1 syringe	28
Psoriatic Arthritis	**Loading Dose**: 2 syringes **Maintenance Dose:** 1 syringe	28 28
Ankylosing Spondylitis	**Loading Dose**: 2 syringes	28
	Maintenance Dose: 1 syringe	28
Non-Radiographic Axial Spondyloarthritis	**1 syringe**	28

TREMFYA (GUSELKUMAB) (EFFECTIVE DATE 05/01/2021)

TREMFYA (GUSELKUMAB) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Indications

- **Plaque Psoriasis** Indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis.

Drug Name:	Tremfya (guselkumab)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderate to severe plaque psoriasis; **AND**
- Prescribed by or in consultation with a dermatologist.

Drug Name:	Tremfya (guselkumab)
Diagnosis:	Plaque Psoriasis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Tremfya (guselkumab) therapy as evidenced by ONE of the following:
  - Reduction in the body surface area (BSA) involvement from baseline
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Drug Name:	Tremfya (guselkumab)
Diagnosis:	Psoriatic Arthritis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active psoriatic arthritis (PsA) [1,3]; **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist

Drug Name:	Tremfya (guselkumab)
Diagnosis:	Psoriatic Arthritis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Tremfya (guselkumab) therapy

XELJANZ (TOFACITINIB), XELJANZ XR (TOFACITINIB EXTENDED-RELEASE) (EFFECTIVE DATE 11/01/2021)

XELJANZ (TOFACITINIB), XELJANZ XR (TOFACITINIB EXTENDED-RELEASE) INDICATIONS (NOTE SPECIFIC POPULATIONS APPROVED)

Drug Name: Xeljanz (tofacitinib) tablets, Xeljanz XR (tofacitinib extended release) tablets

Indications

- **Rheumatoid Arthritis (RA)** Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.
- **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs). Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.
- **Ulcerative Colitis (UC)** Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC), who have an inadequate response or who are intolerant to TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biological DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Drug Name: Xeljanz (tofacitinib) tablets and oral solution

- **Polyarticular Course Juvenile Idiopathic Arthritis** Indicated for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older. Limitations of Use: Use of Xeljanz in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Product Name:	Xeljanz tablets or Xeljanz XR tablets
Diagnosis:	Rheumatoid Arthritis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active rheumatoid arthritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to **ONE** nonbiologic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate [Rheumatrex/Trexall], Arava [leflunomide], Azulfidine [sulfasalazine]); **AND**
- Patient is not receiving Xeljanz/Xeljanz XR in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)* [1,5].

Notes: *Xeljanz/Xeljanz XR may be used with concomitant methotrexate and/or low stable dosages of corticosteroids (equivalent to 10 mg or less of prednisone daily).

XELJANZ (TOFACITINIB), XELJANZ XR (TOFACITINIB EXTENDED-RELEASE) *(CONTINUED)*

Drug Name:	Xeljanz tablets or Xeljanz XR tablets
Diagnosis:	Rheumatoid Arthritis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Xeljanz/Xeljanz XR therapy; **AND**
- Patient is not receiving Xeljanz/Xeljanz XR in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)* [1, 5].

Notes: *Xeljanz/Xeljanz XR may be used with concomitant methotrexate and/or low stable dosages of corticosteroids (equivalent to 10 mg or less of prednisone daily).

Drug Name:	Xeljanz tablets and oral solution
Diagnosis:	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active polyarticular course juvenile idiopathic arthritis; **AND**
- Prescribed by or in consultation with a rheumatologist; **AND**
- Trial and failure, contraindication, or intolerance to one of the following nonbiologic disease-modifying antirheumatic drugs (DMARDs): [6]
  - Arava (leflunomide)
  - methotrexate (Rheumatrex/Trexall)

AND

- One of the following:
  - Trial and failure, contraindication, or intolerance to Humira (adalimumab), or attestation demonstrating a trial may be inappropriate**; **OR**
  - Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR F40.2 for specific phobia diagnostic criteria [3]); **OR**
  - For continuation of prior Xeljanz therapy*

AND

- Patient is not receiving Xeljanz in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)* [1, 5]

*** Notes:** Xeljanz may be used with concomitant methotrexate and/or low stable dosages of corticosteroids (equivalent to 10 mg or less of prednisone daily). **Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

XELJANZ (TOFACITINIB), XELJANZ XR (TOFACITINIB EXTENDED-RELEASE) *(CONTINUED)*

Drug Name:	Xeljanz tablets and oral solution
Diagnosis:	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to therapy; **AND**
- Patient is not receiving Xeljanz in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine) [1, 5]

Notes: *Xeljanz may be used with concomitant methotrexate and/or low stable dosages of corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:	Xeljanz tablets or Xeljanz XR tablets
Diagnosis:	Psoriatic Arthritis
Approval Length:	12 months
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of active psoriatic arthritis (PsA); **AND**
- Prescribed by or in consultation with one of the following:
  - Dermatologist
  - Rheumatologist**; AND**
- **ONE** of the following:
  - Trial and failure, contraindication, or intolerance to **TWO** of the following [2]:
    - Cimzia (certolizumab pegol)
    - Humira (adalimumab)
    - Simponi (golimumab)
    - Stelara (ustekinumab)
    - Tremfya (guselkumab); **OR**
  - Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR F40.2 for specific phobia diagnostic criteria [3]); **OR**
  - For continuation of prior Xeljanz/Xeljanz XR therapy *; **AND**
- Patient is not receiving Xeljanz/Xeljanz XR in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)* [1,5].

* **Notes**: Xeljanz/Xeljanz XR may be used with concomitant methotrexate and/or low stable dosages of corticosteroids (equivalent to 10 mg or less of prednisone daily).

XELJANZ (TOFACITINIB), XELJANZ XR (TOFACITINIB EXTENDED-RELEASE) *(CONTINUED)*

Drug Name:	Xeljanz tablets or Xeljanz XR tablets
Diagnosis:	Psoriatic Arthritis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Xeljanz/Xeljanz XR therapy; **AND**
- Patient is not receiving Xeljanz/Xeljanz XR in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)*[1,5].

Notes: *Xeljanz/Xeljanz XR may be used with concomitant methotrexate and/or low stable dosages of corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:	Xeljanz tablets or Xeljanz XR tablets
Diagnosis:	Ulcerative Colitis
Approval Length:	4 months [A]
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of moderately to severely active ulcerative colitis; **AND**
- Trial and failure, contraindication, or intolerance to **ONE** of the following conventional therapies:
  - 6-mercaptopurine (Purinethol)
  - Aminosalicylate [e.g., mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)]
  - Azathioprine (Imuran)
  - Corticosteroids (e.g., prednisone, methylprednisolone)**; AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- **ONE** of the following:
  - Trial and failure, contraindication, or intolerance to **TWO** of the following, or attestation demonstrating that a trial may be inappropriate**:
    - Humira (adalimumab)
    - Simponi (golimumab)
    - Stelara (ustekinumab); **OR**
  - Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR F40.2 for specific phobia diagnostic criteria [3])**; OR**
  - For continuation of prior Xeljanz/Xeljanz XR therapy *; **AND**
- Patient is not receiving Xeljanz/Xeljanz XR in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)* [1,5].

Notes:

- * Xeljanz/Xeljanz XR may be used with concomitant methotrexate and/or low stable dosages of corticosteroids (equivalent to 10 mg or less of prednisone daily).

. ** Includes attestation that the patient has failed to respond to the TNF inhibitor mechanism of action in the past and should not be made to try a second TNF inhibitor. In this case, only a single step through a preferred agent is required.

XELJANZ (TOFACITINIB), XELJANZ XR (TOFACITINIB EXTENDED-RELEASE) *(CONTINUED)*

Drug Name:	Xeljanz tablets or Xeljanz XR tablets
Diagnosis:	Ulcerative Colitis
Approval Length:	12 months
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to Xeljanz/Xeljanz XR therapy; **AND**
- Patient is not receiving Xeljanz/Xeljanz XR in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)* [1,5].

Notes: *Xeljanz/Xeljanz XR may be used with concomitant methotrexate and/or low stable dosages of corticosteroids (equivalent to 10 mg or less of prednisone daily).

IMMUNOSUPPRESSANTS

Length of Authorization:	1 Year
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

ZORTRESS

- Prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant, administered in combination with basiliximab induction and concurrently with reduced doses of cyclosporine and corticosteroids. Therapeutic drug monitoring of everolimus and cyclosporine is recommended for all patients.
- Prophylaxis of allograft rejection in adult patients receiving a liver transplant, administered no earlier than 30 days post-transplant concurrently in combination with reduced doses of tacrolimus and with corticosteroids. Therapeutic drug monitoring of everolimus and tacrolimus is recommended for all patients receiving these products.

BENLYSTA

Diagnosis of **Systemic Lupus Erythematosus (SLE)**

- Patient is 5 years of age or older (IV) or patient is 18 years of age or older (SQ); **AND**
- Patient has a confirmed diagnosis of SLE with at least 4 diagnostic features (see list of diagnostic SLE criteria below)***** one of which must include a positive autoantibody test (e.g., anti-nuclear antibody [ANA] greater than laboratory reference range and/or anti-double-stranded DNA [anti-dsDNA] greater than 2 fold the laboratory reference range if tested by ELISA); **AND**
- Patient has failed to respond adequately to at least 2 standard therapies such as anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives (excluding intravenous cyclophosphamide); **AND**
- Patient has one of the following:
  - Safety of Estrogen in Lupus National Assessment – Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of 6-12
  - ≥ 2 British Isles Lupus Assessment Group (BILAG) B organ domain scores; **AND**
- Patient must not have an active infection; **AND**
- Patient has not received a live vaccine within 30 days before starting or concurrently with Benlysta; **AND**
- Will not be used in combination with voclosporin; **AND**
- Will be used in combination with standard therapy (e.g., anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives); **AND**
- Patient does not have any of the following exclusion criteria:
  - Severe active central nervous system lupus
  - Individuals who are on other biologics

Diagnosis of **Lupus Nephritis**

- Patient is at least 18 years of age; **AND**
- Patient has active lupus nephritis Class III, IV, or V as confirmed by renal biopsy; **AND**
- Patient has a confirmed diagnosis of SLE with at least 4 diagnostic features (see list of diagnostic SLE criteria below)***** one of which must include a positive autoantibody test (e.g., anti-nuclear antibody [ANA] greater than laboratory reference range and/or anti-double-stranded DNA [anti-dsDNA] greater than 2 fold the laboratory reference range if tested by ELISA); **AND**
- Patient has failed to respond adequately to standard therapies including corticosteroids AND either cyclophosphamide or mycophenolate mofetil; **AND**
- Baseline measurement of one or more of the following: urine protein/creatinine ratio (uPCR), estimated glomerular filtration rate (eGFR), or urine protein; **AND**
- Patient must not have an active infection; **AND**
- Patient has not received a live vaccine within 30 days before starting or concurrently with Benlysta; **AND**
- Will not be used in combination with voclosporin; **AND**
- Will be used in combination with standard therapy (e.g., anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives); **AND**
- Patient does not have any of the following exclusion criteria:
  - Severe active central nervous system lupus
  - Individuals who are on other biologics

*Systemic Lupus Erythematosus Diagnostic Criteria
Patient must have at least 4 out of 11 diagnostic SLE features: 1. Malar rash 2. Discoid rash 3. Photosensitivity 4. Oral ulcers 5. Nonerosive arthritis (involving 2 or more peripheral joints) 6. Pleuritis/pericarditis • Pleuritis - history of pleuritic pain or rubbing heard by a physician or evidence of pleural effusion • Pericarditis - documented by electrocardiogram or rubbing heard by a physician or evidence of pericardial effusion 7. Renal disorder • Persistent proteinuria > 0.5 grams/day or > 3+ on urine dipstick • Cellular casts (red cell, hemoglobin, granular, tubular, or mixed) 8. Seizures/psychosis 9. Hematologic disorder • Hemolytic anemia with reticulocytosis • Leukopenia < 4,000/mm^3 on ≥ 2 occasions • Lymphopenia < 1,500/mm^3 on ≥ 2 occasions • Thrombocytopenia < 100,000/mm^3 in the absence of offending drugs 10. Immunologic disorder • Presence of anti-Sm or antiphospholipid antibodies • Presence of anti-double-stranded DNA [anti-dsDNA] greater than 2 fold the laboratory reference range if tested by ELISA 11. Positive anti-nuclear antibody [ANA] greater than laboratory reference range

CLINICAL CRITERIA FOR RENEWAL (BENLYSTA)

Authorizations can be renewed based on the following criteria:

- Absence of unacceptable toxicity from the drug (e.g., depression, suicidal thoughts, serious infections, signs or symptoms of progressive multifocal leukoencephalopathy [PML], malignancy, severe hypersensitivity reaction/anaphylaxis, serious infusion reactions)

Systemic Lupus Erythematosus (SLE)

- Adequate documentation of disease stability and/or improvement as indicated by the following when compared to baseline:
  - Improvement in the SELENA-SLEDAI score of ≥ 4 points ; **OR**
  - No new BILAG-A organ domain score or 2 new BILAG-B organ domain scores; **OR**
  - No worsening (< 0.30-point increase) in Physician's Global Assessment (PGA) score; **OR**
  - Seroconverted (negative)

Lupus Nephritis

- Adequate documentation of disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline:
  - Urine protein/creatinine ratio (uPCR); **OR**
  - Estimated glomerular filtration rate (eGFR); **OR**
  - Urine protein

PURIXAN* (6-MERCAPTOPURINE)

- Diagnosis of acute lymphatic leukemia (ALL); **OR**
- If requesting for Off-label use, use oncology off-label guidelines; **AND**
- **One** of the following:
  - History of contraindication or intolerance to generic mercaptopurine tablets; **OR**
  - Patient is unable to swallow tablets.

CLINICAL CRITERIA FOR RENEWAL (PURIXAN)

- Patient does not show evidence of progressive disease while on Purixan therapy
- Approval length: 12 months

ASTAGRAF XL

- Diagnosis of prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants; **AND**
- Must have tried tacrolimus immediate release formulations

IMPAVIDO (MILTEFOSINE)

Length of Authorization:	28 days, not renewable
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR APPROVAL

- Patient is ≥ 12 years of age; **AND**
- Patient weighs ≥ 30 kg; **AND**
- Patient has a diagnosis of one of the following:
  - Visceral leishmaniasis (VL) due to *Leishmania donovani*; **OR**
  - Cutaneous leishmaniasis (CL) due to *Leishmania braziliensis*, *Leishmania guyanensis*, and *Leishmania panamensis*; **OR**
  - Mucosal leishmaniasis (ML) due to *Leishmania braziliensis*; **AND**
- Prescribed by or in consultation with an infectious disease specialist; **AND**
- Dosing matches that of manufacturer-recommended weight-based dosing; **AND**
- Patient is not pregnant, as documented by a negative pregnancy test within 7 days or patient is unable to be pregnant; **AND**
- If patient is of reproductive potential; patient has effective contraception for use during treatment and for 5 months following treatment completion; **AND**
- If patient is breastfeeding, patient has been advised not to breastfeed during treatment and for 5 months following treatment completion; **AND**
- Patient does not have Sjögren-Larsson-Syndrome; **AND**
- Patient does not have documented or known hypersensitivity to miltefosine or any excipients within Impavido; **AND**
- Patient does not have renal impairment or serum creatinine or blood urea nitrogen (BUN) levels ≥ 1.5 times the upper limit of normal; **AND**
- Patient does not have hepatic impairment or alanine aminotransferase (ALT) or aspartate aminotransferase (AST) ≥ 3 times the upper limit of normal or bilirubin levels ≥ 2 times the upper limit of normal; **AND**
- Prescriber attestation that the following parameters will be monitored; **AND**
  - Serum creatinine will be monitored at least weekly during therapy and for 4 weeks following treatment completion; **AND**
  - Liver transaminases (e.g., alanine aminotransferase [ALT], aspartate aminotransferase [AST]) and bilirubin; **AND**
  - If diagnosis of visceral leishmaniasis, platelet count; **AND**
- Prescriber attestation that patient has been instructed to use an alternative method of contraception if diarrhea and/or vomiting occur; **AND**
- Prescriber attestation that patient has been instructed to take miltefosine at meals (with food); **AND**
- Prescriber attestation that the risks of infertility have been discussed with the patient; **AND**
- Prescriber attestation that patient has been counseled to encourage fluid intake and other strategies to avoid volume depletion; **AND**
- Patient meets the following diagnosis-specific criteria:
  - If patient has a diagnosis of cutaneous leishmaniasis (CL), the patient meets the following criteria:
    - Patient has failed* local therapy (e.g., heat, cryotherapy, topical ointments/creams, intralesional injections, phototherapy, laser therapy); **AND**
    - Patient has failure* of, intolerance to, or a contraindication to use of a systemic azole antifungal at appropriate doses and for appropriate durations, as recommended by clinical guidelines (e.g., fluconazole, ketoconazole); **AND**

CLINICAL CRITERIA FOR APPROVAL *(CONTINUED)*

- If not immunocompromised, patient has healing or recently healed lesions cause by an increased ML-risk species or, if species unknown, CL was acquired in an increased ML-risk region (as attested by prescriber) and prescriber attests watchful waiting is not clinically appropriate; **OR**
- Patient is immunocompromised and prescriber attests that systemic treatment is clinically indicated; **OR**

– If patient has a diagnosis of mucosal leishmaniasis (ML), the patient meets the following criteria:
- Patient does not require inpatient monitoring (e.g. patient does not have laryngeal/pharyngeal disease and increased risk for respiratory obstruction based on otolaryngologic/radiologic examination); **AND**
- If preferred, patient has failure of, intolerance to, or a contraindication to use of an alternative agent (e.g., amphotericin B deoxycholate, liposomal amphotericin B, sodium stibogluconate, meglumine antimoniate, and pentamidine; some of which may require a sponsored Investigational New Drug [IND] protocol); **OR**

– If patient has a diagnosis of visceral leishmaniasis (VL), the patient meets the following criterial:
- VL is caused by *L. donovani* (acquired in the Indian subcontinent); **AND**
- Patient has failure of, intolerance to, or a contraindication to use of liposomal amphotericin B at the FDA-approved dosage range as a minimum, based on immune function status.

* Failure of cutaneous leishmaniasis treatment can be defined as incomplete healing by 3 months after completion of the treatment course. By 4 to 6 weeks following treatment, the lesion should have decreased in size by > 50% and be re-epithelializing, and there should not be any new lesions. Generally, healing occurs approximately 3 months following treatment. Monitoring of lesions should occur for 6 to 12 months for therapeutic failure.

INBRIJA® (LEVODOPA INHALATION POWDER)

Length of Authorization:	Initial: 6 months. Renewal: 1 Year.
Initiative:	SPC: Parkinson's Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is ≥ 18 years of age; **AND**
- Patient has a diagnosis of advanced Parkinson's disease; **AND**
- Patient experiences motor fluctuations ("OFF" episodes) at least 2 hours during the waking day on average (excluding early morning "OFF" time); **AND**
- Patient is currently on stable anti-Parkinson's medication regimen; **AND**
- Patient is receiving concomitant levodopa-containing medication at least 3 times per day while awake; **AND**
- Patient's current total daily levodopa dose < 1,600 mg/day; **AND**
- Patient experienced inadequate response to or has a contraindication/intolerance to ≥ 2 difference classes of anti-Parkinson's agents for controlling "OFF" symptoms (e.g., dopamine agonists, monoamine oxidase-B [MOA-B] inhibitors, catechol-O-methyltransferase [COMT] inhibitors); **AND**
- Patient does not have any of the following comorbid conditions:
  - Major psychiatric disorder; **OR**
  - Chronic lung disease (e.g., asthma, chronic obstructive pulmonary disease [COPD]); **AND**
- Patient has not taken a non-selective monoamine oxidase inhibitor (MAOI) (e.g., phenelzine and tranylcypromine) currently or in the previous 2 weeks; **AND**
- Patient is able to perform a spirometry maneuver in the "ON" and "OFF" states; **AND**
- The medication is prescribed by or in consultation with a neurologist.

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet approval criteria above; **AND**
- Patient demonstrates disease response compared to pre-treatment baseline as evidenced by improvement in average number of "OFF" episodes per day; **AND**
- Patient has demonstrated absence of unacceptable toxicity from the drug (e.g., falling asleep during activities of daily living, hallucinations, impulse control/compulsive behaviors, dyskinesia exacerbation).

INCRELEX® (MECASERMIN)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Growth Hormone (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Growth Failure with Primary IGFD** (includes patients with mutations of the GH receptor, post-GHR signaling pathway, and IGF-1 gene defects)

- Patient's age is between 2 and 18 years; **AND**
- Patient's bone epiphyses are **not** closed; **AND**
- Patient does not have an active or suspected benign or malignant neoplasia, history of malignancy, or any condition that increases the risk for malignancy; **AND**
- Other causes of secondary forms of IGF-1 deficiency have been ruled out (e.g., GH deficiency, malnutrition, hypothyroidism, chronic treatment with pharmacologic doses of anti-inflammatory corticosteroids, etc.); **AND**
- Patient has had an ophthalmic funduscopic examination prior to the start of therapy and periodically during the course of treatment; **AND**
- Patient has severe primary insulin-like growth factor-1 deficiency; **AND**
- Height standard deviation score is less than or equal to -3.0 for age and sex; **AND**
- Basal IGF-1 standard deviation score is less than or equal to -3.0 for age and sex; **AND**
- Normal or elevated growth hormone (stimulated: greater than 10 ng/mL; unstimulated: greater than 5 ng/mL)

Diagnosis of **Growth Failure with GH gene deletion**

- Patient's age is between 2 and 18 years; **AND**
- Patient's bone epiphyses are **not** closed; **AND**
- Patient does not have an active or suspected benign or malignant neoplasia, history of malignancy, or any condition that increases the risk for malignancy; **AND**
- Other causes of secondary forms of IGF-1 deficiency have been ruled out (e.g., GH deficiency, malnutrition, hypothyroidism, chronic treatment with pharmacologic doses of anti-inflammatory corticosteroids, etc.); **AND**
- Patient has had an ophthalmic funduscopic examination prior to the start of therapy and periodically during the course of treatment; **AND**
- Patient has growth hormone gene deletion; **AND**
- Patient has developed neutralized antibodies to growth hormone

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples include the following: benign and malignant neoplasia; hypersensitivity/allergic reactions; intracranial hypertension; lymphoid tissue hypertrophy; progression of scoliosis; Slipped Capital Femoral Epiphysis (new onset limp, hip/knee pain); severe hypoglycemia; gasping syndrome; etc.; **AND**
- Disease response as evidenced by the child's height velocity greater than 2 cm/year over the previous untreated rate; **AND**
- Child has not reached the 25th percentile of normal adult height for sex

INFUGEM™ (GEMCITABINE)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**

- Patient is at least 18 years of age; **AND**
- Gemcitabine is not obtainable (in any dosage strength) as confirmed by the FDA Drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; **AND**
- Patient has metastatic disease; **AND**
- Used in combination with paclitaxel as first-line treatment; **AND**
- Patients has previous failure on an anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years of age; **AND**
- Gemcitabine is not obtainable (in any dosage strength) as confirmed by the FDA Drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; **AND**
- Patient has unresectable, locally advanced (Stage IIIA or IIIB), or metastatic (Stage IV) disease**; AND**
- Used in combination with cisplatin as first-line treatment

Diagnosis of **Ovarian Cancer**

- Patient is at least 18 years of age; **AND**
- Gemcitabine is not obtainable (in any dosage strength) as confirmed by the FDA Drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; **AND**
- Patient has advanced disease that has relapsed at least 6 months after completion of a platinum-based regimen**; AND**
- Used in combination with carboplatin in patients who are platinum-sensitive

Diagnosis of **Pancreatic Adenocarcinoma**

- Patient is at least 18 years of age; **AND**
- Gemcitabine is not obtainable (in any dosage strength) as confirmed by the FDA Drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; **AND**
- Patient has locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) disease; **AND**
- Used as first-line treatment; **AND**
- Patient has received previous treatment with fluorouracil

Infugem™ is a ready-to-use formulation of gemcitabine approved via 505(b)(2) NDA referencing the lyophilized formulation (Gemzar). This product is nearly identical to the listed product, Gemzar, when the listed product is reconstituted and diluted for administration. No new clinical or nonclinical data were provided with this submission, as no studies were conducted for this 505(b)(2) application.[2]

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe myelosuppression, pulmonary toxicity/respiratory failure (e.g., interstitial pneumonitis, pulmonary fibrosis, pulmonary edema, and adult respiratory distress syndrome [ARDS], etc.), hemolytic-uremic syndrome (HUS), hepatotoxicity, exacerbation of radiation therapy toxicity, capillary leak syndrome (CLS), posterior reversible encephalopathy syndrome (PRES), etc.

INGREZZA® (VALBENAZINE)

Length of Authorization:	12 Months
Initiative:	SPC: Miscellaneous PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Tardive dyskinesia**

- Patient is ≥ 18 years of age; **AND**
- Documentation that AIMS test has been completed (i.e., score or copy of AIMS assessment); **AND**
- Prescribed by or in consultation with a neurologist or psychiatrist (or other mental health provider), provided patient has reasonable access; **AND**
- Documentation of claims history of current or former chronic patient use of a dopamine antagonist (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine)
- Deny if the patient is meeting any of the following:
  - Concurrent use of MAO inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine) or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's Wort); **OR**
  - Use for other movement disorders that are not TD (i.e., chorea, Parkinson's disease)

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria defined for initial approval; **AND**
- Documentation of improvement in TD symptoms

INHALED ANTICHOLINERGICS

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

BEVESPI AEROSPHERE

- Patient has a diagnosis of COPD; AND
- Patient is 18 years of age or older; AND
- Patient must have rescue therapy on file (i.e., Proair, Ventolin, Proventil, Xopenex); AND
- Patient has tried BOTH Anoro Ellipta and Stiolto Respimat
- Patient must not meet any of the following:
  - Be using the medication for asthma; OR
  - Have acutely deteriorating COPD; OR
  - Be using the medication for relief of acute symptoms; OR
  - Be using other LABAs; OR
  - Be using other long-acting anticholinergic agents.

LONHALA MAGNAIR (GLYCOPYRROLATE)

- Patient has a diagnosis of COPD; **AND**
- Patient is 18 years of age or older; **AND**
- Patient does not have history of or current unstable CV disease and/or long QT syndrome. (Magellan Rx Management's recommendation is not to start therapy in these patients; however, decision is up to prescriber. Please document response.)
- Patient has tried a LAMA agent within the last 180 days; OR
- Prescriber should indicate why patient cannot use alternatives; ex. due to technique/delivery mechanism
- Re-Authorization Duration: 1 year
- **Criteria:** Must meet criteria above

SEEBRI NEOHALER

- Patient has a diagnosis of COPD; AND
- Patient is 18 years of age or older; AND
- **Patient has tried** Spiriva

INCRUSE ELLIPTA, TUDORZA

- The patient has tried Spiriva

YUPELRI

- Patient must be ≥ 18 years of age; **AND**
- Patient has a diagnosis of COPD; **AND**
- Patient is a candidate for long-acting anticholinergic treatment based on severity (e.g., GOLD class B-D); **AND**
- Patient is not prescribed other inhaled long-acting anticholinergic agents; **AND**
- Have had an inadequate response, contraindication, or intolerance to one preferred long-acting anticholinergic agent.

STANDARD FORMULARY CRITERIA (*CONTINUED*)

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet above criteria; **AND**
- Patient symptoms are clinically improving, as documented by provider; **AND;**
- Patient demonstrates continued compliance, based on fill history (not using prn); **AND**
- Prescriber documents that nebulized therapy continues to be required.

PRECISION/PLUS FORMULARY CRITERIA

CORE FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

LONHALA MAGNAIR (GLYCOPYRROLATE)

- Patient has a diagnosis of COPD; **AND**
- Patient is 18 or older; **AND**
- Patient does not have history of or current unstable CV disease and/or long QT syndrome. (Magellan Rx Management's recommendation is not to start therapy in these patients; however, decision is up to prescriber. Please document response.)
- Patient has tried a LAMA agent within the last 180 days; **OR**
- Prescriber should indicate why patient cannot use alternatives; ex. due to technique/delivery mechanism
- Re-Authorization Duration: 1 year
- **Criteria:** Must meet criteria above

ENHANCED FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75 – GSN)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

LONHALA MAGNAIR (GLYCOPYRROLATE)

- Patient has a diagnosis of COPD; **AND**
- Patient is 18 or older; **AND**
- Patient does not have history of or current unstable CV disease and/or long QT syndrome. (Magellan Rx Management's recommendation is not to start therapy in these patients; however, decision is up to prescriber. Please document response.); **AND**
- Patient has tried Anoro Ellipta OR Stiolto Respimat; AND
- Patient has tried a LAMA agent within the last 180 days; **OR**
- Prescriber should indicate why patient cannot use alternatives; ex. due to technique/delivery mechanism
- Re-Authorization Duration: 1 year
- **Criteria:** Must meet criteria above

SEEBRI NEOHALER

- Patient has a diagnosis of COPD; AND
- Patient is 18 or older; AND
- **Patient has tried** BOTH Incruse Ellipta and Spiriva

TUDORZA

- The patient has tried both of the following: Incruse Ellipta and Spiriva

YUPELRI

- Patient must be ≥ 18 years of age; **AND**
- Patient has a diagnosis of COPD; **AND**
- Patient is a candidate for long-acting anticholinergic treatment based on severity (e.g., GOLD class B-D); **AND**
- Patient is not prescribed other inhaled long-acting anticholinergic agents; **AND**
- Have had an inadequate response, contraindication, or intolerance to Anoro Ellipta OR Stiolto Respimat

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet above criteria; **AND**
- Patient symptoms are clinically improving, as documented by provider; **AND;**
- Patient demonstrates continued compliance, based on fill history (not using prn); **AND**
- Prescriber documents that nebulized therapy continues to be required

INHALED BETA AGONISTS

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Beta-Adrenergic Agents (IE 2462 / NCPDP 75, 50081, 2193)

STEP CRITERIA (NO GRANDFATHERING)

ARCAPTA®

Patient has trialed and failed any TWO of the following:

- Advair® HFA/Diskus, generic fluticasone/salmeterol (e.g., generic Diskus, generic RespiClick, Wixela™); **OR**
- Breo Ellipta®; **OR**
- Serevent®; **OR**
- Symbicort®; **OR**
- Striverdi®

CLINICAL CRITERIA – ALBUTEROL HFA BY PRASCO, PROAIR HFA/DIGIHALER/RESPICLICK, PROVENTIL HFA, VENTOLIN HFA, LEVALBUTEROL HFA AND XOPENEX HFA (NO GRANDFATHERING)

Trial and failure of **TWO** of the following: albuterol HFA by Cipla USA, Civica, Lupin, Par Pharm, Perrigo, Sandoz, or Teva

PRECISION/PLUS FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Beta-Adrenergic Agents (IE 2462 / NCPDP 75, 50081 and 2193)

STEP CRITERIA (NO GRANDFATHERING)

For precision excluded items on the precision exclusion list, follow the Precision Exception process as well as any drug specific criteria below.

ARCAPTA®

Patient has trialed and failed any TWO of the following:

- Advair® HFA/Diskus, generic fluticasone/salmeterol (e.g., generic Diskus, generic RespiClick, Wixela®); **OR**
- Breo Ellipta®; **OR**
- Serevent®; **OR**
- Symbicort®; **OR**
- Striverdi®

ENHANCED FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Beta-Adrenergic Agents (IE 2462 / NCPDP 75 – HICL, 50081, 2193)

STEP CRITERIA (NO GRANDFATHERING)

ARCAPTA®

Patient has trialed and failed any TWO of the following:

- Advair® HFA/Diskus, generic fluticasone/salmeterol (e.g., generic Diskus, generic RespiClick, Wixela™); **OR**
- Breo Ellipta®; **OR**
- Serevent®; **OR**
- Striverdi®; **OR**
- Symbicort®

CLINICAL CRITERIA – ALBUTEROL HFA BY PRASCO, PROAIR HFA/DIGIHALER/RESPICLICK, PROVENTIL HFA, VENTOLIN HFA, LEVALBUTEROL HFA AND XOPENEX HFA (NO GRANDFATHERING)

Trial and failure of **TWO** of the following: albuterol HFA by Cipla USA, Civica, Lupin, Par Pharm, Perrigo, Sandoz, or Teva

CORE FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Beta-Adrenergic Agents (IE 2462 / NCPDP 75 – HICL, 50081, 2193)

STEP CRITERIA (NO GRANDFATHERING)

ARCAPTA®

Patient has trialed and failed any TWO of the following:

- Breo Ellipta®; **OR**
- generic fluticasone/salmeterol (e.g., generic Diskus, generic RespiClick, Wixela™); **OR**
- Budesonide/formoterol; **OR**
- Striverdi®

INHALED BETA AGONISTS COMBINATIONS

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Beta-Adrenergic Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

GENERIC BUDESONIDE/FORMOTEROL

- Patient is 6 years of age or older with a diagnosis of asthma or patient has a diagnosis of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; **AND**
- At least 6 months use of the brand product (Symbicort) within the previous 365 days (document drug, duration, dose and date of use); **AND**
- Documentation provided stating the brand product (Symbicort) has not been effective; **AND**
- Justification provided for why the authorized generic (AG) is expected to provide benefit when the brand product (Symbicort) has not been shown to be effective

DULERA®

Diagnosis of **asthma, COPD, or any other reversible airway disease(s)**

- Patient has failed a trial of two of the following: Advair®, Breo Ellipta®, generic fluticasone/salmeterol (e.g., generic Diskus, generic RespiClick, Wixela®), Symbicort®

AIRDUO® RESPICLICK AND AIRDUO DIGIHALER

Diagnosis of **asthma**

- Patient must be 12 years of age or older; **AND**
- Patient has failed a trial of two of the following: Advair®, Breo Ellipta®, generic fluticasone/salmeterol (e.g., generic Diskus, generic RespiClick, Wixela®), Symbicort®

DUAKLIR® (NO GRANDFATHERING)

- Patient is ≥ 18 years old; **AND**
- Patient has a diagnosis of COPD; **AND**
- Patient is not using the medication for asthma or for acute relief of bronchospasm; **AND**
- Patient is not experiencing acutely deteriorating COPD; **AND**
- Patient has tried both Anoro™ Ellipta and Stiolto® Respimat

UTIBRON NEOHALER (NO GRANDFATHERING)

Diagnosis of COPD

- Patient is 18 or older; AND
- Patient has tried both Anoro™ Ellipta and Stiolto® Respimat

ENHANCED FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Beta-Adrenergic Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

GENERIC BUDESONIDE/FORMOTEROL

- Patient is 6 years of age or older with a diagnosis of asthma or patient has a diagnosis of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; **AND**
- At least 6 months use of the brand product (Symbicort) within the previous 365 days (document drug, duration, dose and date of use); **AND**
- Documentation provided stating that the brand product (Symbicort) has not been effective; **AND**
- Justification provided for why the authorized generic (AG) is expected to provide benefit when the brand product (Symbicort) has not been shown to be effective

DULERA®

Diagnosis of **asthma, COPD, or any other reversible airway disease(s)**

- Patient has failed a trial of two of the following: Advair®, Breo Ellipta®, generic fluticasone/salmeterol (e.g., generic Diskus, generic RespiClick, Wixela®), Symbicort®

AIRDUO® RESPICLICK

Diagnosis of **asthma**

- Patient must be 12 years of age or older; **AND**
- Patient has failed a trial of two of the following: Advair®, Breo Ellipta®, generic fluticasone/salmeterol (e.g., generic Diskus, generic RespiClick, Wixela®), Symbicort®

DUAKLIR® (NO GRANDFATHERING)

- Patient is ≥ 18 years old; **AND**
- Patient has a diagnosis of COPD; **AND**
- Patient is not using the medication for asthma or for acute relief of bronchospasm; **AND**
- Patient is not experiencing acutely deteriorating COPD; **AND**
- Patient has tried both Anoro™ Ellipta and Stiolto® Respimat

UTIBRON NEOHALER (NO GRANDFATHERING)

Diagnosis of COPD

- Patient is 18 or older; AND
- Patient has tried ALL of the following: Anoro™ Ellipta, Stiolto® Respimat, and Bevespi

INHALED GLUCOCORTICOIDS

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Beta-Adrenergic Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

ASMANEX, ALVESCO, OR ARMONAIR RESPICLICK/DIGIHALER

- May be approved if the patient has had a trial and failure of **two** of the following: Arnuity Ellipta, Flovent, Qvar, Qvar RediHaler or Pulmicort Flexhaler

XHANCE

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of nasal polyps; **AND**
- The patient has tried and failed generic mometasone nasal spray

AZELASTINE-FLUTICASONE SPRAY

- The patient has failed trials of fluticasone nasal spray AND azelastine nasal spray

PRECISION/PLUS FORMULARY CRITERIA

CORE FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Beta-Adrenergic Agents (IE 2462 / NCPDP 75, 50081 and 2193)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

AZELASTINE-FLUTICASONE SPRAY

- The patient has failed trials of fluticasone nasal spray AND azelastine nasal spray

ENHANCED FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Beta-Adrenergic Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

ALVESCO, ARMONAIR RESPICLICK/DIGIHALER, PULMICORT FLEXHALER

- May be approved if the patient has had a trial and failure of **two** of the following: Arnuity Ellipta, Flovent, Qvar, Qvar RediHaler or Asmanex

XHANCE

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of nasal polyps; **AND**
- The patient has tried and failed generic mometasone nasal spray

AZELASTINE-FLUTICASONE SPRAY

- The patient has failed trials of fluticasone nasal spray AND azelastine nasal spray

INJECTABLE DRUGS – BENEFIT BUILDER

Length of Authorization:	Up to 1 year, dependent on medication
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75) [For specialty medications] MNC: Category A: PA required (IE 2462 / NCPDP 75) [For non-specialty medications]

Injectables are a benefit builder category, Check CRM. For the client which chooses to prior auth these agents, see below

- If there are already clinical criteria for the product use the criteria pertaining to that medication
- If no criteria available:
  - Look at indication – if used for an FDA labeled indication, approve unless there is
    - Alternative available in oral formulation, if applicable; **OR**
      - If product is in oral formulation, must have medical reason cannot take: (i.e., trouble swallowing, G-tube, etc.)
    - If generic alternative available in the class; **OR**
    - Preferred product in the class

INJECTAFER® (FERRIC CARBOXYMYALTOSE INJECTION)

Length of Authorization:	35 days, may be renewed
Initiative:	SPC: Miscellaneous PA Required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Iron deficiency anemia in non-dialysis-dependent chronic kidney disease (NDD-CKD)**

- Patient is 18 or older; **AND**
- Laboratory values must be obtained within 28 days prior to the anticipated date of administration; **AND**
- Other causes of anemia (e.g., blood loss, vitamin deficiency) have been ruled out; **AND**
- The patient does not have a history of allergic reaction to any intravenous iron product; **AND**
- Other supplemental iron is to be discontinued prior to administration of ferric carboxymaltose; **AND**
- Patient must not be receiving dialysis; **AND**
- Patient has iron-deficiency anemia with a Hemoglobin (Hb) < 11.5 g/dL; **AND**
  - Ferritin ≤ 100 ng/mL; **OR**
  - Ferritin ≤ 300 ng/mL when transferrin saturation (TSAT) ≤ 30%; **AND**

Diagnosis of **Iron deficiency anemia in patients intolerant to or who have had unsatisfactory response to oral iron**

- Patient is 18 or older; **AND**
- Laboratory values must be obtained within 28 days prior to the anticipated date of administration; **AND**
- Other causes of anemia (e.g., blood loss, vitamin deficiency) have been ruled out; **AND**
- The patient does not have a history of allergic reaction to any intravenous iron product; **AND**
- Other supplemental iron is to be discontinued prior to administration of ferric carboxymaltose; **AND**
- Patient had an intolerance or inadequate response to a minimum of 14 days of oral iron; **AND**
- Patient has iron-deficiency anemia with a Hemoglobin (Hb) < 12 g/dL; **AND**
  - Ferritin ≤ 100 ng/mL; **OR**
  - Ferritin ≤ 300 ng/mL when transferrin saturation (TSAT) ≤ 30%

Diagnosis of **Cancer- and Chemotherapy-Induced Anemia**

- Patient is 18 or older; **AND**
- Laboratory values must be obtained within 28 days prior to the anticipated date of administration; **AND**
- Other causes of anemia (e.g., blood loss, vitamin deficiency) have been ruled out; **AND**
- The patient does not have a history of allergic reaction to any intravenous iron product; **AND**
- Other supplemental iron is to be discontinued prior to administration of ferric carboxymaltose; **AND**
- May be considered in instances where the recommended IV iron preparations with demonstrated efficacy in patients with cancer (i.e., low-molecular-weight iron dextran, ferric gluconate, and iron sucrose) are not appropriate; **AND**
  - Used as a single agent; **AND**
    - Patient has a ferritin < 30 ng/mL **and** a TSAT < 20%; **OR**
    - Patient has a ferritin > 500 - 800 ng/mL **and** a TSAT < 50% **and** does not wish to have an allogenic transfusion; **OR**
  - Used in combination with erythropoiesis-stimulating agents (ESAs); **AND**
    - Patient has a ferritin < 30 ng/mL **and** a TSAT < 20% and failed to demonstrate an increase in Hb after 4 weeks of IV or oral iron therapy; **OR**
    - Patient has a ferritin 30 - 500 ng/mL **and** a TSAT < 50% and is receiving myelosuppressive chemotherapy

CLINICAL CRITERIA FOR RENEWAL

- Refer to initial criteria above

INLYTA® (AXITINIB)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Renal Cell Carcinoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with STRONG CYP3A4/5 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with MODERATE CYP3A4/5 inducers (e.g., bosentan, efavirenz, etravirine, modafinil, nafcillin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with strong CYP3A4/5 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin, grapefruit, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has advanced disease; **AND**
  - Used as first-line therapy in combination with avelumab **or** pembrolizumab ; **AND**
  - Used as second-line therapy after failure of one prior systemic therapy ; **AND**
    - Used as single-agent therapy; **OR**
- Patient has relapsed or stage IV disease; **AND**
  - Used for non-clear cell histology; **AND**
    - Used as single-agent therapy; **OR**
  - Used for clear-cell histology; **AND**
    - Used as a single-agent as subsequent therapy; **OR**
    - Used in combination with pembrolizumab; **OR**
    - Used in combination with avelumab as first-line therapy

Diagnosis of **Thyroid Carcinoma (Follicular Carcinoma/Hürthle Cell Carcinoma/Papillary Carcinoma)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with STRONG CYP3A4/5 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with MODERATE CYP3A4/5 inducers (e.g., bosentan, efavirenz, etravirine, modafinil, nafcillin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with strong CYP3A4/5 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin, grapefruit, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has unresectable recurrent, persistent, or distant metastatic disease; **AND**
- Patient has progressive and/or symptomatic disease that is not susceptible to radioactive iodine (RAI) therapy; **AND**
- Treatment with clinical trials or other systemic therapies are not available or appropriate

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., arterial and venous thromboembolic events, hemorrhage, hypertension/hypertensive crisis, cardiac failure, gastrointestinal perforation and fistula formation, impaired wound healing, hepatic impairment/hepatotoxicity, thyroid dysfunction, reversible posterior leukoencephalopathy syndrome [RPLS], proteinuria, major adverse cardiovascular events [MACE])

INQOVI® (DECITABINE AND CEDAZURIDINE)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Myelodysplastic syndrome (MDS)**

- Patient is at least 18 years old; **AND**
- Therapy will not be substituted for intravenous decitabine within the same cycle; **AND**
- Used as single agent therapy; **AND**
- Patient has a confirmed diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated de novo and secondary MDS; **AND**
- Patient should have received no more than one previous cycle of decitabine or one previous cycle of azacitidine; **AND**
- Patient has one of the following French-American-British (FAB) sub-types with an International Prognostic Scoring System (IPSS) group risk classification of Intermediate-1, Intermediate-2, or High-risk:
  - Refractory anemia
  - Refractory anemia with ringed sideroblasts
  - Refractory anemia with excess blasts
    Chronic myelomonocytic leukemia (CMML)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe myelosuppression, serious infectious complications, etc.; **AND**
- Adequate documentation of disease stability and/or improvement, as indicated by one of the following: a decrease in bone marrow blasts percentage, increase in platelets, increase in hemoglobin or decrease in transfusions (if transfusion dependent), an increase in WBC/ANC over pretreatment values, or reduction in abnormal cytogenetic metaphases

INREBIC® (FEDRATINIB)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Myelofibrosis (MF) (including primary, post-polycythemia vera and post-essential thrombocythemia MF)**

- Patient is at least 18 years of age; **AND**
- Therapy will not be used in combination with another JAK2-inhibitor type drug (e.g., ruxolitinib, etc.); **AND**
- Baseline thiamine (vitamin B1), amylase, and lipase levels are within normal limits prior to initiating of therapy and will continue to be monitored periodically while on treatment; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with moderate and strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, modafinil, etc.); **AND**
  - Coadministration with dual CYP3A4 and CYP2C19 inhibitors (e.g., fluconazole, fluvoxamine, etc.); **AND**
- Patient has intermediate-2 or high-risk disease; **AND**
  - Patient has a baseline platelet count of ≥ 50 X 10^9/L within the previous 30 days; **OR**
  - Patient has palpable splenomegaly (i.e., at least 5 cm below costal margin); **OR**
- Patient has MF-accelerated phase or MF-blast phase/acute myeloid leukemia with hypomethylating agents (azacitidine or decitabine); **AND**
  - Used as induction therapy or for the palliation of splenomegaly or other disease-related symptoms

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia**

- Patient is at least 18 years of age; **AND**
- Therapy will not be used in combination with another JAK2-inhibitor type drug (e.g., ruxolitinib, etc.); **AND**
- Baseline thiamine (vitamin B1), amylase, and lipase levels are within normal limits prior to initiating of therapy and will continue to be monitored periodically while on treatment; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with moderate and strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, modafinil, etc.); **AND**
  - Coadministration with dual CYP3A4 and CYP2C19 inhibitors (e.g., fluconazole, fluvoxamine, etc.); **AND**
- Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible); **AND**
  - Patient has lymphoid, myeloid, or mixed lineage neoplasm; **AND**
  - Patient has JAK2 rearrangement in blast phase; **OR**
- Patient has myeloid or lymphoid neoplasms; **AND**
  - Patient has JAK2 rearrangement in chronic phase

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include encephalopathy (including Wernicke's encephalopathy), anemia, thrombocytopenia, hepatotoxicity (elevated AST/ALT), gastrointestinal toxicity (severe nausea, vomiting, diarrhea), amylase/lipase elevations, etc.; **AND**
- **Myelofibrosis**
  - Treatment response with a decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
- **Myeloid/Lymphoid Neoplasms with Eosinophilia**
  - Disease response as evidenced by at least **one** of the following:
    - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
    - Stabilization or improvement as evidenced by a complete response (CR) (i.e., morphologic, cytogenetic, or molecular complete response [CR]), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

INTERFERONS

Length of Authorization:	1 Year
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

ALFERON N

- Patients > 1 year of age: Chronic hepatitis; **OR**
- Patients > 18 years of age: Condyloma acuminata, chronic hepatitis C, hairy cell leukemia, malignant melanoma, AIDS-related Kaposi's sarcoma, follicular non-Hodgkin's lymphoma

INTRON-A (INTERFERON ALFA 2B)

Length of Authorization:	See table below
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Hepatitis C	Initial authorization: 16 weeks of therapy Renewal: Coverage will be provided up to a total length of therapy of 24 months
Hepatitis B	Adults: Coverage will be provided for 48 weeks and may not be renewed Pediatrics: Coverage will be provided for up to 24 weeks of therapy and may not be renewed
NHL FL	Coverage will be provided for 6 months and may be renewed up to a total length of therapy of 18 months
Hairy Cell Leukemia	Coverage will be provided for 6 months and may not be renewed
Malignant Melanoma, Adult T-Cell Leukemia/ Lymphoma	Coverage will be provided for 6 months and may be renewed up to a total length of therapy of 52 weeks (12 months)
Condylomata Acuminata	Coverage will be provided for two 3-week courses and may not be renewed.
All other indications	Coverage will be provided for 6 months and may be renewed

Hairy cell leukemia

- Patient is 18 years of age or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis

Malignant Melanoma

- Patient is 18 years of age or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Used as single agent as adjuvant therapy after surgical treatment; **AND**
- Patient is free of disease but is at a high risk for systemic recurrence

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Follicular Non-Hodgkin lymphoma

- Patient is 18 years of age or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Used as initial treatment for clinically aggressive disease; **AND**
- Used in conjunction with anthracycline-containing chemotherapy

Condylomata Acuminata

- Patient is 18 years of age or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Used as intralesional treatment; **AND**
- Disease involves external surfaces of the genital and perianal areas; **AND**
- Prior failure to all of the following topical agents: podofilox (Condylox™), sinecatechins (Veregen®), imiquimod (Aldara®), and trichloroacetic acid (TCA)

AIDS-Related Kaposi Sarcoma

- Patient is 18 years of age or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis

Chronic Hepatitis B

- Patient 1 year of age or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Patient has been HBsAg positive for at least 6 months; **AND**

Patients without cirrhosis • Patient has elevated serum ALT ≥ 2 times Upper Limit of Normal (ULN); **OR** • Patient has evidence of significant histologic disease (e.g., significant inflammation and/or fibrosis) plus one of the following: – HBV DNA > 2,000 IU/mL (HBeAg negative); **OR** – HBV DNA > 20,000 IU/mL (HBeAg positive)
Patients with compensated cirrhosis • HBV DNA > 2,000 IU/mL; **OR** • Patient has elevated serum ALT > 2 times Upper Limit of Normal (ULN)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Chronic Hepatitis C

- Patient is 3 years of age or older; **AND**
- Documented diagnosis of chronic hepatitis C; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Baseline serum ALT level has been obtained prior to initiating therapy

** ***Note:*** *Please consult the current AASLD clinical practice guidelines for recommended agents for use in the treatment of chronic hepatitis B and chronic hepatitis C.*

Bone Cancer – Giant Cell Tumor of the Bone

- Patient is 18 years of age or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Used as a single agent or combined with denosumab and/or radiation therapy and/or serial embolization for localized disease; **AND**
  - Disease is resectable with unacceptable morbidity and/or has unresectable axial lesions; **OR**
- Used as a single agent for unresectable metastatic disease

Mycosis Fungoides (MF)/Sézary Syndrome (SS) (excluding patients with stage IA-IIA MF with B1 blood involvement)

- Patient is 18 years of age or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Adult T-Cell Leukemia/Lymphoma

- Patient is 18 years of age or older; **AND**
- Confirmation that patient will receive continuous monitoring for the presence of persistently severe or worsening signs or symptoms of neuropsychiatric, autoimmune, ischemic, and infections disorders; **AND**
- Patient does not have decompensated liver disease (Child-Pugh score greater than 6 [class B or C]); **AND**
- Patient does not have autoimmune hepatitis; **AND**
- Used in combination with zidovudine for chronic/smoldering or acute disease; **AND**
  - Used as first-line therapy; **OR**
  - Used as continuation treatment in responders to first-line therapy; **OR**
  - Used as alternate therapy in non-responders to first-line therapy (if not previously used)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: cardiovascular disorders, ischemic and hemorrhagic cerebrovascular events, depression and suicidal behavior, severe cytopenias including aplastic anemia and severe decreases in neutrophil and platelet counts, serious hypersensitivity reactions, elevated triglycerides, exacerbation of psoriasis and sarcoidosis, peripheral neuropathy, autoimmune disorders (thrombocytopenia, vasculitis, Raynaud's phenomenon, rheumatoid arthritis, lupus erythematosus, and rhabdomyolysis), pulmonary disorders, hepatotoxicity, thyroid abnormalities, ocular symptoms, etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor/lesion or tumor/lesion spread; **AND**
  - **Hairy Cell Leukemia**: May not be renewed
  - **Condylomata Acuminata**: May not be renewed
  - **Melanoma:** Patient has **not** received more than 52 weeks of therapy
  - **Adult T-Cell Leukemia/Lymphoma**
    - When used in combination with zidovudine: Patient has **not** received more than 52 weeks of therapy
    - When used in combination with arsenic trioxide: Patient has **not** received more than 8 weeks of therapy
  - **Hepatitis C**: Disease response as defined by normalization of ALT at 16 weeks of treatment; therapy may be extended to 18 to 24 months (72 to 96 weeks)
  - **Hepatitis B**: May not be renewed
  - **NHL-FL:** Patient has **not** received more than 18 months of therapy

IRESSA® (GEFITINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **non-small cell lung cancer:**

- Patient is at least 18 years old; **AND**
- Patient's tumor has EGFR exon 19 deletions or exon 21 (L858R) substitution mutations as confirmed by an FDA-approved or CLIA-compliant test; **AND**
- Used as a single agent; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with acid-reducing agents (i.e., proton pump inhibitors), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **OR**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **OR**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **OR**
- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **OR**
  - Used as continuation therapy in patients with disease progression while on gefitinib for asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited metastases.

In addition to the above criteria:

- ***In patients with metastatic NSCLC and EGFR exon 19 deletions or exon 21 substitution mutations, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic erlotinib***

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., interstitial lung disease, hepatotoxicity, gastrointestinal perforation, severe/persistent diarrhea, ocular disorders including keratitis, and bullous and exfoliative skin disorders)

IRON CHELATORS

Length of Authorization:	6 Months
Initiative:	SPC: Iron Chelators (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

FERRIPROX

Diagnosis of **Transfusional iron overload due to a thalassemia syndrome**

- (Not to be approved in other diagnoses associated with chronic anemia: sickle cell anemia, aplastic anemia, etc.)
- Failure of Exjade®/Jadenu®/desferasirox (after a minimum of three months of therapy) as demonstrated by serum ferritin consistently > 500 mcg/L despite maximization of Exjade® dosage at 40 mg/kg/day.

RENEWAL FOR FERRIPROX

- Serum ferritin must have been measured within the past 30 days (copy of lab results must be submitted).
- Ferritin levels must be > 500 mcg/L.
- Dose must not exceed 99 mg/kg/day.

JADENU®, JADENU® SPRINKLES, EXJADE®, DEFERASIROX

Diagnosis of **chronic iron overload due to blood transfusions demonstrated by transfusion of at least 100 mL/kg of packed red blood cells and a serum ferritin consistently greater than 1000 mcg/L**

- Patient is over 2; **AND**
- Patient must have serum creatinine < two times the age appropriate upper limit of normal or creatinine clearance ≥ 40 mL/min; **AND**
- Patient must have platelet counts ≥ 50 x 10^9/L; **OR**

Diagnosis of **chronic iron overload in patients with non-transfusion-dependent thalassemia (NTDT) syndromes**

- Patient is over 10; **AND**
- Liver iron concentration of at least 5 mg iron per gram of dry weight; **AND**
- Serum ferritin greater than 300 mcg/L; **AND**
- Patient must have serum creatinine < two times the age appropriate upper limit of normal or creatinine clearance ≥ 40 mL/min; **AND**
- Patient must have platelet counts ≥ 50 x 10^9/L

RENEWAL FOR JADENU®, JADENU® SPRINKLES, EXJADE®, DEFERASIROX

For **Transfusional Iron Overload**

- Patient has demonstrated clinical improvement in response to treatment; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use; **AND**
- Serum ferritin levels must be > 500 mcg/L

For **Non-Transfusion-Dependent Thalassemia**

- Patient has demonstrated clinical improvement in response to treatment; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use; **AND**
- Serum ferritin levels must be > 300 mcg/L

CLINICAL CRITERIA

SYPRINE® (TRIENTENE)

Diagnosis of **Wilson's Disease**

- Must be intolerant to penicillamine (first line); **OR**
- Diagnosis of Manganism (orphan designation)

ACCRUFER (FERRIC MALTOL)

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of iron deficiency; **AND**
- Patient does not have a history of any of the following; **AND**
  - Hypersensitivity to the active substance or to any of the excipients
  - Hemochromatosis and other iron overload syndromes
  - Receiving repeated blood transfusions
- Patient has tried and failed, has a contraindication, or has experienced intolerance/adverse reaction to 2 oral iron products (must be different salts; e.g., ferrous fumarate, ferrous gluconate, ferrous sulfate, polysaccharide-iron complex)

RENEWAL FOR ACCRUFER

- Patient continues to meet the initial criteria; **AND**
- Patient is considered to have clinically meaningful response to treatment; **AND**
- Patient is not experiencing any treatment-limiting adverse reactions of the medication.

ISTODAX®, ROMIDEPSIN (LIQUID)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **T-cell Lymphoma**

- Patient is 18 years of age or older; **AND**
- Used as single-agent therapy; **AND**
- Peripheral T-cell Lymphoma (PTCL) (for Istodax)(Non-Cutaneous):
  Including: Anaplastic large cell lymphoma; Peripheral T-cell lymphoma not otherwise specified; Angioimmunoblastic T-cell lymphoma; Enteropathy-associated T-cell lymphoma; Monomorphic epitheliotropic intestinal T-cell lymphoma; Nodal peripheral T-cell lymphoma with TFH phenotype; Follicular T-cell lymphoma
  - Patient has failed prior systemic therapy; **OR**
  - Used as initial palliative intent therapy
- Cutaneous T-cell Lymphoma (CTCL)**:**
  (Including: Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders [primary cutaneous anaplastic large cell lymphoma], Mycosis Fungoides/Sézary Syndrome)
  - Patient has failed prior systemic therapy; **OR**
  - Used as primary treatment for Mycosis Fungoides/Sézary Syndrome in patients without stage IA-IIA disease with B1 blood involvement
- Extranodal NK/T-Cell Lymphoma (nasal type)
  - Used for relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen (asparaginase-based) not previously used
- Hepatosplenic T-Cell Lymphoma
  - Used for refractory disease after two first-line therapy regimens
- Breast Implant Associated Anaplastic Large Cell Lymphoma (ALCL)
  - Used as subsequent therapy for relapsed/refractory disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hematological abnormalities (e.g., neutropenia, lymphopenia, anemia, leukopenia, thrombocytopenia, etc.), severe infections (e.g., pneumonia, sepsis, viral reactivation of Epstein Barr or hepatitis B), severe tumor lysis syndrome, and ECG T-wave and/or ST-segment changes, etc.

ISTURISA® (OSILODROSTAT)

Length of Authorization:	12 weeks initial, 6 months renewal
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cushing's disease**

- Patient is ≥ 18 years of age; **AND**
- Patient must not have hypersensitivity to any component of the product osilodrostat; **AND**
- Patient is not a candidate for pituitary surgery; **OR**
- Patient has had pituitary surgery that was not curative; **AND**
- Patient has had a baseline electrocardiogram; **AND**
- Patient has had hypokalemia or hypomagnesemia corrected if applicable; **AND**
- Patient is not currently receiving glucocorticoid therapy or will have discontinued therapy for 1 week or at least 5 half-lives prior to the start of treatment

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet the above criteria; **AND**
- Patient must have disease improvement and/or stabilization of disease; **AND**
- 24-hour urine free cortisol (UFC) ≤ upper limit of normal (ULN); **AND**
- Patient has not experienced any treatment-restricting adverse effects (e.g. hypocortisolism, QTc prolongation, elevations in adrenal hormone precursors and androgens)

IXEMPRA® (IXABEPILONE)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**

- Patient is 18 years or older; **AND**
- If used in combination with capecitabine, the patient must not have an AST or ALT > 2.5 x ULN or bilirubin > 1 x ULN; **AND**
- Patient has metastatic or recurrent disease; **AND**
  - Used as a single agent for human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
    - Patient's disease is hormone receptor negative; **OR**
    - Patient's disease is hormone receptor positive with visceral crisis or is refractory to endocrine therapy; **OR**
  - Used in combination with trastuzumab for human epidermal growth factor receptor 2 (HER2)-positive disease; **AND**
    - Patient's disease is hormone receptor negative; **OR**
    - Patient's disease is hormone receptor positive and used with or without endocrine therapy; **OR**
- Patient has locally advanced or metastatic disease; **AND**
  - Patient has failed on an anthracycline* and a taxane** (or taxane resistant and further anthracycline therapy is contraindicated); **AND**
    - Must be used in combination with capecitabine; **OR**
    - Must be used as a single agent after failure on capecitabine

*Anthracycline resistance: defined as progression of disease while on therapy or within 6-months in the adjuvant setting, or 3-months in the metastatic setting.
**Taxane resistance: defined as progression of disease while on therapy or within 12-months in the adjuvant setting, or 4-months in the metastatic setting.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include peripheral neuropathy, myelosuppression (neutropenia, leukopenia, anemia, and thrombocytopenia), hepatic impairment, hypersensitivity reactions, cardiac ischemia, impaired cardiac function, etc.

JAKAFI® (RUXOLITINIB)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Myelofibrosis (MF) (including primary, post-polycythemia vera and post-essential thrombocythemia MF)**

- Patient is at least 18 years of age; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has symptomatic low- to intermediate-1-risk disease; **OR**
- Patient has intermediate-2 or high-risk disease; **AND**
  - Starting platelet count (< 30 days old) is ≥ 50 X 10^9/L; **OR**
  - Patient has palpable splenomegaly (i.e., at least 5 cm below costal margin) ; **OR**
- Patient has MF-accelerated phase or MF-blast phase/acute myeloid leukemia with hypomethylating agents (azacitidine or decitabine); **AND**
  - Used as induction therapy or for the palliation of splenomegaly or other disease-related symptoms

Diagnosis of **Polycythemia Vera**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient has had an inadequate response (or intolerance) to a 3 month or longer trial of hydroxyurea or peginterferon alfa-2a therapy; **AND**
- Patient has symptomatic low risk or high risk disease with indications for cytoreductive therapy

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Essential Thrombocythemia**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient has had an inadequate response or loss of response to hydroxyurea, peginterferon alfa-2a therapy, or anagrelide

Diagnosis of **Graft Versus Host Disease (GvHD)**

- Patient is at least 12 years of age (unless noted); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Used for disease related to allogeneic hematopoietic stem cell transplantation; **AND**
- Used in combination with systemic corticosteroids for steroid-refractory disease; **AND**
  - Patient has acute graft versus host disease (aGVHD); **OR**
  - Patient has chronic graft versus host disease (cGVHD); **AND**
    - Patient has failed one or two lines of systemic therapy

Diagnosis of **Myelodysplastic/Myeloproliferative Overlap Neoplasms (MDS/MPN)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Used in combination with a hypomethylating agent (e.g., decitabine, azacitidine, etc.) for chronic myelomonocytic leukemia (CMML)-2; **OR**
- Used as a single agent or in combination with a hypomethylating agent (e.g., decitabine, azacitidine, etc.) for BCR-ABL negative atypical chronic myeloid leukemia (aCML)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible); **AND**
  - Patient has lymphoid, myeloid, or mixed lineage neoplasm; **AND**
  - Patient has JAK2 rearrangement in blast phase; **OR**
- Patient has myeloid or lymphoid neoplasms; **AND**
  - Patient has JAK2 rearrangement in chronic phase

Diagnosis of **Pediatric Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 1 year of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient has Ph-like B-ALL; **AND**
  - Used as induction therapy in combination with Total Therapy XVII regimen (prednisone, vincristine, daunorubicin, pegaspargase, cyclophosphamide, cytarabine, 6-MP, intrathecal [IT] therapy [methotrexate OR cytarabine OR methotrexate, cytarabine, and corticosteroid]); **AND**
    - Patient has disease with mutations associated with JAK-STAT pathway activation; **OR**
  - Used as consolidation therapy in combination with COG AALL1521 regimen (cyclophosphamide, cytarabine, 6-MP, vincristine, pegaspargase, IT methotrexate); **AND**
    - Patient has CRLF2+ or CRLF2- with JAK2 fusions, EPOR rearrangements, SH2B3 alterations, IL7R insertions/deletions; **OR**
  - Used as consolidation therapy in combination with the standard risk/high risk (SR/HR) arm of the Total Therapy XVII regimen (high-dose methotrexate, pegaspargase, 6-MP, intrathecal [IT] therapy [methotrexate OR cytarabine OR methotrexate, cytarabine, and corticosteroid]); **AND**
    - Patient has with mutations associated with JAK-STAT pathway activation

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **CAR-T Cell Related Toxicity**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Used for the management of grade 4 cytokine release syndrome; **AND**
- Patient is refractory to high-dose corticosteroids and anti-interleukin-6 therapy

CLINICAL CRITERIA FOR RENEWAL

Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include serious infections (bacterial, mycobacterial, fungal, and viral), severe hematologic toxicity (neutropenia, thrombocytopenia, and anemia), non-melanoma skin cancer, lipid elevations (including total cholesterol, LDL, and triglycerides), etc.; **AND**

Myelofibrosis:

- Treatment response with a decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding)

Polycythemia Vera:

- Treatment response such as hematocrit control and/or spleen volume reduction

Essential Thrombocythemia:

- Disease response as evidenced by at least one of the following:
  - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
  - Platelet count ≤ 400 x 10^9/L, WBC count < 10 x 10^9/L, absence of leukoerythroblastosis
  - Absence of any signs of progressive disease or hemorrhagic or thrombotic events

aGvHD:

- Treatment response such as stabilization or improvement in disease; **AND**
- In patients who have had a response and have discontinued therapeutic doses of corticosteroids, tapering of Jakafi® should be considered

cGvHD:

- Treatment response as evidenced by stabilization or improvement in disease

Myelodysplastic/Myeloproliferative Overlap Neoplasms (MDS/MPN):

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

Myeloid/Lymphoid Neoplasms with Eosinophilia:

- Disease response as evidenced by at least one of the following:
  - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
  - Stabilization or improvement as evidenced by a complete response (CR) (i.e., morphologic, cytogenetic, or molecular complete response [CR]), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

Pediatric Acute Lymphoblastic Leukemia (ALL):

- Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH

CAR-T Cell Related Toxicity:

- May not be renewed

JELMYTO® (MITOMYCIN)

Length of Authorization:	Coverage will be provided initially for three months and may be renewed one time only for 11 months *(maximum total of 17 doses from initial and maintenance treatments)*
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Urothelial Carcinoma:**

- Patient must be at least 18 years of age; **AND**
- Patient does not have a perforation of the bladder or upper urinary tract; **AND**
- Therapy will be used for intra-pyelocalyceal instillation only; **AND**
- Must be used as a single agent; **AND**
- Patient has a diagnosis of low-grade, upper tract urothelial cancer (LG-UTUC); **AND**
- Patient has newly diagnosed or recurrent non-invasive disease; **AND**
- Patient has at least one measurable papillary tumor 5 to ≤ 15 mm, located above the ureteropelvic junction (in the absence of or following tumor debulking); **AND**
- Patient has not received intravesical BCG treatment within the previous 6 months of starting therapy; **AND**
- Patient does **not** have any of the following:
  - History of carcinoma in situ (CIS) in the urinary tract;
  - Invasive urothelial carcinoma within 5 years;
  - High grade papillary urothelial carcinoma within 2 years

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Patient has a complete response (CR) to initial therapy (consisting of 6 weekly cycles) defined as a negative ureteroscopic evaluation and negative cytology wash (required for extending treatment for an additional 11 monthly instillations) ; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe ureteric obstruction, severe thrombocytopenia and/or neutropenia, etc.; **AND**
- Patient has not received more than a total of 17 drug doses/instillations

JEMPERLI® (DOSTARLIMAB-GXLY)

Length of Authorization:	6 months and may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Mismatch Repair Deficient (dMMR)/Microsatellite Instability-High (MSI-H) Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, nivolumab, atezolizumab, durvalumab, pembrolizumab, etc.), unless otherwise specified; **AND**
- Patient does not have uncontrolled central nervous system metastatic cancer; **AND**
- Patient does not have interstitial lung disease; **AND**
- Patient has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) cancer as determined by an FDA-approved or CLIA-compliant test; **AND**
- Used as a single agent; **AND**
- Patient has advanced or recurrent disease; **AND**
  - Patient has endometrial carcinoma; **AND**
    - Patient does not have endometrial sarcoma; **AND**
    - Disease has progressed on or following treatment with a platinum-containing regimen; **OR**
  - Patient has solid tumors**; AND**
    - Disease has progressed on or following prior treatment and there are no satisfactory alternative treatment options

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe infusion reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, dermatologic adverse reactions/rash, etc.), complications of allogeneic HSCT after immunotherapy, etc.

JEVTANA® (CABAZITAXEL)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Prostate Cancer:**

- Patient is 18 years of age or older; **AND**
- Must be used in combination with a steroid (e.g., prednisone or dexamethasone); **AND**
- Patient has castration-resistant metastatic disease; **AND**
  - Used as a single agent; **AND**
    - Patient must have been previously treated with docetaxel unless contraindicated or intolerant to docetaxel; **OR**
  - Used in combination with carboplatin; **AND**
    - Used for fit patients with aggressive variant disease [(e.g., low prostate-specific antigen and bulky disease, high LDH, high CEA, lytic bone metastases, neuroendocrine prostate cancer histology) or unfavorable genomics (defects in at least two of the following: PTEN, TP53, and RB1)]; **AND**
      - Patient has received prior docetaxel and no prior novel hormone therapy (e.g., abiraterone, enzalutamide, darolutamide, apalutamide, etc.); **OR**
      - Patient has received prior novel hormone therapy and no prior docetaxel; **OR**
      - Patient has received prior docetaxel and prior novel hormone therapy; **AND**
        - Patient does not have visceral metastases

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by lack of disease progression, improvement in tumor size and/or improvement in patient symptoms; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: bone marrow suppression (neutropenia, anemia, thrombocytopenia, and/or pancytopenia), severe hypersensitivity reactions, gastrointestinal adverse reactions (severe diarrhea, nausea, vomiting), urinary disorders including severe hemorrhagic cystitis, renal failure, hepatic impairment, interstitial lung disorders, etc.

JUXTAPID® (LOMITAPIDE)

Length of Authorization:	6 Months – May be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Homozygous familial hypercholesterolemia (HoFH)**

- Patient at least 18 years old; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the Juxtapid REMS program; **AND**
- Patient does not have moderate to severe hepatic impairment (Child-Pugh B or C) or active liver disease (including unexplained persistent elevations of serum transaminases); **AND**
- Baseline alanine and aspartate aminotransferases (ALT, AST), alkaline phosphatase, and total bilirubin lab values must be obtained prior to initiating treatment; **AND**
- Baseline low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment and required for renewal; **AND**
- Will not be used in combination with evinacumab-dgnb; **AND**
- Patient will avoid concomitant use with strong or moderate CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, nefazodone, ritonavir, aprepitant, ciprofloxacin, diltiazem, fluconazole, erythromycin, verapamil, grapefruit juice, etc.); **AND**
- Females of reproductive potential must have a negative pregnancy test prior to starting therapy and will continue to use effective contraception while on therapy; **AND**
- Patient has a confirmed diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) by any of the following:
  - Documented DNA test for functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality; **OR**
  - Untreated LDL-C >500 mg/dL or treated LDL-C ≥ 300 mg/dL; **AND**
    - Cutaneous or tendon xanthoma before age 10 years; **OR**
    - Untreated LDL-C levels consistent with HeFH in both parents; **AND**
- Must be used as an adjunct to a low-fat diet supplying < 20% of calories from fat; **AND**
- Patient tried and failed at least a 3-month trial of adherent therapy with: ezetimibe (Zetia) used in combination with the highest available (or maximally tolerated*) dose of atorvastatin (Lipitor) or rosuvastatin (Crestor), unless contraindicated; **AND**
- Patient tried and failed at least a 3 month trial of adherent therapy with: combination therapy consisting of the highest available (or maximally tolerated*) dose of atorvastatin **or** rosuvastatin, ezetimibe, **and** a PCSK9 inhibitor indicated for HoFH (e.g., evolocumab, etc.), unless contraindicated; **AND**
- Despite the pharmacological treatment, unless contraindicated, with PCSK9, statin and ezetimibe, patient's LDL cholesterol ≥ 100 mg/dL (or ≥70 mg/dL for patients with clinical atherosclerotic cardiovascular disease [ASCVD]); **AND**
- Therapy will be used in conjunction with other lipid-lowering therapy including rosuvastatin/atorvastatin, ezetimibe, and a PCSK9 inhibitor, unless contraindicated

*****If the patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms.

- Documentation must demonstrate that the patient experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following:
  - Muscle symptoms resolve after discontinuation of statin; **AND**
  - Muscle symptoms occurred when re-challenged at a lower dose of the same statin; **AND**
  - Muscle symptoms occurred after switching to an alternative statin; **AND**
  - Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease); **OR**
- The patient has been diagnosed with rhabdomyolysis associated with statin use
  - The diagnosis should be supported by acute neuromuscular illness or dark urine; **AND**
  - An acute elevation in creatine kinase (usually > 5,000 IU/L or 5 times the upper limit of normal [ULN])

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: elevations in transaminases (ALT, AST), hepatic steatosis, severe diarrhea, severe nausea/vomiting, etc.; **AND**
- Documented reduction of low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) compared to initial baseline labs (prior to initiating lomitapide); **AND**
- Documentation of dosage adjustment if ALT or AST is ≥ 3 times the upper limit of normal (ULN); **AND**
- **Female patients only**: Obtain a negative pregnancy test in females of reproductive potential; **AND**
- Patient continues to adhere to low-fat diet and lipid-lowering therapy established prior to the original lomitapide approval; **AND**

JYNARQUE™ (TOLVAPTAN)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Autosomal Dominant Polycystic Kidney Disease [ADPKD]**

- Patient is at least 18 years of age; **AND**
- Confirmation the patient does not have liver disease (including cirrhosis); **AND**
- Patient will not be on concomitant therapy with **strong** CYP3A–inhibitors (e.g., ketoconazole, nefazodone, clarithromycin, etc.); **AND**
- Patient will not be on concomitant therapy with a V2-agonist (e.g., desmopressin (DDAVP)); **AND**
- Patient will not be on concomitant therapy with a **strong** CYP3A– inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifampin, etc); **AND**
- Patient will not be on concomitant therapy with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented:
  - **Moderate** CYP3A–inhibitors (e.g., atazanavir, ciprofloxacin, erythromycin, grapefruit juice, fluconazole, etc); **AND**
- Patient is able to sense or respond to thirst; **AND**
- Patient does not have hypovolemia or hypovolemic hyponatremia; **AND**
- Patient does not have anuria; **AND**
- Patient has confirmed ADPKD as diagnosed using ultrasonography (patient meets the modified Ravine diagnostic criteria), or using CT-scanning or MRI; **AND**
- Used to slow kidney function decline in patients at risk of rapidly progressing disease, defined as one or more of the following:
  - Increase in total kidney volume of ≥ 5% per year
  - Decrease in eGFR of ≥ 5 mL/min in 1 year
  - Decrease in eGFR of ≥ 2.5 mL/min per year over 5 years; **AND**
- Patient has a baseline total kidney volume measurement; **AND**
- Patient does not have uncorrected urinary outflow obstructions; **AND**
- Both patient AND prescriber are enrolled in the Jynarque REMS program

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., osmotic demyelination, liver injury or ALT/AST ever exceeded 3 times the ULN during treatment, dehydration, hypovolemia); **AND**
- Patient has shown an improvement to therapy based on one or more of the following:
  - Stabilization or improvement from baseline in total kidney volume (TKV); **OR**
  - Stabilization or improvement in the rate of kidney function decline; **OR**
  - Improvement in signs and/or symptoms of disease (e.g., medically significant kidney pain, hypertension, albuminuria)

KADCYLA® (ADO-TRASTUZUMAB EMTANSINE)

Length of Authorization:	6 Months, may be renewed Use as adjuvant treatment of HER2-positive breast cancer is limited to 14 cycles/42 weeks.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**

- Patient at least 18 years of age; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Used as single agent therapy; **AND**
- Therapy will not be substituted with or for any trastuzumab-based formulation (i.e., trastuzumab [or trastuzumab biosimilar product], fam-trastuzumab deruxtecan-nxki, trastuzumab-hyaluronidase, pertuzumab/trastuzumab, and hyaluronidase-zzxf, etc.); **AND**
- Used as adjuvant therapy in patients with:
  - Locally advanced residual or node positive disease following completion of planned chemotherapy and mastectomy or lumpectomy; **OR**
  - Inflammatory disease with a response to preoperative systemic therapy, followed by surgery, and need to complete planned chemotherapy; **OR**
  - Early breast cancer with residual invasive disease after neoadjuvant taxane and trastuzumab-based therapy; **OR**
- Patient has metastatic or recurrent unresectable disease; **AND**
  - Used as second-line therapy; **OR**
  - Patient had disease recurrence during or within 6 months of completing adjuvant therapy
- Patient has inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
  - Used as second-line therapy

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

Diagnosis of **Central Nervous System (CNS) Cancer**

- Patient at least 18 years of age; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Used as single agent therapy; **AND**
- Therapy will not be substituted with or for any trastuzumab-based formulation (i.e., trastuzumab [or trastuzumab biosimilar product], fam-trastuzumab deruxtecan-nxki, trastuzumab-hyaluronidase, pertuzumab/trastuzumab, and hyaluronidase-zzxf, etc.); **AND**
- Used for the treatment of brain metastases in patients with breast cancer; **AND**
  - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
  - Used for relapsed disease in patients with limited brain metastases and either stable systemic disease or reasonable systemic treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

Diagnosis of **Non-Small Cell Lung Cancer**

- Patient at least 18 years of age; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Used as single agent therapy; **AND**
- Therapy will not be substituted with or for any trastuzumab-based formulation (i.e., trastuzumab [or trastuzumab biosimilar product], fam-trastuzumab deruxtecan-nxki, trastuzumab-hyaluronidase, pertuzumab/trastuzumab, and hyaluronidase-zzxf, etc.)

Diagnosis of **Salivary Gland Tumors**

- Patient at least 18 years of age; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Used as single agent therapy; **AND**
- Therapy will not be substituted with or for any trastuzumab-based formulation (i.e., trastuzumab [or trastuzumab biosimilar product], fam-trastuzumab deruxtecan-nxki, trastuzumab-hyaluronidase, pertuzumab/trastuzumab, and hyaluronidase-zzxf, etc.); **AND**
- Patient has recurrent carcinoma that is unresectable, with distant metastasis, or second primary

*HER2-positive overexpression criteria: [7,8]
• Immunohistochemistry (IHC) assay 3+; **OR** • Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number ≥ 4.0 signals/cell; **OR** • Dual-probe in situ hybridization (ISH) assay **and** concurrent IHC indicating one of the following: – HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number < 4.0 signals/cell **and** concurrent IHC 3+; **OR** – HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 6.0 signals/cell **and** concurrent IHC 2+ or 3+; **OR** – HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 4.0 and < 6.0 signals/cell **and** concurrent IHC 3+

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hepatotoxicity, pulmonary toxicity (i.e., interstitial lung disease, pneumonitis), thrombocytopenia, neurotoxicity, infusion-related and hypersensitivity reactions, hemorrhage, extravasation at infusion site, etc.; **AND**
- Left ventricular ejection fraction (LVEF) within the previous 3 months as follows:
  - Metastatic or Recurrent Breast Cancer: LVEF is > 45% OR LVEF is 40% to ≤ 45% and **absolute** decrease is < 10% from baseline; **OR**
  - All other indications: LVEF is ≥ 50% OR LVEF is 45% to < 50% and absolute decrease is < 10% from baseline; **AND**
- Adjuvant treatment of breast cancer is limited to 14 cycles (42 weeks total)

KALYDECO® (IVACAFTOR)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of Cystic Fibrosis

- Patient is at least 4 months old; **AND**
- Patient has a baseline percent predicted forced expiratory volume in 1 second (FEV_1)—*reported measurements may be used on renewal*; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with any other cystic fibrosis transmembrane conductance regulator (CFTR)-targeted therapy containing one or more of the following: ivacaftor, lumacaftor, tezacaftor, elexacaftor; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, St. John's wort, etc.); **AND**
  - Coadministration with strong or moderate CYP3A inhibitors (e.g., ketoconazole, fluconazole, itraconazole, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
    (***Note**: Concomitant use of moderate or strong CYP3A inhibitors is not recommended in patients below 6 months of age*.)
- **Patients aged 4 months to less than 6 months:** Patient does not have hepatic impairment; **AND**
- **Pediatric patients only:** Patient has a baseline ophthalmological test obtained prior to initiation of therapy and will continue to have follow-up ophthalmological examinations periodically thereafter; **AND**
- Patient has one mutation in the *CFTR* gene, as confirmed by an FDA-cleared or CLIA-compliant CF mutation test, that is responsive to ivacaftor based on clinical and/or in vitro assay data*****; **AND**
- Patient does not have a mutation in the *CFTR* gene that is unresponsive to ivacaftor potentiation (e.g., homozygous for the *F508del* mutation, etc.)

******CFTR* **Gene Mutations that produce CFTR Protein and are responsive to ivacaftor:**
711+3A→G; F311del; I148T; R75Q; S589N; 2789+5G→A*; F311L; I175V; R117C*; S737F; 3272-26A→G*; F508C; I807M; R117G; S945L*; 3849+10kbC→T*; F508C; S1251N†; I1027T; R117H*; S977F*; A120T; F1052V; I1139V; R117L; S1159F; A234D; F1074L; K1060T; R117P; S1159P; A349V; G178E; L206W*; R170H; S1251N*; A455E*; G178R*; L320V; R347H*; S1255P*; A1067T; G194R; L967S; R347L; T338I; D110E; G314E; L997F; R352Q*; T1053I; D110H; G551D*; L1480P; R553Q; V232D; D192G; G551S*; M152V; R668C; V562I; D579G*; G576A; M952I; R792G; V754M; D924N; G970D; M952T; R933G; V1293G; D1152H*; G1069R; P67L*; R1070Q; W1282R; D1270N; G1244E*; Q237E; R1070W*; Y1014C; E56K; G1249R; Q237H; R1162L; Y1032C; E193K; G1349D*; Q359R; R1283M; E822K; H939R; Q1291R; S549N*; E831X*; H1375P; R74W; S549R*.*

***** Table may not be all-inclusive; verify gene mutations responsive to elexacaftor/tezacaftor/ivacaftor in the current prescribing information

CLINICAL CRITERIA FOR RENEWAL

- Disease response as indicated by one or more of the following:
  - Decreased pulmonary exacerbations compared to pretreatment baseline
  - Improvement or stabilization of lung function as measured by percent predicted FEV_1 within the previous 30 days compared to pre-treatment baseline
  - Decrease in decline of lung function as measured by percent predicted FEV_1 within the previous 30 days compared to pre-treatment baseline
  - Improvement in quality of life (e.g., Cystic Fibrosis Questionnaire-Revised [CFQ-R] score), weight gain, or growth; **AND**
- Patient has not received a lung transplant; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: elevated transaminases (ALT or AST), development of non-congenital cataracts or lens opacities, etc.

KANUMA® (SEBELIPASE ALFA)

Length of Authorization:	6 Months, may be renewed annually thereafter
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Lysosomal Acid Lipase (LAL) Deficiency:**

- Diagnosis has been confirmed by either biallelic pathogenic variants in *LIPA* or deficient LAL enzyme activity in peripheral blood leukocytes, fibroblasts, or dried blood spots; **AND**
- Patient is at least 1 month old

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity reactions [e.g., anaphylaxis, abdominal pain, fever, chills, pruritus, rash, vomiting]); **AND**
- Treatment has resulted in clinical benefit as evidenced in one or more of the following:
  - Improvement in weight-for-age z-scores for patients exhibiting growth failure
  - Improvement in LDL
  - Improvement in HDL
  - Improvement in triglycerides
  - Improvement of AST or ALT

KEPIVANCE® (PALIFERMIN)

Length of Authorization:	Coverage will be provided for 3 months consisting of one course of therapy (6 doses) and may not be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Mucositis**

- Patient is 1 year of age or older; **AND**
- Patient has a hematologic malignancy (e.g., NHL, Hodgkin's disease, AML, ALL, CML, CLL, or MM); **AND**
- Patient will be receiving an autologous hematopoietic stem cell transplant; **AND**
- Patient will be receiving a preparative regimen which includes myelotoxic therapy predicted to result in ≥ WHO Grade 3 mucositis***** in the majority of patients; **AND**
- Patient will not receive melphalan 200 mg/m^2 as a conditioning regimen; **AND**
- Kepivance will not be administered within 24 hours before, during infusion of, or within 24 hours after administration of myelotoxic chemotherapy

*WHO Grade	Symptoms	NIH CTCAE
1	Oral soreness, erythema	Asymptomatic or mild symptoms; intervention not indicated
2	Erythema, ulcers; patient can swallow solid food	Moderate pain or ulcer that does not interfere with oral intake; modified diet indicated
3	Ulcers with extensive erythema; patient cannot swallow food, require liquid diet only	Severe pain; interfering with oral intake
4	Mucositis to extent that alimentation not possible	Life-threatening consequences; urgent intervention indicated
5	N/A	Death

WHO (World Health Organization); NIH (National Institute of Health);
CTCAE (Common Terminology Criteria for Adverse Events

CLINICAL CRITERIA FOR RENEWAL

- Coverage may **not** be renewed

KERENDIA® (FINERENONE)

Length of Authorization:	12 months, may be renewed
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient must be ≥ 18 years of age; **AND**
- Patient has chronic kidney disease (CKD) associated with type 2 diabetes; **AND**
- Patient has an eGFR of ≥ 25 mL/min/1.73 m^2; **AND**
- Patient has a serum potassium of ≤ 5.0 mEq/L; **AND**
- Patient is not receiving concomitant treatment with strong CYP3A4 inhibitors; **AND**
- Patient does not have adrenal insufficiency.

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet initial criteria; **AND**
- Patient is considered to have clinically meaningful response to treatment; **AND**
- The patient is not experiencing any treatment-limiting adverse reactions of the medication

KEVEYIS™ (DICHLORPHENAMIDE)

Length of Authorization:	Initial 2 months, renewal 6 months
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Hyperkalemic or Hypokalemic Primary Periodic Paralysis, and related variants**

- Patient must have a definitive diagnosis* of Primary Periodic Paralysis (PPP); **AND**
- Patient must be 18 years of age or older; **AND**
- Baseline values for frequency and severity of attacks of muscle weakness have been obtained (necessary for renewal); **AND**
- Patient will avoid concomitant use with high-dose aspirin; **AND**
- Patient continues to have paralytic attacks despite dietary intervention and avoidance of triggers ‡; **AND**
- Patient does not have any of the following contraindications for use:
  - Hepatic insufficiency with encephalopathy
  - Severe pulmonary obstruction
  - Sulfonamide hypersensitivity

***Diagnosis of Hyperkalemic Periodic Paralysis (HyperPP) [6,9]**

- Heterozygous pathogenic variant in *SCN4A*; **OR**
- Other hereditary and acquired forms of hyperkalemia (e.g., drug abuse; renal, adrenal, and thyroid dysfunction, potassium-sparing diuretics use, etc.) have been excluded; **AND**
  - Patient had two or more attacks of muscle weakness with documented serum potassium >4.5 mmol/mEq per L; **OR**
  - Patient had one attack of muscle weakness and one attack of weakness in one relative with documented serum potassium > 4.5 mmol/mEq per L; **OR**
  - Patient has at least three of the following:
    - Onset before third decade
    - Duration of attack (muscle weakness involving 1 or more limbs) less than 2 hours
    - The presence of triggers ‡
    - Myotonia
    - A family history of or genetically confirmed skeletal calcium or sodium channel mutation
    - Positive long exercise test (LET)

***Diagnosis of Hypokalemic Periodic Paralysis (HypoPP) [5,9]**

- Heterozygous pathogenic variant in *CACNA1S* or *SCN4A*; **OR**
- Other causes of hypokalemia have been excluded (e.g., renal, adrenal, thyroid dysfunction; renal tubular acidosis; diuretic and laxative abuse, etc.); **AND**
- Absence of myotonia (clinically or latent detected by needle EMG), except eye lids; **AND**
  - Patient had two or more attacks of muscle weakness with documented serum potassium < 3.5 mmol/mEq per L; **OR**
  - Patient had one attack of muscle weakness and one attack of weakness in one relative with documented serum potassium < 3.5 mmol/mEq per L; **OR**
  - Patient has at least three of the following:
    - Onset in the first or second decade
    - Duration of attack (muscle weakness involving at least 1 limb) longer than two hours
    - The presence of triggers ‡
    - Improvement in symptoms with potassium intake
    - A family history of or genetically confirmed skeletal calcium or sodium channel mutation

• Positive long exercise test (LET)
‡Triggers of Paralytic Attacks [5,6]
• Hypokalemic PPP – Strenuous work/exercise – Carbohydrate-rich meals – Cold exposure – High salt intake – Stress/excitement/fear – Prolonged immobility – Glucocorticoid use (especially parenteral) – Anesthesia administration – Alcohol • Hyperkalemic PPP – Potassium-rich medications and foods – Carbohydrate-rich meals – Fasting – Strenuous work/exercise – Cold exposure – Anesthesia administration

CLINICAL CRITERIA FOR RENEWAL

- Disease response indicated by a decrease in the frequency and/or severity of attacks of muscle weakness from pretreatment baseline; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity reactions, hypokalemia, metabolic acidosis, falls)

KEYTRUDA® (PEMBROLIZUMAB)

Length of Authorization:	• 6 months, may be renewed (unless otherwise specified) • Anal, Bladder Cancer/Urothelial Carcinoma, Cervical, cHL, CNS metastases, Cutaneous Melanoma (in combination with ipilimumab), cSCC, Endometrial Carcinoma, Esophageal, GEJ, Gastric, HCC, MPM, MCC, MSI-H/dMMR Cancer, Mycosis Fungoides/Sezary Syndrome, NSCLC, PMBCL, RCC, SCCHN, Thymic Carcinoma, TMB-H Cancer, TNBC (recurrent unresectable or metastatic disease), Uveal Melanoma, and Vulvar can be authorized up to a maximum of 24 months of therapy • Adjuvant therapy in Cutaneous Melanoma can be authorized up to a maximum of 12 months of therapy • Neoadjuvant therapy in TNBC can be authorized up to a maximum of 24 weeks of therapy • Adjuvant therapy in TNBC can be authorized up to a maximum of 27 weeks of therapy
Initiative:	SPC: Oncology (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cutaneous Melanoma:**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as first-line therapy as a single agent for unresectable or metastatic disease; **OR**
- Used as subsequent therapy for unresectable or metastatic* disease after disease progression or maximum clinical benefit from BRAF targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.); **AND**
  - Used as a single agent; **AND**
    - Anti-PD-1 immunotherapy was not previously used; **OR**
    - Used as re-induction therapy in patients who experienced disease control *(i.e., complete response, partial response, or stable disease with no residual toxicity)* from prior anti-PD-1 immunotherapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**
- Used in combination with ipilimumab; **AND**
  - Used after progression on single-agent anti-PD-1 immunotherapy and combination ipilimumab/anti-PD-1 immunotherapy not previously used; **OR**
  - Used as re-induction therapy in patients who experienced disease control *(i.e., complete response, partial response, or stable disease with no residual toxicity)* from prior combination ipilimumab/anti-PD-1 immunotherapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**
- Used as a single agent for adjuvant treatment; **AND**
  - Patient has lymph node involvement and has undergone complete resection, complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; **OR**
  - Patient has satellite/in-transit metastases or recurrence and has no evidence of disease after complete excision; **OR**
  - Patient has undergone TLND and/or complete resection of nodal recurrence; **OR**
  - Patient has undergone complete resection of distant metastatic disease

**Metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Uveal Melanoma:**

- Patient must be at least 18 years old; **AND**
- Used as a single agent; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Patient has distant metastatic disease

Diagnosis of **Gastric Cancer**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Patient is not a surgical candidate or has unresectable, recurrent, locally advanced, or metastatic disease; **AND**
- Patient has adenocarcinoma; **AND**
  - Used as a single agent; **AND**
    - Tumor expresses PD-L1 (Combined Positive Score [CPS] ≥ 1) as determined by an FDA-approved or CLIA compliant test; **AND**
    - Patient progressed on or after at least two prior systemic treatments; **OR**
  - Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy; **AND**
    - Used as first-line therapy for HER2-positive disease

Diagnosis of **Esophageal or Gastroesophageal Junction Cancer:**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Patient is not a surgical candidate or has unresectable, recurrent, locally advanced, or metastatic disease; **AND**
  - Used in combination with platinum- and fluoropyrimidine-based chemotherapy; **AND**
    - Used as first-line therapy; **OR**
  - Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy *(GEJ cancer only)*; **AND**
    - Used as first-line therapy for HER2-positive disease; **AND**
    - Patient has adenocarcinoma; **OR**
  - Used as a single agent; **AND**
    - Patient has squamous cell carcinoma; **AND**
      - Tumor expresses PD-L1 (CPS ≥ 10) as determined by an FDA-approved or CLIA compliant test; **AND**
      - Patient progressed on or after at least one prior systemic treatment; **OR**
    - Patient has adenocarcinoma; **AND**
      - Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved or CLIA compliant test; **AND**
      - Patient progressed on or after at least two prior systemic treatments

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Merkel Cell Carcinoma (MCC):**

- Patient must be at least 6 months old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as a single agent; **AND**
  - Patient has recurrent regional disease and both curative surgery and curative radiation therapy are not feasible; **OR**
  - Patient has recurrent locally advanced or metastatic disease

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**:

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used for stage III disease; **AND**
  - Used as first-line therapy as a single-agent in patients who are not candidates for surgical resection or definitive chemoradiation with tumors that are expressing PD-L1 (TPS ≥ 1%) as determined by an FDA-approved or CLIA compliant test❖ and with no EGFR or ALK genomic tumor aberrations ; **OR**
- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **AND**
    - Used for one of the following:
      - PD-L1 expression-positive (TPS ≥ 1%) tumors, as detected by an FDA or CLIA compliant test❖, that are negative for actionable molecular markers*
      - Patients with performance status (PS) 0-1 who have tumor that are negative for actionable molecular markers* and PD-L1 expression < 1%
      - Patients with PS 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E mutation, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation; **AND**
    - Used in combination with pemetrexed **AND** either carboplatin or cisplatin for non-squamous cell histology; **OR**
    - Used in combination with carboplatin **AND** either paclitaxel or albumin-bound paclitaxel for squamous cell histology; **OR**
    - Used as single agent therapy *(for PD-L1 expression-positive tumors ONLY)* †; **OR**
  - Used as subsequent therapy; **AND**
    - Used in patients with tumors expressing PD-L1 (TPS ≥ 1%) as determined by an FDA-approved or CLIA compliant test❖; **AND**
      - Used as single agent therapy; **OR**
    - Used for one of the following:
      - Patients with PS 0-1 who have ROS1 rearrangement-positive tumors and prior targeted therapy; **OR**
      - Patients with PS 0-1 who are positive for one of the following molecular markers: BRAF V600E mutations, NTRK 1/2/3 gene fusions, or MET exon 14 skipping mutation; **AND**
    - Used in combination with carboplatin **AND** either paclitaxel or albumin-bound paclitaxel for squamous cell histology; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Used in combination with pemetrexed **AND** either carboplatin or cisplatin for non-squamous cell histology; **OR**

– Used as continuation maintenance therapy in patients with a PS 0-2 who have achieved tumor response or stable disease following initial therapy; **AND**
  - Used in combination with pemetrexed following a first-line pembrolizumab/pemetrexed/(carboplatin or cisplatin) regimen for disease of non-squamous cell histology; **OR**
  - Used as a single agent following a pembrolizumab/(carboplatin or cisplatin)/(paclitaxel or albumin-bound-paclitaxel) regimen for disease of squamous cell histology; **OR**
  - Used as a single agent following a first-line pembrolizumab monotherapy regimen

** Note: Actionable molecular genomic biomarkers include EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, and RET rearrangement. If there is insufficient issue to allow testing for all of EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

Diagnosis of **Squamous Cell Carcinoma of the Head and Neck (SCCHN)**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as first-line therapy; **AND**
  – Patient is unfit for surgery or has locally advanced, unresectable, recurrent/persistent, or metastatic disease; **AND**
    - Used as a single-agent for tumors expressing PD-L1 (CPS ≥ 1) as determined by an FDA-approved test or CLIA-compliant test❖; **OR**
    - Used in combination with fluorouracil and a platinum chemotherapy agent; **OR**
  – Used as subsequent therapy; **AND**
    - Patient has locally advanced, unresectable, recurrent/persistent, or metastatic disease; **AND**
      - Used as a single-agent therapy for disease that has progressed on or after platinum-containing chemotherapy; **OR**
      - Used in combination with fluorouracil and either carboplatin or cisplatin in patients with non-nasopharyngeal disease and performance status 0-1

Diagnosis of **Adult Classical Hodgkin Lymphoma (cHL)**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as a single agent for relapsed or refractory disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Pediatric Classical Hodgkin Lymphoma (cHL)**

- Patient is at least 6 months of age*; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as a single agent; **AND**
  - Patient has refractory disease; **OR**
  - Patient has relapsed disease after two or more prior lines of therapy; **OR**
  - Used in patients heavily pretreated with platinum or anthracycline-based chemotherapy; **OR**
  - Used as subsequent therapy in patients with an observed decrease in cardiac function

** Pediatric Classical Hodgkin Lymphoma may be applicable to adolescent and young adult (AYA) patients up to the age of 39 years.*

Diagnosis of **Primary Mediastinal Large B-Cell Lymphoma (PMBCL)**

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified;
- Used as single agent; **AND**
- Patient has relapsed or refractory disease; **AND**
- Patient does not require urgent cytoreductive therapy; **AND**
- Patient is at least 6 months old

Diagnosis of **Bladder Cancer/Urothelial Carcinoma**

- Patient must be 18 years of age or older; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as a single agent; **AND**
- Patient has Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) defined as one of the following:
  - Persistent disease despite adequate BCG therapy; **OR**
  - Disease recurrence after an initial tumor free state following an adequate BCG course of therapy*; **OR**
  - T1 disease following a single induction course of BCG therapy; **AND**
- Patient has carcinoma in situ (CIS); **AND**
- Patient is ineligible for or has elected not to undergo cystectomy

** Adequate BCG therapy is defined as administration of at least five of six doses of an initial induction course AND at least two of three doses of maintenance therapy or at least two of six doses of a second induction course*

OR

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient has one of the following diagnoses:
  - Locally advanced or metastatic urothelial carcinoma; **OR**
  - Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder; **OR**
  - Metastatic or local bladder cancer recurrence post-cystectomy; **OR**
  - Primary carcinoma of the urethra; **AND**
    - Used for metastatic or recurrent disease *(excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes)*; **OR**
    - Used for clinical stage T3-4, cN1-2 disease, or cN1-2 palpable inguinal lymph nodes (*first-line therapy only*); **AND**
  - Metastatic upper genitourinary (GU) tract tumors; **OR**
  - Metastatic urothelial carcinoma of the prostate; **AND**
- Used for disease that progressed during or following platinum-containing chemotherapy***** **OR**
- Used as second-line treatment after therapy other than a platinum or an immune checkpoint inhibitor; **OR**
- Used as first-line therapy in cisplatin-ineligible patients; **AND**
  - Patient is carboplatin-ineligible; **OR**
  - Tumors express PD-L1 (CPS ≥ 10) as determined by an FDA-approved or CLIA-compliant test ❖

*** Note:**
- If platinum treatment occurred greater than 12 months ago, the patient should be re-treated with platinum-based therapy if the patient is still platinum eligible (see below for cisplatin- or carboplatin-ineligible comorbidities).
- Cisplatin-ineligible comorbidities may include the following: GFR < 60 mL/min, PS ≥ 2, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, or grades ≥ 2 peripheral neuropathy. Carboplatin may be substituted for cisplatin particularly in those patients with a GFR <60 mL/min or a PS of 2.
- Carboplatin-ineligible comorbidities may include the following: GFR < 30 mL/min, PS ≥ 3, grade ≥ 3 peripheral neuropathy, or NYHA class ≥ 3, etc.

Diagnosis of **Cervical Cancer**

- Patient must be 18 years of age or older; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Patient has persistent, recurrent, or metastatic disease; **AND**
- Tumor expresses PD-L1 (e.g., CPS ≥ 1) as determined by an FDA-approved test or CLIA-compliant test❖; **AND**
  - Used as a single agent: **AND**
    - Disease has progressed on or after chemotherapy; **OR**
  - Used in combination with chemotherapy

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Microsatellite Instability-High (MSI-H) Cancer**

- Patient must be at least 6 months of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as a single agent; **AND**
- Patient's disease must be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); **AND**
- Pediatric patients must not have a diagnosis of MSI-H central nervous system cancer; **AND**
- Patient has one of the following cancers**:**
  - Colorectal cancer
    - Used as primary treatment of unresectable or medically inoperable, locally advanced, or metastatic disease *(excluding use as neoadjuvant therapy in rectal cancer)*; **OR**
    - Used for unresectable (or medically inoperable) metastases that remains unresectable after primary systemic therapy; **OR**
    - Used for unresectable advanced or metastatic disease that has progressed following treatment with one of the following:
      - Fluoropyrimidine, oxaliplatin, and/or irinotecan-based chemotherapy; **OR**
      - Non-intensive therapy
  - Pancreatic adenocarcinoma
    - Used as subsequent therapy for locally advanced or metastatic disease after progression; **OR**
    - Used for recurrent or metastatic disease after resection; **OR**
    - Used as first-line therapy for metastatic disease in patients with poor performance status (i.e., ECOG ≥2)
  - Bone cancer (Ewing sarcoma, chondrosarcoma [excluding dedifferentiated or mesenchymal subtypes], or osteosarcoma [excluding high-grade undifferentiated pleomorphic sarcoma])
    - Used for unresectable or metastatic disease that has progressed following prior treatment; **AND**
    - Patient has no satisfactory alternative treatment options
  - Gastric adenocarcinoma **or** esophageal/gastroesophageal junction adenocarcinoma or squamous cell carcinoma
    - Used as subsequent therapy for patients who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease
  - Ovarian cancer (epithelial ovarian, fallopian tube, and primary peritoneal cancers)
    - Patient has carcinosarcoma (i.e., malignant mixed Müllerian tumor [MMMT]), clear cell, endometrioid, mucinous, or serous histology; **AND**
    - Used for patients with persistent or recurrent disease; **AND**
    - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 with no radiographic evidence of disease)
  - Uterine cancer (endometrial carcinoma)
    - Used as second-line therapy for recurrent, metastatic, or high-risk disease that has progressed following prior treatment
  - Penile cancer
    - Used as subsequent treatment for unresectable or metastatic disease that has progressed following prior treatment; **AND**
    - Patient has no satisfactory alternative treatment options
  - Testicular cancer
    - Used as third-line therapy

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Hepatobiliary adenocarcinoma (gallbladder cancer, intra-/extra-hepatic cholangiocarcinoma)
  - Used as primary treatment for unresectable or metastatic disease; **OR**
  - Used for unresectable or metastatic disease that has progressed following prior treatment
- Vulvar squamous cell carcinoma
  - Used for advanced, recurrent, or metastatic disease as second-line therapy
- Cervical cancer
  - Used as second-line therapy for persistent, recurrent, or metastatic disease
- Small bowel adenocarcinoma or Advanced Ampullary Cancer
  - Used for advanced or metastatic disease; **AND**
    - Used as initial therapy; **OR**
    - Used as subsequent therapy in patients without a contraindication to oxaliplatin
- Breast cancer
  - Used for recurrent unresectable or metastatic disease **OR** inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
  - Patient has progressed following prior treatment; **AND**
  - Patient has no satisfactory alternative treatment options
- Occult primary/cancer of unknown primary (CUP)
  - Used in symptomatic patients with PS 1-2 OR asymptomatic patients with PS 0 and aggressive disease; **AND**
  - Patient has adenocarcinoma or carcinoma not otherwise specified; **AND**
  - Patient has one of the following:
    - Axillary involvement in men if clinically indicated
    - Lung nodules or breast marker-negative pleural effusion
    - Resectable liver disease
    - Peritoneal mass or ascites with non-ovarian histology
    - Retroperitoneal mass of non-germ cell histology in selected patients
    - Unresectable liver disease or disseminated metastases; **OR**
- Very Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN)
  - Patient has non-nasopharyngeal cancer; **AND**
  - Patient is unfit for surgery or has locally advanced, unresectable, recurrent/persistent, or metastatic disease
- Prostate Cancer
  - Patient has castration-resistant metastatic disease; **AND**
  - Patient will continue androgen deprivation therapy (ADT); **AND**
    - Patient received prior docetaxel and no prior novel hormone therapy; **OR**
    - Patient received prior novel hormone therapy and no prior docetaxel; OR
    - Patient received prior docetaxel and prior novel hormone therapy (excluding patients with visceral metastases)
- Neuroendocrine Tumors (Poorly differentiated neuroendocrine carcinoma, poorly differentiated unknown primary, or large or small cell carcinoma [other than lung])
  - Patient progressed following prior treatment and has no satisfactory alternative treatment options

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Vulvar Squamous Cell Carcinoma**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as a single agent; **AND**
- Patient has advanced, recurrent, or metastatic disease; **AND**
- Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved test or CLIA-compliant test; **AND**
- Used as second-line therapy for disease progression on or after chemotherapy

Diagnosis of **Thymic Carcinoma**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as a single agent; **AND**
  - Used as first line therapy for unresectable, locally advanced, or metastatic disease in patients who are unable to tolerate first-line combination regimens; **OR**
  - Used as postoperative treatment in patients who are unable to tolerate first-line combination regimens; **OR**
  - Used as second-line therapy for unresectable or metastatic disease

Diagnosis of **Malignant Pleural Mesothelioma (MPM)**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as subsequent therapy as a single agent.

Diagnosis of **Central Nervous System (CNS) Cancer**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as single agent therapy; **AND**
- Primary tumor is due to melanoma or PD-L1 positive non-small cell lung cancer (NSCLC); **AND**
  - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
  - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **T-Cell Lymphoma/Extranodal NK**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as a single agent for relapsed or refractory nasal type disease; **AND**
- Disease progressed following additional treatment with an alternative asparaginase-based chemotherapy regimen not previously used; **AND**
- Participation in a clinical trial is unavailable

Diagnosis of **Anal Carcinoma**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Patient has metastatic squamous cell carcinoma; **AND**
- Used as a single agent for subsequent therapy.

Diagnosis of **Gestational Trophoblastic Neoplasia**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as single-agent therapy for multiagent chemotherapy-resistant disease; **AND**
  - Patient has intermediate placental site trophoblastic (PSTT) or epithelioid trophoblastic tumor (ETT); **AND**
    - Patient has recurrent or progressive disease; **AND**
    - Patient was previously treated with a platinum/etoposide containing regimen; **OR**
  - Patient has high risk disease (i.e., ≥ 7 prognostic score or stage IV disease)

Diagnosis of **Hepatocellular Carcinoma (HCC)**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as a single agent; **AND**
- Patient was previously treated with sorafenib; **AND**
- Patient has Child-Pugh Class A liver impairment *(i.e., excluding Child-Pugh Class B and C)*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Mycosis Fungoides/Sézary Syndrome**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as primary therapy or for relapsed or persistent disease; **AND**
  - Patient has stage III Mycosis Fungoides; **OR**
  - Patient has stage IV Sézary Syndrome; **OR**
- Used for disease refractory to multiple previous therapies

Diagnosis of **Renal Cell Carcinoma (RCC)**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Patient has clear cell histology; **AND**
  - Used in combination with axitinib; **AND**
    - Used as first-line therapy for advanced, relapsed, or stage IV disease; **OR**
    - Used as subsequent therapy for relapsed or stage IV disease; **OR**
  - Used in combination with lenvatinib ; **AND**
    - Used for relapsed or stage IV disease; **OR**
  - Patient has non-clear cell histology; **AND**
    - Used as a single agent for relapsed or stage IV disease

Diagnosis of **Endometrial Carcinoma (Uterine Cancer)**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Patient has advanced or recurrent disease; **AND**
- Disease has progressed following prior systemic therapy; **AND**
- Patient is not a candidate for curative surgery or radiation; **AND**
- Used in combination with lenvatinib

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Soft Tissue Sarcoma**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as a single agent; **AND**
  - Patient has alveolar soft part sarcoma (ASPS); **OR**
  - Patient has cutaneous angiosarcoma; **OR**
  - Patient has myxofibrosarcoma, undifferentiated pleomorphic sarcoma (UPS), or undifferentiated sarcoma (Retroperitoneal/Intra-Abdominal or Extremity/Body Wall, Head/Neck soft tissue sarcomas); **AND**
    - Used as subsequent therapy for advanced or metastatic disease

Diagnosis of **Tumor Mutational Burden-High (TMB-H) Cancer**

- Patient must be at least 6 months old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Patient has solid tumors that are tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb) as determined by an FDA-approved or CLIA-compliant test; **AND**
- Used as a single agent; **AND**
- Pediatric patients must not have a diagnosis of TMB-H central nervous system cancer; **AND**
- Patient has one of the following cancers:
  - **Bone Cancer (Ewing Sarcoma, Chordoma, Chondrosarcoma** *[chondroid or conventional histology]*, Chondrosarcoma *[excluding dedifferentiated or mesenchymal subtypes]*, or Osteosarcoma *[excluding undifferentiated pleomorphic sarcoma]*)
    - Patient has unresectable or metastatic disease that progressed following prior treatment; **AND**
    - Patient has no satisfactory alternative treatment options
  - **Breast Cancer**
    - Patient has recurrent unresectable or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
    - Patient has progressed following prior treatment; **AND**
    - Patient has no satisfactory alternative treatment options
  - **Cervical Cancer**
    - Used as second-line therapy for unresectable or metastatic disease; **AND**
    - Patient has no satisfactory alternative treatment options
  - **Gastric Adenocarcinoma OR Esophageal/Gastroesophageal Junction Adenocarcinoma or Squamous Cell Carcinoma**
    - Used as subsequent therapy for patients who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease
  - **Hepatobiliary Adenocarcinoma (gallbladder cancer, intra-/extra-hepatic cholangiocarcinoma)**
    - Used for unresectable or metastatic disease that has progressed following prior treatment
  - **Salivary Gland Tumors**
    - Used for recurrent metastatic disease in patients with a PS 0-3; **OR**
    - Used for unresectable locoregional recurrence or second primary with prior radiation therapy

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- **Thyroid Carcinoma**
  - Anaplastic Carcinoma
    - Used as first- or second-line therapy for metastatic disease
  - Follicular Carcinoma, Papillary Carcinoma, Hürthle Cell Carcinoma
    - Patient has unresectable locoregional recurrent/persistent or metastatic disease not amenable to radioactive iodine (RAI)
  - Medullary Carcinoma
    - Patient has unresectable locoregional or recurrent/persistent metastatic disease
- **Uterine Cancer** (uterine sarcoma *[excluding low-grade endometrial stromal sarcoma]*, endometrial carcinoma)
  - Used as second-line therapy for unresectable or metastatic disease that progressed following prior treatment; **AND**
  - Patient has no satisfactory alternative treatment options
- **Vulvar Squamous Cell Carcinoma**
  - Used for advanced, recurrent, or metastatic disease as second-line therapy; **AND**
  - Patient has no satisfactory alternative treatment options
- **Testicular Cancer**
  - Used as third-line therapy
- **Occult Primary/Cancer of Unknown Primary (CUP)**
  - Used in symptomatic patients with PS 1-2 OR asymptomatic patients with PS 0 and aggressive disease; **AND**
    - Patient has squamous cell carcinoma; **AND**
      - Patient has multiple lung nodules, pleural effusion, or disseminated metastases; **OR**
    - Patient has adenocarcinoma or carcinoma not otherwise specified; **AND**
      - Patient has one of the following:
        - Axillary involvement in men if clinically indicated
        - Lung nodules or breast marker-negative pleural effusion
        - Resectable liver disease
        - Peritoneal mass or ascites with non-ovarian histology
        - Retroperitoneal mass of non-germ cell histology in selected patients
        - Unresectable liver disease or disseminated metastases
- **Ovarian Cancer (epithelial ovarian, fallopian tube, and primary peritoneal cancers)**
  - Patient has carcinosarcoma (i.e., malignant mixed Mullerian tumor [MMMT]), clear cell, endometrioid, mucinous, or serous histology; **AND**
  - Used for patients with persistent or recurrent disease; **AND**
  - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 with no radiographic evidence of disease); **AND**
  - Patient has no satisfactory alternative treatment options
- **Well-Differentiated Grade 3 Neuroendocrine Tumors**
  - Patient has locally advanced or metastatic disease with unfavorable biology (e.g., relative high Ki-67 [≥55%], rapid growth rate, negative SSR-based PET imaging); **AND**
  - Patient progressed following prior treatment and has no satisfactory alternative treatment options
- **Neuroendocrine Tumors (Poorly differentiated neuroendocrine carcinoma, poorly differentiated unknown primary, or large or small cell carcinoma [other than lung])**
  - Patient progressed following prior treatment and has no satisfactory alternative treatment options

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Cutaneous Squamous Cell Carcinoma (cSCC)**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Used as a single agent; **AND**
  - Patient has recurrent or metastatic disease; **OR**
  - Patient has locally advanced, high-risk, or very high-risk disease that is not curable by surgery or radiation; **OR**
  - Patient has inoperable or not fully resectable new regional disease that is not curable by radiation therapy

Diagnosis of **Adrenal Gland Tumors**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Patient has locoregional unresectable or metastatic adrenocortical carcinoma (ACC); **AND**
- Used with or without mitotane

Diagnosis of **Triple Negative Breast Cancer (TNBC)**

- Patient must be at least 18 years old; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, etc.) unless otherwise specified; **AND**
- Patient has recurrent unresectable or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
  - Used in combination with chemotherapy; **AND**
  - Tumor expresses PD-L1 (CPS ≥ 10) as determined by an FDA-approved or CLIA-compliant test❖; **OR**
- Patient has high-risk early-stage disease; **AND**
  - Used as neoadjuvant therapy in combination with chemotherapy; **OR**
  - Used as adjuvant therapy as a single agent

❖ If confirmed using an immunotherapy assay: http://www.fda.gov/companiondiagnostics

Genomic Aberration/Mutational Driver Targeted Therapies (Note: *not all inclusive, refer to guidelines for appropriate use*)				
Sensitizing *EGFR* mutation-positive tumors	*ALK* rearrangement-positive tumors	*ROS1* rearrangement-positive tumors	*BRAF* V600E-mutation positive tumors	*NTRK* Gene Fusion positive tumors
– Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab *(exon-20 insertion)*	– Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib	– Ceritinib – Crizotinib – Entrectinib	– Dabrafenib ± Trametinib – Vemurafenib	– Larotrectinib – Entrectinib
PD-1/PD-L1 expression-positive tumors (≥1%)	*MET* Exon-14 skipping mutations	*RET* rearrangement-positive tumors	KRAS G12C mutations	
– Pembrolizumab – Atezolizumab – Nivolumab ± ipilimumab	– Capmatinib – Crizotinib – Tepotinib	– Selpercatinib – Cabozantinib – Vandetanib – Pralsetinib	– Sotorasib	

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, dermatologic adverse reactions/rash, etc.), hepatotoxicity when used in combination with axitinib, etc; **AND**
- For the following indications, patient has not exceeded a maximum of 24 months of therapy:
  - Anal Carcinoma
  - Bladder Cancer/Urothelial Carcinoma
  - Cervical Cancer
  - Classical Hodgkin Lymphoma (cHL)
  - CNS Metastases
  - Cutaneous Melanoma (in combination with ipilimumab only)
  - Cutaneous Squamous Cell Carcinoma (cSCC)
  - Endometrial Carcinoma
  - Esophageal/Gastroesophageal Cancer
  - Gastric Cancer
  - Hepatocellular Carcinoma (HCC)
  - Malignant Pleural Mesothelioma (MPM)
  - Merkel Cell Carcinoma (MCC)
  - MSI-H/dMMR Cancer
  - Mycosis Fungoides/Sezary Syndrome
  - Non-Small Cell Lung Cancer (NSCLC)

CLINICAL CRITERIA FOR RENEWAL *(CONTUNED)*

- Primary Mediastinal Large B-Cell Lymphoma (PMBCL)
- Renal Cell Carcinoma (RCC)
- Squamous Cell Carcinoma of the Head and Neck (SCCHN)
- Thymic Carcinoma
- Tumor Mutational Burden-High (TMB-H) Cancer
- Triple Negative Breast Cancer (recurrent unresectable or metastatic disease)
- Uveal Melanoma
- Vulvar Squamous Cell Carcinoma

Cutaneous Melanoma (adjuvant treatment)

- Patient has not exceeded a maximum of 12 months of therapy

Triple Negative Breast Cancer (neoadjuvant treatment)

- Patient has not exceeded a maximum of 24 weeks of therapy

Triple Negative Breast Cancer (adjuvant treatment)

- Patient has not exceeded a maximum of 27 weeks of therapy

Cutaneous Melanoma (subsequent treatment after prior anti-PD-1 immunotherapy)

- Refer to criteria under initial

Continuation Maintenance Therapy for NSCLC

- Refer to criteria under initial

KISQALI® (RIBOCICLIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology (IE 2462 / NCPDP 75)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

CORE FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Standard, Precision/Plus, Core: For Kisqali® and Kisqali Femara®: For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Ibrance®

Diagnosis of **Breast Cancer**

- Patient is at least 18 years of age; **AND**
- Baseline ECG indicates QTcF is less than 450 msec; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin, nefazodone, grapefruit, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with drugs that prolong QT (e.g., amiodarone, quinidine, sotalol, etc.) and the QT interval (e.g., clarithromycin, haloperidol, methadone, etc.); **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
- Patient has hormone receptor (HR)-positive disease; **AND**
- Used for recurrent, unresectable, advanced, or metastatic disease OR patient has inflammatory disease with no response to pre-operative systemic therapy; **AND**
- Patient has no visceral crisis; **AND**
- Patient is postmenopausal, premenopausal with ovarian ablation/suppression, or male with suppression of testicular steroidogenesis; **AND**
  - Used as initial therapy in combination with a non-steroidal aromatase inhibitor (i.e., anastrozole, letrozole, etc.) or fulvestrant; **OR**
  - Used as subsequent therapy in combination with fulvestrant

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: QT interval prolongation, hepatobiliary toxicity, neutropenia, severe interstitial lung disease/pneumonitis, severe cutaneous adverse reactions (e.g., Stevens-Johnson Syndrome [SJS], toxic epidermal necrolysis [TEN], drug-induced hypersensitivity syndrome [DiHS], drug reaction with eosinophilia and systemic symptoms [DRESS]); **AND**
- QTcF interval is not > 500 msec; **OR**
- QTcF interval has not had a > 60 msec change from baseline along with any of the following: Torsades de Pointes, polymorphic ventricular tachycardia, unexplained syncope, or signs/symptoms of serious arrhythmia

ENHANCED FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Enhanced: For Kisqali® and Kisqali Femara®: For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Ibrance® OR Verzenio

Diagnosis of **Breast Cancer**

- Patient is at least 18 years of age; **AND**
- Baseline ECG indicates QTcF is less than 450 msec; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin, nefazodone, grapefruit, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with drugs that prolong QT (e.g., amiodarone, quinidine, sotalol, etc.) and the QT interval (e.g., clarithromycin, haloperidol, methadone, etc.); **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
- Patient has hormone receptor (HR)-positive disease; **AND**
- Used for recurrent, unresectable, advanced, or metastatic disease OR patient has inflammatory disease with no response to pre-operative systemic therapy; **AND**
- Patient has no visceral crisis; **AND**
- Patient is postmenopausal, premenopausal with ovarian ablation/suppression, or male with suppression of testicular steroidogenesis; **AND**
  - Used as initial therapy in combination with a non-steroidal aromatase inhibitor (i.e., anastrozole, letrozole, etc.) or fulvestrant; **OR**
  - Used as subsequent therapy in combination with fulvestrant

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: QT interval prolongation, hepatobiliary toxicity, neutropenia, severe interstitial lung disease/pneumonitis, severe cutaneous adverse reactions (e.g., Stevens-Johnson Syndrome [SJS], toxic epidermal necrolysis [TEN], drug-induced hypersensitivity syndrome [DiHS], drug reaction with eosinophilia and systemic symptoms [DRESS]); **AND**
- QTcF interval is not > 500 msec; **OR**
- QTcF interval has not had a > 60 msec change from baseline along with any of the following: Torsades de Pointes, polymorphic ventricular tachycardia, unexplained syncope, or signs/symptoms of serious arrhythmia

KORLYM® (MIFEPRISTONE)

Length of Authorization:	6 Months
Initiative:	MNC: Hormone Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of Endogenous Cushing's syndrome with secondary hyperglycemia; **OR**
- Diagnosis of Type 2 DM;
- Patient must have failed or not be candidate for pituitary surgery

KOSELUGO® (SELUMETINIB)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE: 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Neurofibromatosis Type-1 (NF1)**

- Patient is at least 2 years or older; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with strong or moderate CYP3A4 inhibitors (e.g., fluconazole, itraconazole) if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Patient will not receive vitamin E supplementation greater than 100% of the daily recommended dose**; AND**
- Patient does not have severe hepatic impairment (i.e., Child-Pugh C); **AND**
- Patient will have a comprehensive ophthalmic exam prior to initiating therapy and at regular intervals during treatment, and for new or worsening visual changes; **AND**
- Patient serum creatinine phosphokinase (CPK) will be measured at baseline and periodically during treatment as clinically indicated; **AND**
- Will not be used in combination with other MEK inhibitors (e.g., binimetinib, cobimetinib, trametinib); **AND**
- Patient has a confirmed diagnosis of NF1 as defined by either of the following:
  - Patient has positive genetic testing for NF1 as evidenced by heterozygous pathogenic variants in *NF1*-gene; **OR**
  - Patient at least one of the diagnostic criteria for NF1 listed below:
    - Six or more cafe-au-lait macules (≥ 0.5cm in pre-pubertal subjects or ≥ 1.5 cm in post-pubertal subjects)
    - Two or more neurofibromas or one plexiform neurofibroma
    - Freckling in axilla or groin
    - Optic glioma
    - Two or more Lisch nodules
    - A distinctive bony lesion (dysplasia of the sphenoid bone or dysplasia or thinning of long bone cortex)
    - A first-degree relative with NF1; **AND**
- Patient has symptomatic plexiform neurofibromas (PN) (e.g., lesions causing significant morbidity defined by, but not limited to, head and neck lesions that could compromise the airway or great vessels, paraspinal lesions that can cause myelopathy brachial or lumbar plexus lesions that could cause nerve compression and loss of function, lesions that could result in major deformity [e.g., orbital lesions] or are significantly disfiguring, lesions of the extremity that cause limb hypertrophy or loss of function, and painful lesions); **AND**
- Patient PN are inoperable (i.e., PN could not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Central Nervous System Cancers**

- Patient is at least 18 years or older; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with strong or moderate CYP3A4 inhibitors (e.g., fluconazole, itraconazole) if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Patient will not receive vitamin E supplementation greater than 100% of the daily recommended dose**; AND**
- Patient does not have severe hepatic impairment (i.e., Child-Pugh C); **AND**
- Patient will have a comprehensive ophthalmic exam prior to initiating therapy and at regular intervals during treatment, and for new or worsening visual changes; **AND**
- Patient serum creatinine phosphokinase (CPK) will be measured at baseline and periodically during treatment as clinically indicated; **AND**
- Will not be used in combination with other MEK inhibitors (e.g., binimetinib, cobimetinib, trametinib); **AND**
- Used as single-agent therapy; **AND**
- Used for BRAF fusion or BRAF V600E activating mutation positive recurrent or progressive pilocytic astrocytoma; **AND**
- Patient has had prior fractionated external beam radiation therapy (EBRT)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., cardiomyopathy, ocular toxicities [e.g., retinal vein occlusion or retinal pigment epithelial detachment], severe diarrhea, severe skin rashes, rhabdomyolysis, bleeding) **AND**
- Left ventricular ejection fraction (LVEF) has not had an **absolute** decrease from baseline ≥ 10% and is not below the lower limit of normal (LLN)

CNS Cancer

- Patient has not received more than twenty-six 28-day course treatments

KRYSTEXXA® (PEGLOTICASE)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE: 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Gout**

- Patient is at least 18 years of age; **AND**
- Patients at higher risk for glucose-6-phosphate dehydrogenase (G6PD) deficiency have been screened and found negative for G6PD before starting Krystexxa; **AND**
- Documentation of baseline serum uric acid level ≥ 8 mg/dL (current lab reports are required for renewal); **AND**
- Therapy will not be given in combination with other urate lowering therapies such as allopurinol, febuxostat, probenecid, lesinurad, etc.; **AND**
- Patient has one of the following:
  - Two or more gout flares per year that were inadequately controlled by colchicine, nonsteroidal anti-inflammatory drugs (NSAIDS), or oral or injectable corticosteroids; **OR**
  - Nonresolving subcutaneous tophi; **AND**
  - Radiographic damage of any modality that is attributable to gout
- Documented contraindication, intolerance, or clinical failure (i.e., inability to reduce serum uric acid to < 6 mg/dL) during a minimum 3-month trial on previous therapy with maximum tolerated dose of xanthine oxidase inhibitors (e.g., allopurinol or febuxostat) or uricosuric agents (e.g., probenecid, lesinurad, etc.)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with (i.e., reduction of symptoms, reduction of tophi); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: anaphylaxis, infusion reactions, exacerbation of congestive heart failure; **AND**
- Documentation of serum uric acid level < 6 mg/dL prior to scheduled infusion

KUVAN® (SAPROPTERIN)

Length of Authorization:	1 Year
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **phenylketonuria (PKU)**

- Physician must be a metabolic specialist.
- Patient must be on a Phenylalanine (Phe) restricted diet.
- Confirm that Phe levels cannot be maintained within recommended range with dietary intervention alone.
- Document baseline Phe level. Baseline level should be greater than 600 µmol/L.

INITIAL RENEWAL

Technician: Document current Phe level. Pharmacist: After initial 2-month approval confirm that patient has had at least a 30% reduction in baseline.

RENEWAL AFTER 1 YEAR

Technician: Document current Phe level.

Pharmacist: Once responsiveness is established, dose should be adjusted within the range of 5-20mg/kg PO once daily. Maximum dosing is 20mg/kg/day. Phe levels below should be maintained.

- Neonates thru 12 – 120-360 µmol/dL (2–6 mg/dL)
- Greater than 12 – 120-960 µmol/dL (2–15 mg/dL)
- During pregnancy – 120-360 µmol/dL (2–6 mg/dL)

KYMRIAH® (TISAGENLECLEUCEL)

Length of Authorization:	Coverage is for one treatment course, may not be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Submission of medical records related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation via direct upload through the PA web portal or by fax.

Diagnosis of **Adult B-Cell Precursor Acute Lymphoblastic Leukemia (ALL):**

- Patient does not have an active infection or inflammatory disorder; **AND**
- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy and will not receive live vaccines during tisagenlecleucel treatment and until immune recovery following treatment; **AND**
- Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Prophylaxis for infection will be followed according to local guidelines; **AND**
- Healthcare facility has enrolled in the Kymriah REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
- Patient has not received prior CAR-T therapy; **AND**
- Patient has not received prior anti-CD19 therapy, (e.g., blinatumomab) **or** patient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**
- Used as single agent therapy (not applicable to lymphodepleting or bridging chemotherapy); **AND**
- Patient is 18 to 25 years of age; **AND**
- Patient has a performance status (Karnofsky/Lansky) ≥ 50; **AND**
  - Patient has Philadelphia chromosome (Ph)-positive disease; **AND**
    - Patient has refractory disease; **OR**
    - Disease is in second or greater relapse with failure of two (2) tyrosine kinase inhibitors (e.g., dasatinib, imatinib, ponatinib, nilotinib, bosutinib, etc.); **OR**
  - Patient has Philadelphia chromosome (Ph)-negative disease; **AND**
    - Disease is refractory or in second or later relapse

Diagnosis of **Pediatric B-Cell Precursor Acute Lymphoblastic Leukemia (ALL):**

- Patient does not have an active infection or inflammatory disorder; **AND**
- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy and will not receive live vaccines during tisagenlecleucel treatment and until immune recovery following treatment; **AND**
- Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Prophylaxis for infection will be followed according to local guidelines; **AND**
- Healthcare facility has enrolled in the Kymriah REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
- Patient has not received prior CAR-T therapy; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient has not received prior anti-CD19 therapy, (e.g., blinatumomab) **or** patient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**
- Used as single agent therapy (not applicable to lymphodepleting or bridging chemotherapy); **AND**
- Patient is 2 to 17 years of age; **AND**
- Patient has a performance status (Karnofsky/Lansky) ≥ 50; **AND**
  - Patient has Philadelphia chromosome (Ph)-positive disease; **AND**
    - Disease is tyrosine kinase inhibitor (TKI) intolerant or refractory; **OR**
    - Patient has relapsed disease post-hematopoietic stem cell transplant (HSCT); **OR**
  - Patient has Philadelphia chromosome (Ph)-negative disease; **AND**
    - Disease is refractory or in second or later relapse

Diagnosis of **B-Cell Lymphoma:**

- Patient is 18 years of age or older; **AND**
- Patient does not have an active infection or inflammatory disorder; **AND**
- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy and will not receive live vaccines until immune recovery following Kymriah treatment; **AND**
- Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Prophylaxis for infection has been followed according to local guidelines; **AND**
- Healthcare facility has enrolled in the Kymriah REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
- Patient has not received prior CAR-T therapy; **AND**
- Patient has not received prior anti-CD19 therapy, (e.g., blinatumomab) **or** patient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**
- Used as single agent therapy (not applicable to lymphodepleting or bridging chemotherapy); **AND**
- Patient has an ECOG performance status of 0-1; **AND**
- Patient does not have primary central nervous system lymphoma; **AND**
  - Patient has histologic transformation of follicular lymphoma or nodal marginal zone lymphoma to diffuse large B-cell lymphoma (DLBCL) OR Richter's transformation of CLL to DLBCL; **AND**
    - Patient received at least 2 prior lines of chemoimmunotherapy which must have included an anthracycline or anthracenedione-based regimen, unless contraindicated; **OR**
  - Patient has diffuse large B-cell lymphoma, AIDS-related B-cell lymphoma (e.g., diffuse large B-cell lymphoma, primary effusion lymphoma, and HHV8-positive diffuse large B-cell lymphoma, not otherwise specified), high-grade B-cell lymphomas, or monomorphic post-transplant lymphoproliferative disorder (B-cell type); **AND**
    - Used as additional therapy for patients with intention to proceed to transplant who have a partial response following second-line therapy for relapsed or refractory disease; **AND**
    - Used for treatment of disease that is in second or greater relapse

CLINICAL CRITERIA FOR RENEWAL

Coverage cannot be renewed

KYNAMRO® (MIPOMERSEN)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Homozygous familial hypercholesterolemia (HoFH)**

- Patient at least 18 years old; **AND**
- Prescriber must be enrolled in and meet the conditions of the Kynamro REMS program; **AND**
- Therapy is **not** being used as an adjunct to LDL apheresis; **AND**
- Patient does not have moderate to severe hepatic impairment (Child-Pugh B or C) or active liver disease (including unexplained persistent elevations of serum transaminases); **AND**
- Baseline alanine and aspartate aminotransferases (ALT, AST), alkaline phosphatase, and total bilirubin lab values must be obtained prior to initiating treatment; **AND**
- Baseline low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment and required for renewal; **AND**
- Diagnoses of HoFH must be confirmed by the presence of at least one of the following:
  - Documented DNA test for functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality; **OR**
  - Untreated LDL-C >500 mg/dL or treated LDL-C ≥ 300 mg/dL ; **AND**
    - Cutaneous or tendon xanthoma before age 10 years; **OR**
    - Untreated LDL-C in both parents consistent with HeFH ; **AND**
- Must be used as an adjunct to a low-fat diet supplying < 20% of energy from fat; **AND**
- Patient has tried and failed at least a 3-month trial of adherent therapy with: ezetimibe (Zetia) used in combination with the highest available (or maximally tolerated*) dose of atorvastatin (Lipitor) or rosuvastatin (Crestor), unless contraindicated; **AND**
- Patient has tried and failed at least a 3 month trial of adherent therapy with: combination therapy consisting of the highest available (or maximally tolerated*) dose of atorvastatin **or** rosuvastatin, ezetimibe, **and** a PSCK9 inhibitor indicated for HoFH (e.g., evolocumab, etc.), unless contraindicated; **AND**
- Despite pharmacological treatment with a PCSK9 inhibitor, statin, and ezetimibe, the patient's LDL cholesterol ≥ 100 mg/dL (or ≥ 70 mg/dL for patients with clinical atherosclerotic cardiovascular disease (ASCVD))

*If the patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms.

- Documentation must demonstrate that the patient experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following:
  - Muscle symptoms resolve after discontinuation of statin; **AND**
  - Muscle symptoms occurred when re-challenged at a lower dose of the same statin; **AND**
  - Muscle symptoms occurred after switching to an alternative statin; **AND**
  - Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease); **OR**
- The patient has been diagnosed with rhabdomyolysis associated with statin use
  - The diagnosis should be supported by acute neuromuscular illness or dark urine **AND** an acute elevation in creatine kinase (usually > 5,000 IU/L or 5 times the upper limit of normal [ULN])

CLINICAL CRITERIA FOR RENEWAL

- Documented reduction of low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) from pre-mipomersen baseline; **AND**
- Documentation of dosage adjustment if ALT or AST is ≥ 3 times the upper limit of normal (ULN); **AND**
- Patient has demonstrated continued adherence to lipid-lowering therapy with rosuvastatin/atorvastatin, ezetimibe, PCSK9-I plus mipomersen; **AND**
- Absence of unacceptable toxicity from the drug (e.g., elevations in transaminases [ALT, AST], hepatic steatosis, serious injection site reactions, flu-like symptoms, hypersensitivity reactions)

KYNMOBI™ (APOMORPHINE)

Length of Authorization:	6 months initial, 1 year renewal
Initiative:	SPC: Parkinson's Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diangosis of **Parkinson Disease (PD)**

- Patient is ≥ 18 years of age; **AND**
- Patient is experiencing "off" episodes of PD at least 2 hours per day on average; **AND**
- Patient is on a stable levodopa-based therapy; **AND**
- Patient has tried and failed adequate trials of adjunct therapies (e.g., dopamine agonists, subcutaneous apomorphine, levodopa extended-release, levodopa intestinal infusion, catechol-o-methyl transferase [COMT] inhibitors, monoamine oxidase B (MAO-B) inhibitors, amantadine derivatives); **AND**
- Patients will NOT be on a concomitant 5HT3 antagonists (e.g., ondansetron, granisetron, dolansetron, palonosetron, alosetron); **AND**
- Patient will be prescribed a non-5HT3 antagonist aniemtic (e.g., trimethobenzamide) for initial therapy; **AND**
- Patient does not have a known hypersensitivity to apomorphine or any ingredient of the product, including sodium metabisulfite; **AND**
- Patient does not have a major psychotic disorder

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient has demonstrated a beneficial response to therapy (e.g., decrease in frequency and duration from baseline in motor fluctuations ["off" episodes"]); **AND**
- Patient is absent of unacceptable toxicity from the drug (e.g., nausea or vomiting, oral mucosal irritation or stomatitis, decreased impulse control, syncope or hypotension, hallucinations or psychotic-like behavior, QTc prolongation, fibrotic complications, priapism, retinal atrophy or degeneration, excessive daytime sleepiness including falling asleep during activities that require active participation)

KYPROLIS® (CARFILZOMIB)

Length of Authorization:	6 Months, may be renewed *Combination therapy with lenalidomide and dexamethasone as subsequent treatment in multiple myeloma is limited to eighteen 28-day treatment cycles* *Combination therapy with cyclophosphamide, thalidomide, and dexamethasone as subsequent treatment in multiple myeloma is limited to twelve 28-day treatment cycles.)* *Treatment of Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma is limited to six 21-day induction therapy treatment cycles and eight 56-day maintenance therapy treatment cycles*
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma:**

- Patient is at least 18 years of age; **AND**
- Used as primary therapy for symptomatic disease or for disease relapse after 6 months following primary induction therapy with the same regimen; **AND**
  - Used in combination with lenalidomide and dexamethasone; **OR**
  - Used in combination with dexamethasone and cyclophosphamide**; OR**
- Used for previously treated relapsed, progressive, or refractory disease; **AND**
  - Used as a single agent; **OR**
  - Used in combination with dexamethasone with or without lenalidomide; **OR**
  - Used in combination with dexamethasone and daratumumab; **OR**
  - Used in combination with dexamethasone and cyclophosphamide with or without thalidomide; **OR**
  - Used in combination with dexamethasone and isatuximab-irfc; **OR**
  - Used in combination with panobinostat; **AND**
    - Patient has received at least 2 prior regimens, including bortezomib and an immunomodulatory agent (e.g., lenalidomide, thalidomide); **OR**
  - Used in combination with pomalidomide and dexamethasone; **AND**
    - Patient has received at least 2 prior therapies, including a proteasome inhibitor (e.g., bortezomib) and an immunomodulatory agent (e.g., lenalidomide, thalidomide); **AND**
    - Disease has progressed on or within 60 days of completion of the last therapy

Diagnosis of **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma:**

- Patient is at least 18 years of age; **AND**
- Used in combination with rituximab and dexamethasone (CaRD regimen); **AND**
  - Used as primary therapy; **OR**
  - Used for relapsed disease; **AND**
    - CaRD regimen was previously used as primary therapy; **AND**
    - Patient achieved a response from CaRD that lasted for at least 24 months.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Systemic Light Chain Amyloidosis**

- Patient is at least 18 years of age; **AND**
- Patient has relapsed or refractory non-cardiac disease; **AND**
  - Used as a single agent; **OR**
  - Used in combination with dexamethasone

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include cardiac toxicity, pulmonary toxicity, pulmonary hypertension, dyspnea, severe infusion-related reactions, tumor lysis syndrome (TLS), thrombocytopenia, hepatic toxicity/failure, thrombotic microangiopathy (including thrombotic thrombocytopenic purpura/hemolytic uremic syndrome [TTP/HUS]), acute renal failure, severe hypertension, posterior reversible encephalopathy syndrome (PRES), venous thromboembolic events, hemorrhage, progressive multifocal leukoencephalopathy (PML), etc.; **AND**
- Combination therapy with lenalidomide and dexamethasone as treatment in multiple myeloma may be renewed up to a maximum of eighteen 28-day treatment cycles.
- Combination therapy with cyclophosphamide, thalidomide, and dexamethasone as subsequent treatment in multiple myeloma may be renewed up to a maximum of twelve 28-day treatment cycles.
- Treatment of Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma may be renewed up to a maximum of six 21-day induction therapy treatment cycles and eight 56-day maintenance therapy treatment cycles

LAMPIT (NIFURTIMOX)

Length of Authorization:	60 days, no renewal
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is < 18 years old and weighs ≥ 2.5 kg; **AND**
- Patient has a diagnosis of Chagas disease confirmed by serologic testing by one of the following:
  - For patients < 8 months of age: direct observation of *Trypanosoma cruzi* by concentration test; **OR**
  - For patients 8 months to < 18 years of age: positive conventional ELISA result for both recombinant ELISA and total purified antigen ELISA; **AND**
- Patient was counseled to not drink alcohol while on treatment; **AND**
- Female patients of child-bearing age were counseled to use effective contraception during treatment; male patients with female partners of reproductive potential were counseled to use condoms; **AND**
- Prescriber attestation that the patient's pregnancy status will be evaluated and monitored; **AND**
- Prescriber attestation that the patient's body weight will be monitored every 14 days to assess the need for dose adjustments.

LARTRUVO (OLARATUMAB)

Length of Authorization:	Coverage may be renewed every 6 months for patients currently receiving olaratumab who continue to show clinical benefit. Initiating treatment with olaratumab is not supported by Phase 3 data.
Initiative:	SPC: Oncology agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Soft tissue sarcoma (STS)**

- Based on the recently completed results of the ANNOUNCE phase 3 soft tissue sarcoma study of Lartruvo in combination with doxorubicin, which did not confirm clinical benefit, specifically improvement in overall survival, the FDA recommends that patients who are currently receiving Lartruvo should consult with their healthcare provider about whether to remain on the treatment. The FDA also recommends that Lartruvo should not be initiated in new patients outside of an investigational study.

CLINICAL CRITERIA FOR RENEWAL

- Patient has been receiving olaratumab; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe infusion-related reactions, severe neutropenia)

LENVIMA® (LENVATINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Thyroid Carcinoma (Follicular/Hurthle Cell/Papillary)**

- Patient is 18 years of age or older; **AND**
- Patient's thyroid function has been assessed prior to initiating therapy and will receive ongoing monitoring during treatment; **AND**
- Patient will avoid coadministration with medicinal products that have a known potential to prolong the QT/QTc interval (e.g., Class Ia and III antiarrhythmics, etc.); **AND**
- Patient's cancer is locally recurrent or resectable, persistent, or metastatic; **AND**
- Patient's cancer is progressive and/or symptomatic; **AND**
- Patient has failed treatment with radioactive iodine; **AND**
- Will not be used in combination with other chemotherapy.

Diagnosis of **Thyroid Carcinoma (Medullary)**

- Patient is 18 years of age or older; **AND**
- Patient's thyroid function has been assessed prior to initiating therapy and will receive ongoing monitoring during treatment; **AND**
- Patient will avoid coadministration with medicinal products that have a known potential to prolong the QT/QTc interval (e.g., Class Ia and III antiarrhythmics, etc.); **AND**
- Patient has recurrent or persistent distant metastatic disease that is progressive or symptomatic; **AND**
  - Patient has failed prior treatment with vandetanib or cabozantinib; **OR**
  - Clinical trials or other systemic therapies with vandetanib or cabozantinib are not available and/or appropriate for the patient

Diagnosis of **Thyroid Carcinoma (Anaplastic)**

- Patient is 18 years of age or older; **AND**
- Patient's thyroid function has been assessed prior to initiating therapy and will receive ongoing monitoring during treatment; **AND**
- Patient will avoid coadministration with medicinal products that have a known potential to prolong the QT/QTc interval (e.g., Class Ia and III antiarrhythmics, etc.); **AND**
- Used as single agent therapy; **AND**
- Patient has metastatic disease; **AND**
- Patient is not tolerating or has had no response to other recommended treatments; **AND**
- Used in patients without curative options; **AND**
- Used as first or second line therapy

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Renal Cell Cancer (RCC)**

- Patient is 18 years of age or older; **AND**
- Patient's thyroid function has been assessed prior to initiating therapy and will receive ongoing monitoring during treatment; **AND**
- Patient will avoid coadministration with medicinal products that have a known potential to prolong the QT/QTc interval (e.g., Class Ia and III antiarrhythmics, etc.); **AND**
- Patient has advanced, relapsed, or stage IV disease; **AND**
  - Used in combination with everolimus; **AND**
    - Used as subsequent therapy for clear cell histology; **OR**
    - Patient has predominantly non-clear cell histology; **OR**
  - Used in combination with pembrolizumab; **AND**
    - Patient has clear cell histology

Diagnosis of **Hepatocellular Carcinoma (HCC)**

- Patient is 18 years of age or older; **AND**
- Patient's thyroid function has been assessed prior to initiating therapy and will receive ongoing monitoring during treatment; **AND**
- Patient will avoid coadministration with medicinal products that have a known potential to prolong the QT/QTc interval (e.g., Class Ia and III antiarrhythmics, etc.); **AND**
- Used as single-agent therapy; **AND**
- Patient has Child-Pugh Class A disease (i.e., excludes Child-Pugh Class B or C disease); **AND**
  - Patient has unresectable disease **AND**
    - Used as first-line therapy; **OR**
    - Patient is not a transplant candidate**; OR**
  - Patient is not a candidate for surgery or has local disease; **OR**
  - Patient has metastatic disease or has an extensive liver tumor burden

Diagnosis of **Endometrial Carcinoma (Uterine Cancer)**

- Patient is 18 years of age or older; **AND**
- Patient's thyroid function has been assessed prior to initiating therapy and will receive ongoing monitoring during treatment; **AND**
- Patient will avoid coadministration with medicinal products that have a known potential to prolong the QT/QTc interval (e.g., Class Ia and III antiarrhythmics, etc.); **AND**
- Patient has advanced or recurrent disease that is NOT microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); **AND**
- Patient has disease progression following prior systemic therapy; **AND**
- Patient is not a candidate for curative surgery or radiation; **AND**
- Used in combination with pembrolizumab

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Thymic Carcinoma**

- Patient is 18 years of age or older; **AND**
- Patient's thyroid function has been assessed prior to initiating therapy and will receive ongoing monitoring during treatment; **AND**
- Patient will avoid coadministration with medicinal products that have a known potential to prolong the QT/QTc interval (e.g., Class Ia and III antiarrhythmics, etc.); **AND**
- Used as a single agent; **AND**
  - Used, as first line therapy or postoperative treatment, in patients who are unable to tolerate first-line combination regimens; **OR**
  - Used as second-line therapy for unresectable or metastatic disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug.
  Examples of unacceptable toxicity include life-threatening hypertension, severe cardiac dysfunction, hepatotoxicity, proteinuria/nephrotic syndrome, renal failure/impairment, gastrointestinal perforation/fistula formation, severe/recurrent diarrhea, severe QT interval prolongation (grade 3 or 4), Reversible Posterior Leukoencephalopathy Syndrome (RPLS), arterial thromboembolic events, hemorrhagic events, severe hypocalcemia, impaired wound healing, etc.

LEUKOTRIENE ANTAGONISTS

Length of Authorization:	1 year
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

ZYFLO AND ZILEUTON:

- The patient must fail a trial of montelukast or zafirlukast

LEUPROLIDE PRODUCTS

Length of Authorization:	varies by product and diagnosis, see specific criteria below
Initiative:	SPC: Hormonal Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Endometriosis (Lupron Depot®, Trelstar®, Zoladex®, Fensolvi®, Eligard®)**

- Patient is 18 years of age or older; **AND**
- Diagnosis has been confirmed by a workup/evaluation (vs. presumptive treatment)

Length of Authorization:	6 months, eligible for renewal one time

Diagnosis of **Uterine Leiomyomata (fibroids): (Lupron Depot®, Trelstar®, Eligard®, Fensolvi®)**

- Patient is 18 years of age or older; **AND**
- Diagnosis has been confirmed by a workup/evaluation (vs. presumptive treatment); **AND**
- Documentation patient is receiving iron therapy;

Length of Authorization:	3 months **not** eligible for renewal.

Diagnosis of **Dysfunctional uterine bleeding (Endometrial thinning) [Zoladex]**

- Patient is 18 years of age or older; **AND**
- Used prior to endometrial ablation

Length of Authorization:	Coverage will be provided for 2 doses only (given 4 weeks apart) and medication is **not** eligible for renewal

Diagnosis of **Breast Cancer (Eligard®, Lupron Depot®, Zoladex®, Fensolvi®)**

- Patient is 18 years of age or older; **AND**
- Patient is pre-menopausal or peri-menopausal woman; or is a male with suppression of testicular steroidogenesis; **AND**
- Patient's disease is hormone receptor positive; **AND**
  - Used in combination with adjuvant endocrine therapy; **OR**
  - Endocrine therapy for recurrent or metastatic disease; **OR**
  - Used as palliative treatment for advanced disease- (Zoladex® only).

Diagnosis of **Ovarian Cancer (Eligard®, Lupron Depot®, Fensolvi®)**

- Patient is 18 years of age or older; **AND**
- Used as single agent; **AND**
- Patient has a diagnosis of stage II-IV granulosa cell tumors of the ovary; **AND**
  - Patient's disease has relapsed; **OR**
- Patient has a diagnosis of Epithelial Ovarian Cancer or Fallopian Tube Cancer or Primary Peritoneal cancer; **AND**
  - Patient's disease is persistent or recurrent (excluding immediate treatment of biochemical relapse).

Length of Authorization:	1 year, eligible for renewal(s)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Head and Neck Cancer (Lupron Depot®, Fensolvi®, Eligard®):**

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of androgen receptor-positive recurrent salivary gland tumor; **AND**
  - Patient has distant metastases with a performance status score of 0-3; **OR**
  - Patient has unresectable locoregional recurrence or second primary with prior radiation therapy

Length of Authorization: 1 year, eligible for renewal(s)

Diagnosis of **Central Precocious Puberty (CPP) (Leuprolide acetate, Lupron Depot-Ped®, Supprelin® LA, Trelstar®, Triptodur®, Fensolvi®, Eligard®)**

- Patient is less than 13 years old (between the ages of 2 and 13 years for Triptodur® and Supprelin®); **AND**
- Onset of secondary sexual characteristics earlier than age 8 for girls and 9 for boys associated with pubertal pituitary gonadotropin activation; **AND**
- Will not be used in combination with growth hormone; **AND**
- Patient does not have a hypersensitivity to gonadotropin releasing hormone (GnRH) or GnRH analog type medications; **AND**
- Diagnosis is confirmed by a pubertal gonadal sex steroid levels and a pubertal LH response to stimulation by native GnRH; **AND**
- Bone age advanced greater than 2 standard deviations (SD) beyond chronological age ; **AND**
- Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor)

Length of Authorization: 1 year, eligible for renewal(s)

Diagnosis of **Prostate Cancer; (Leuprolide [all formulations], Eligard®, Trelstar®, Vantas®, Zoladex®, and Camcevi)**

- Patient is 18 years of age or older; **AND**
- **For Camcevi:** Patient has advanced disease

Length of Authorization: 1 year, eligible for renewal(s)

Diagnosis of **Prevention/Management of Menstrual Bleeding Associated with Hematopoetic Stem Cell Transplant (HCT)**

- Patient is pre-menopausal; **AND**
  - Patient will receive conditioning myeloablative treatment with cytotoxic chemotherapy; **OR**
  - Patient has menorrhagia due to thrombocytopenia related to delayed platelet engraftment

Length of Authorization: 3 months **not** eligible for renewal

CLINICAL CRITERIA FOR RENEWAL

Diagnosis of **Central Precocious Puberty**

- Patient is less than 13 years old**; AND**
- Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in growth velocity and bone age advancement, a decrease in the ratio of bone age to chronological age (BA:CA), and improvement in final height prediction; **AND**
- Absence of unacceptable toxicity from the drug (e.g., convulsions, development or worsening of psychiatric symptoms); **AND**
- Will not be used in combination with growth hormone

Diagnosis of **Prostate Cancer; Breast/Ovarian Cancer; Head and Neck Cancer**

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread
- Absence of unacceptable toxicity from the drug (e.g., severe QT/QTc interval prolongation, severe hyperglycemia and diabetes, cardiovascular toxicity, hypercalcemia, severe injection site reactions, tumor flare phenomenon, severe hypersensitivity reactions)

Diagnosis of **Oncology Indications (Zoladex® only)**

- Tumor response with stabilization of disease or decrease in size of tumor; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe QT/QTc interval prolongation, severe hyperglycemia and diabetes, cardiovascular toxicity, hypercalcemia, severe injection site reactions, tumor flare phenomenon, severe hypersensitivity reactions)

Diagnosis of **Non-Oncology Indications (except Endometriosis) (Zoladex® only)**

- Disease response; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe QT/QTc interval prolongation, severe hyperglycemia and diabetes, cardiovascular toxicity, hypercalcemia, severe injection site reactions, tumor flare phenomenon, severe hypersensitivity reactions)

Diagnosis of **Endometriosis**

- Patient has not received a total of 12 months of therapy of a GnRH-agonist (e.g., leuprolide acetate); **AND**
- Patient continues to have symptoms of endometriosis or symptoms recur after the initial 6-month course of therapy; **AND**
- Patient will have bone density assessment prior to retreatment; **AND**
- Extended GnRH-agonist treatment will be used in combination with norethindrone add-back therapy; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe QT/QTc interval prolongation, severe hyperglycemia and diabetes, cardiovascular toxicity, hypercalcemia, severe injection site reactions, tumor flare phenomenon, severe hypersensitivity reactions)

Diagnosis of **Uterine leiomyomata (fibroids)/ Menses suppression/control associated with HCT**

- May not be renewed

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

- Examples of secondary sexual characteristics:
  - In ***females***: growth of pubic and underarm hair, enlargement of breasts, and menstruation.
  - In ***males***: growth of abdominal, chest, pubic, and underarm hair; enlargement of larynx (Adam's apple); deepening of voice, enlargement (growth) of the penis.

LEVOLEUCOVORIN (FUSILEV®AND KHAPZORY™)

Length of Authorization:	90 days, and may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

FUSILEV

- **Bone Cancer (Osteosarcoma), Dedifferentiated Chondrosarcoma, High-Grade Undifferentiated Pleomorphic Sarcoma (UPS)**
  - Patient is at least 6 years old; **AND**
  - Patient does not have pernicious anemia or vitamin B12 deficiency megaloblastic anemia; **AND**
  - Racemic *d, l*-leucovorin calcium is not obtainable (in any dosage strength) as confirmed by FDA drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; **AND**
    - Patient is undergoing high-dose methotrexate chemotherapy treatment; **OR**
    - Used as rescue therapy in combination with a chemotherapy regimen containing high-dose methotrexate
- **Reduction of toxicity due to impaired elimination or inadvertent overdose with folic acid antagonists**
  - Patient is at least 6 years old; **AND**
  - Patient does not have pernicious anemia or vitamin B12 deficiency megaloblastic anemia; **AND**
  - Racemic *d, l*-leucovorin calcium is not obtainable (in any dosage strength) as confirmed by FDA drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; **AND**
  - Patient is undergoing treatment with a folic acid antagonist, such as methotrexate; **AND**
  - Patient has developed toxicity due to impaired elimination or inadvertent overdosage of the folic acid antagonist (i.e., methotrexate)
- **Colorectal cancer**
  - Patient is at least 6 years old; **AND**
  - Patient does not have pernicious anemia or vitamin B12 deficiency megaloblastic anemia; **AND**
  - Racemic *d,l*-leucovorin calcium is not obtainable (in any dosage strength) as confirmed by FDA drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; **AND**
  - Must be used in combination with fluorouracil-based regimens
- **Gestational Trophoblastic Neoplasia**
  - Patient is at least 6 years old; **AND**
  - Patient does not have pernicious anemia or vitamin B12 deficiency megaloblastic anemia; **AND**
  - Racemic *d, l*-leucovorin calcium is not obtainable (in any dosage strength) as confirmed by FDA drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; **AND**
  - Used in combination with a methotrexate-based regimen

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- **Used in combination with high-dose methotrexate for the following**:
  - Acute Lymphoblastic Leukemia/Pediatric Acute Lymphoblastic Leukemia
  - Adult T-cell Leukemia/Lymphoma
  - AIDS-related B-cell Lymphoma
  - Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)
  - Burkitt Lymphoma
  - Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
  - CNS Cancer (Primary CNS Lymphoma, Brain Metastases, & Leptomeningeal Metastases)
  - Diffuse Large B-Cell Lymphoma
  - Extranodal NK/T-cell Lymphoma (nasal type)
  - Follicular Lymphoma
  - Hepatosplenic T-Cell Lymphoma
  - High Grade B-Cell Lymphomas
  - Mantle Cell Lymphoma
  - Pediatric Aggressive Mature B-Cell Lymphomas
  - Peripheral T-cell Lymphoma
  - Post-Transplant Lymphoproliferative Disorders (PTLD)
  - Rhabdomyosarcoma

    AND
  - For all the indications above:
    - Patient is at least 6 years old; **AND**
    - Patient does not have pernicious anemia or vitamin B12 deficiency megaloblastic anemia; **AND**
    - Racemic *d,l*-leucovorin calcium is not obtainable (in any dosage strength) as confirmed by FDA drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
- **Used in combination with fluorouracil-based regimens for the following**:
  - Anal Carcinoma
  - Bladder Cancer (non-urothelial and urothelial with variant histology)
  - Esophageal, Esophagogastric Junction, & Gastric Cancer
  - Gallbladder Cancer, Extrahepatic Cholangiocarcinoma, and Intrahepatic Cholangiocarcinoma
  - Neuroendocrine and Adrenal Tumors (Poorly Differentiated - High Grade/Large or Small Cell & Tumors of the Pancreas)
  - Occult Primary
  - Ovarian-Epithelial/Fallopian Tube/Primary Peritoneal Mucinous Carcinomas
  - Pancreatic Adenocarcinoma
  - Small Bowel Adenocarcinoma
  - Thymoma and Thymic Carcinoma; **AND**
  - For all the indications above:
    - Patient is at least 6 years old; **AND**
    - Patient does not have pernicious anemia or vitamin B12 deficiency megaloblastic anemia; **AND**
    - Racemic *d,l*-leucovorin calcium is not obtainable (in any dosage strength) as confirmed by FDA drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

KHAPZORY

- **Bone Cancer (Osteosarcoma) Dedifferentiated Chondrosarcoma, High-Grade Undifferentiated Pleomorphic Sarcoma (UPS))**
  - Patient is at least 6 years old; **AND**
  - Patient had an inadequate response, or has a contraindication or intolerance, to Fusilev™ (levoleucovorin)**; AND**
  - Patient does not have pernicious anemia or vitamin B12 deficiency megaloblastic anemia; **AND**
  - Racemic *d,l*-leucovorin calcium is not obtainable (in any dosage strength) as confirmed by FDA drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; **AND**
  - Patient is undergoing high-dose methotrexate chemotherapy treatment; **OR**
  - Used as rescue therapy in combination with a chemotherapy regimen containing high dose methotrexate
- **Reduction of toxicity due to impaired elimination or inadvertent overdose with folic acid antagonists**
  - Patient is at least 6 years old; **AND**
  - Patient had an inadequate response, or has a contraindication or intolerance, to Fusilev™ (levoleucovorin)**; AND**
  - Patient does not have pernicious anemia or vitamin B12 deficiency megaloblastic anemia; **AND**
  - Racemic *d,l*-leucovorin calcium is not obtainable (in any dosage strength) as confirmed by FDA drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; **AND**
  - Patient is undergoing treatment with a folic acid antagonist, such as methotrexate; **AND**
  - Patient has developed toxicity due to impaired elimination or inadvertent overdosage of the folic acid antagonist (i.e., methotrexate)
- **Colorectal cancer**
  - Patient is at least 6 years old; **AND**
  - Patient had an inadequate response, or has a contraindication or intolerance, to Fusilev™ (levoleucovorin)**; AND**
  - Patient does not have pernicious anemia or vitamin B12 deficiency megaloblastic anemia; **AND**
  - Racemic *d,l*-leucovorin calcium is not obtainable (in any dosage strength) as confirmed by FDA drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; **AND**
  - Must be used in combination with fluorouracil-based regimens
- **Gestational Trophoblastic Neoplasia**
  - Patient is at least 6 years old; **AND**
  - Patient had an inadequate response, or has a contraindication or intolerance, to Fusilev™ (levoleucovorin)**; AND**
  - Patient does not have pernicious anemia or vitamin B12 deficiency megaloblastic anemia; **AND**
  - Racemic *d, l*-leucovorin calcium is not obtainable (in any dosage strength) as confirmed by FDA drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; **AND**
  - Used in combination with a methotrexate-based regimen

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

KHAPZORY

- **Used in combination with high-dose methotrexate for the following:**
  - Acute Lymphoblastic Leukemia/ Pediatric Acute Lymphoblastic Leukemia
  - Adult T-cell Leukemia/Lymphoma
  - AIDS-related B-cell Lymphoma
  - Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)
  - Burkitt Lymphoma
  - Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
  - CNS Cancer (Primary CNS Lymphoma, Brain Metastases, & Leptomeningeal Metastases)
  - Diffuse Large B-Cell Lymphoma
  - Extranodal NK/T-cell Lymphoma (nasal type)
  - Follicular Lymphoma
  - Hepatosplenic T-Cell Lymphoma
  - High Grade B-Cell Lymphoma
  - Mantle Cell Lymphoma
  - Pediatric Aggressive Mature B-Cell Lymphomas
  - Peripheral T-cell Lymphoma
  - Post-Transplant Lymphoproliferative Disorders (PTLD)
  - Rhabdomyosarcoma

    AND
  - For all the indications above:
    - Patient is at least 6 years old; **AND**
    - Patient had an inadequate response, or has a contraindication or intolerance, to Fusilev™ (levoleucovorin)**;** **AND**
    - Patient does not have pernicious anemia or vitamin B12 deficiency megaloblastic anemia; **AND**
    - Racemic *d,l*-leucovorin calcium is not obtainable (in any dosage strength) as confirmed by FDA drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- **Used in combination with fluorouracil-based regimens for the following:**
  - Anal Carcinoma
  - Bladder Cancer (non-urothelial and urothelial with variant histology)
  - Esophageal, Esophagogastric Junction, & Gastric Cancer
  - Gallbladder Cancer, Extrahepatic Cholangiocarcinoma, and Intrahepatic Cholangiocarcinoma
  - Neuroendocrine and Adrenal Tumors (Poorly Differentiated - High Grade/Large or Small Cell & Tumors of the Pancreas)
  - Occult Primary
  - Ovarian-Epithelial/Fallopian Tube/Primary Peritoneal Mucinous Carcinomas
  - Pancreatic Adenocarcinoma
  - Small Bowel Adenocarcinoma
  - Thymoma and Thymic Carcinoma; **AND**
  - For all the indications above**:**
    - Patient is at least 6 years old; **AND**
    - Patient had an inadequate response, or has a contraindication or intolerance, to Fusilev™ (levoleucovorin)**; AND**
    - Patient does not have pernicious anemia or vitamin B12 deficiency megaloblastic anemia; **AND**
    - Racemic *d,l*-leucovorin calcium is not obtainable (in any dosage strength) as confirmed by FDA Drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

CLINICAL CRITERIA FOR RENEWAL

- Patient does not have pernicious anemia or vitamin B12 deficiency; **AND**
- Racemic *d,l*-leucovorin calcium is not obtainable (in any dosage strength) as confirmed by FDA Drug shortage website located at: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity reactions, seizures, and severe gastrointestinal disorders such as stomatitis, severe diarrhea, and severe nausea and vomiting)

LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEMS (MIRENA®, SKYLA®, LILETTA®, KYLEENA®)

Length of Authorization:	Coverage will be provided for one intrauterine system once every 3 years for Skyla and may be renewed. Coverage will be provided for one intrauterine system once every 5 years for Mirena *(treatment of heavy menstrual bleeding **plus** intrauterine contraception)* and Kyleena and may be renewed. Coverage will be provided for one intrauterine system once every 6 years Mirena *(intrauterine contraception **only**)* and may be renewed. Coverage will be provided for one intrauterine system once every 6 years for Liletta and may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Note: Verify via CRM that intrauterine devices (IUD) are covered

- Patient must not have any of the following contraindications for use:
  - Pregnancy or suspicion of pregnancy
  - Cannot be used for post-coital contraception
  - Congenital or acquired uterine anomaly if it distorts the uterine cavity
  - Acute pelvic inflammatory disease (PID) or a history of PID unless there has been a subsequent intrauterine pregnancy
  - Postpartum endometritis or infected abortion in the past 3 months
  - Known or suspected uterine or cervical neoplasia
  - Known or suspected breast cancer or other progestin-sensitive cancer
  - Uterine bleeding of unknown etiology
  - Untreated acute cervicitis or vaginitis or other lower genital tract infections
  - Acute liver disease or liver tumor (benign or malignant)
  - Increased susceptibility to pelvic infection
  - A previous intrauterine device (IUD) that has not been removed
  - Hypersensitivity to any component); **AND**
- Patient has been appropriately counseled on the warnings and precautions for use (e.g., ectopic pregnancy, intrauterine pregnancy, sepsis, pelvic infection/pelvic inflammatory disease, endometritis, bleeding pattern alterations, perforation, expulsion, ovarian cysts, breast cancer); **AND**

Coverage is provided in the following conditions:

- Intrauterine contraception/Prevention of pregnancy
- Treatment of heavy menstrual bleeding in women who choose to use intrauterine contraception (Mirena **only**)

CLINICAL CRITERIA FOR RENEWAL

MIRENA

- If used continuously, system is to be replaced by the end of the 7th year for continued contraceptive protection use **only** or replaced by the end of the 5th year for continued treatment of heavy menstrual bleeding **plus** intrauterine contraception *(Note: System may be replaced to restart treatment when removed prior to the end of the 7th year for contraception, or 5th year when used for heavy menstrual bleeding plus contraception)*; **AND**
- Absence of unacceptable toxicity from the system. Examples of unacceptable toxicity include uncontrolled pelvic infection, coagulopathy, focal migraine with asymmetrical visual loss or other symptoms indicating transient cerebral ischemia, exceptionally severe headache, marked increase of blood pressure, severe arterial disease such as stroke or myocardial infarction, uterine or cervical malignancy, and jaundice

SKYLA

- If used continuously, system is to be replaced by the end of the 3rd year for continued contraceptive protection *(Note: System may be replaced to restart treatment when removed prior to the end of the 3rd year for contraception protection)*; **AND**
- Absence of unacceptable toxicity from the system. Examples of unacceptable toxicity include uncontrolled pelvic infection, coagulopathy, focal migraine with asymmetrical visual loss or other symptoms indicating transient cerebral ischemia, exceptionally severe headache, marked increase of blood pressure, severe arterial disease such as stroke or myocardial infarction, uterine or cervical malignancy, and jaundice

LILETTA

- If used continuously, system is to be replaced by the end of the 6th year for continued contraceptive protection *(Note: System may be replaced to restart treatment when removed prior to the end of the 6th year for contraception protection)*; **AND**
- Absence of unacceptable toxicity from the system. Examples of unacceptable toxicity include uncontrolled pelvic infection, coagulopathy, focal migraine with asymmetrical visual loss or other symptoms indicating transient cerebral ischemia, exceptionally severe or frequent headache, marked increase of blood pressure, severe arterial disease such as stroke or myocardial infarction, uterine or cervical malignancy, and jaundice

KYLEENA

- If used continuously, system is to be replaced by the end of the 5th year for continued contraceptive protection *(Note: System may be replaced to restart treatment when removed prior to the end of the 5th year for contraception protection)*; **AND**
- Absence of unacceptable toxicity from the system. Examples of unacceptable toxicity include uncontrolled pelvic infection, coagulopathy, focal migraine with asymmetrical visual loss or other symptoms indicating transient cerebral ischemia, exceptionally severe headache, marked increase of blood pressure, severe arterial disease such as stroke or myocardial infarction, uterine or cervical malignancy, and jaundice

LIBTAYO® (CEMIPLIMAB-RWLC)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cutaneous Squamous Cell Carcinoma (CSCC)**

- Patient is 18 years of age or older; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, pembrolizumab, atezolizumab, durvalumab, nivolumab, dostarlimab, etc.), unless otherwise specified; **AND**
- Used as single-agent therapy; **AND**
- Patient has nodal or distant metastatic disease, locally advanced disease, inoperable or not fully resectable regional disease, or regional recurrence; **AND**
- Patient is not a candidate for curative surgery or curative radiation therapy

Diagnosis of **Basal Cell Carcinoma (BCC)**

- Patient is 18 years of age or older; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, pembrolizumab, atezolizumab, durvalumab, nivolumab, dostarlimab, etc.), unless otherwise specified; **AND**
- Used as single-agent therapy; **AND**
- Patient has locally advanced OR nodal, regional, or distant metastatic disease; **AND**
  - Patient has previously been treated with a hedgehog pathway inhibitor (e.g., vismodegib, sonidegib, etc.) or is not a candidate for treatment; **OR**
- Patient has diffuse BCC formation (e.g., Gorlin syndrome, other genetic forms of multiple BCC); **AND**
  - Patient is not a candidate for treatment with a hedgehog pathway inhibitor

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is 18 years of age or older; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, pembrolizumab, atezolizumab, durvalumab, nivolumab, dostarlimab, etc.), unless otherwise specified; **AND**
- Used as single-agent therapy; **AND**
- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Patient has tumors with high PD-L1 expression (Tumor Proportion Score [TPS] ≥ 50%) as determined by an FDA-approved or CLIA compliant test❖; **AND**
- Patient has tumors with negative actionable molecular markers*; **AND**
  - Used as first-line therapy; **OR**
  - Used as continuation maintenance therapy in patients who achieved a tumor response or stable disease after first-line therapy with cemiplimab

❖ *If confirmed using an immunotherapy assay-http://www.fda.gov/companiondiagnostics*

> ** Note: Actionable molecular genomic biomarkers include EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, and RET rearrangement. If there is insufficient tissue to allow testing for all of EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET, and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe infusion reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis/renal dysfunction, skin reactions, etc.), etc; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

Non-Small Cell Lung Cancer (continuation maintenance therapy):

- *Refer to initial criteria*

LIPOTROPICS

Length of Authorization:	1 Year
Initiative:	MNC: Lipotropics (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

ANTARA, LIPOFEN, TRIGLIDE (NO GRANDFATHERING)

Diagnosis of **Primary hypercholesterolemia, mixed dyslipidemia, or severe hypertriglyceridemia**

- Patient is 18 years of age or older; **AND**
- Patient does not have any of the following contraindications: severe renal impairment, active liver disease, gallbladder disease, breast feeding, hypersensitivity to fenofibrate; **AND**
- **For Antara**: Patient must have a history of failure, contraindication or intolerance to **or** is not successfully managed with generic fenofibrate 54mg (generic Lofibra) or Fenofibrate 160mg (generic Lofibra)
- **For Lipofen and Triglide**: Patient must have a history of failure, contraindication or intolerance to **or** is not successfully managed with any generic fenofibrate

LOVAZA

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of severe hypertriglyceridemia defined as pre-treatment triglyceride level ≥ 500 mg/dL; **AND**
- Patient is on an appropriate lipid-lowering diet and exercise regimen.

VASCEPA

- Patient is 18 years of age or older; **AND**
- Patient is on a diet to reduce triglyceride (TG) levels **AND** has a diagnosis of severe hypertriglyceridemia, defined as pre-treatment TG level ≥ 500 mg/dL; **OR**
- Patient is on a maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated TG levels (≥ 150 mg/dL) **AND** has either:
  - Established cardiovascular disease; **OR**
  - Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.

CLINICAL CRITERIA FOR RENEWAL

- Patient must have documentation of positive clinical response to therapy; **AND**
- Patient must continue to be on an appropriate lipid-lowering diet and exercise regimen.

CRESTOR, LESCOL, LIPITOR, LIVALO, PRAVACHOL, ZOCOR: STEP THERAPY (NO GRANDFATHERING)

The patient must step through any one generic statin

ZYPITAMAG: STEP THERAPY STANDARD ONLY (NO GRANDFATHERING)

Zypitamag:

- The patient must step through any one generic statin **and** Livalo

ROSZET: STEP THERAPY (NO GRANDFATHERING)

Trial and failure of generic ezetimibe and a generic statin

VYTORIN: STEP THERAPY (NO GRANDFATHERING)

Trial and failure of either generic Vytorin (ezetimibe and simvastatin) **OR** the combination of generic ezetimibe and a generic statin

LONSURF® (TRIFLURIDINE AND TIPIRACIL)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Colorectal Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has advanced or metastatic disease; **AND**
- Used as a single agent or in combination with bevacizumab; **AND**
- Used as subsequent therapy for disease progression through all available regimens besides regorafenib

Diagnosis of **Gastric and Gastro-Esophageal Junction Adenocarcinoma**

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Patient has recurrent, metastatic, or unresectable locally advanced disease OR patient is not a surgical candidate; **AND**
- Patient has received at least two (2) prior lines of chemotherapy that included: a fluoropyrimidine-, a platinum, and either a taxane or irinotecan; **AND**
- Patient has been previously treated with HER2/neu-targeted therapy (if HER2 positive disease) (e.g., trastuzumab)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe myelosuppression)

LORBRENA® (LORLATINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years old**; AND**
- Patient will avoid concomitant therapy with all of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented:
  - Coadministration with *moderate* CYP3A inducers (e.g., bosentan, efavirenz, modafinil, nafcillin, etc.); **AND**
  - Coadministration with *strong* CYP3A inhibitors (clarithromycin, cobicistat, danazol, fluvoxamine, itraconazole, ketoconazole, etc.); **AND**
  - Coadministration with fluconazole; **AND**
- Therapy will not be used concomitantly with *strong* CYP3A inducers (e.g., apalutamide, carbamazepine, rifampin, etc.); **AND**
- Baseline electrocardiogram (ECG) has been obtained prior to initiating therapy and will be monitored periodically while on therapy; **AND**
- Used as a single agent; **AND**
- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Patient's disease is anaplastic lymphoma kinase (ALK)-positive as detected by FDA-approved or CLIA-compliant test**; OR**
  - Patient's disease is ROS1 rearrangement-positive as detected by FDA-approved or CLIA-compliant test; **AND**
    - Disease has progressed on crizotinib, entrectinib, or ceritinib as first line therapy

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hepatotoxicity, CNS effects (i.e., seizures, hallucinations, mood and cognitive function changes), AV-block, hyperlipidemia, interstitial lung disease (ILD)/pneumonitis, hypertension, hyperglycemia, etc

LUCEMYRA™ (LOFEXIDINE)

Length of Authorization:	3 days (16 tabs/day x3 days), 1 Rx per 6 months
Initiative:	MNC: Miscellaneous: PA required (IE 2462/NCPDP 75)

CRITERIA FOR INITIAL APPROVAL

- For requests that exceed the 3-day limit:
  - All clinical information in the criteria below should be gathered
  - Recommendation to submit to medical director (Marci Chodroff) for review or consult internal behavioral health pharmacist (Daphne Atria) for review (if turnaround time [TAT] allows; consults should be limited to a 3-hour TAT)
  - If TAT does not allow, PA review to use clinical judgment in review.

Initial Authorization Duration: 3 days (16 tabs/day x3 days), 1 Rx per 6 months

Note: 3 days was determined by MRx clinical review based on APA guidelines for outpatient clonidine supply.

Info for PA pharmacist:

- 2006 American Psychiatric Association (APA) Practice guideline for the treatment of patients with substance use disorders, 2nd edition: Outpatients should not be given more than a 3-day supply of clonidine for unsupervised use because treatment requires careful dose titration and clonidine overdoses can be life-threatening.
- Clonidine tablets are a low-cost generic on commercial formularies
- 2020 American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use recommends the inclusion of clonidine as a practice to support opioid withdrawal. Clonidine is not US FDA-approved for the treatment of opioid withdrawal, but it has been extensively used off-label for this purpose.

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is using the drug for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation; **AND**
- Patient is at least 18 years of age; **AND**
- Patient is **not** pregnant or breastfeeding; **AND**
- Patient does not have congenital long QT syndrome a prolonged QT interval; **AND**
- Patient does not have severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure, or marked bradycardia; **AND**
- Prescriber has provided clinical office note documentation that the patient has tried and failed, has a contraindication, or experienced intolerance/an adverse reaction to an **adequate trial** of buprenorphine, methadone, and clonidine. An **adequate trial** of buprenorphine is 4-16 mg per day and then a tapering of the dose over a period of 3-5 days or as long as 30 days or more. An **adequate trial** of methadone is 20-30 mg per day and then a tapering of the dose over a period of 6-10 days. An **adequate trial** of clonidine is maximum doses for the first 2-3 days and then a tapering of the dose over a period of 7-10 days**; **AND**
- Provide verbal attestation of a comprehensive treatment plan between provider and patient; **AND**
- Provide verbal attestation that patient has a referral **OR** active involvement in substance abuse counseling **OR** reason patient is unable to have counseling; **AND**
- Provide verbal attestation that that patient is **not** prescribed concurrent opioid medication without explanation (verified by state opioid database, if available); **AND**
- Provide verbal attestation that the patient is capable of and instructed on self-monitoring for hypotension, orthostasis, bradycardia, and associated symptoms; **AND**
- Provide verbal attestation that the patient has been provided with a tapering schedule and instructions on when to contact their health care provider for further guidance.

  **2020 American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use

RE-AUTHORIZATION DURATION

See above criteria

LUMAKRAS™ (SOTORASIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with systemic acid-reducing agents (e.g., PPI or H_2 receptor antagonist). If acid-reducing therapy is unavoidable, locally acting antacids may be considered; **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient does not have active brain metastases; **AND**
- Patient has locally advanced, metastatic, or recurrent (excluding locoregional) disease; **AND**
- Patient has presence of *KRAS G12C* mutation(s) in tumor or plasma specimens as detected by an FDA or CLIA-compliant test (**Note**: if no mutation is detected in a plasma specimen, tumor tissue should be tested); **AND**
- Used as a single agent; **AND**
- Used as subsequent therapy after prior treatment with an immune checkpoint inhibitor and/or platinum-based chemotherapy

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: interstitial lung disease, hepatotoxicity, etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

LUMIZYME® (ALGLUCOSIDASE ALFA)

Length of Authorization:	1 Year, may be renewed
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Pompe disease (Acid alpha-glucosidase [GAA] deficiency)**

- Will not be used in combination with other enzyme replacement therapies (e.g., avalglucosidase-alfa); **AND**
- Patient has not experienced a severe hypersensitivity reaction, including anaphylaxis, to alglucosidase alfa; **AND**
- Patient is not susceptible to fluid volume overload or has an acute underlying respiratory illness or compromised cardiac or respiratory function for which fluid restriction is indicated; **AND**
- Diagnosis has been confirmed by one of the following:
  - Deficiency of acid alpha-glucosidase (GAA) enzyme activity; **OR**
  - Detection of biallelic pathogenic variants in the *GAA* gene by molecular genetic testing; **AND**
- Documented baseline values for one or more of the following:
  - **Infantile-onset disease**: muscle weakness, motor function, respiratory function, cardiac involvement, percent predicted forced vital capacity (FVC), and/or 6-minute walk test (6MWT); **OR**
  - **Late-onset (non-infantile) disease**: FVC and/or 6MWT

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., anaphylaxis and hypersensitivity reactions, immune-mediated cutaneous reactions, systemic immune-mediated reactions, acute cardiorespiratory failure, cardiac arrhythmia and sudden cardiac death during general anesthesia); **AND**
- Patient is being monitored for antibody formation (including neutralizing antibodies); **AND**
- Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following:
  - Infantile-onset disease: stabilization or improvement in muscle weakness, motor function, respiratory function, cardiac involvement, FVC, and/or 6MWT
  - Late-onset (non-infantile) disease: stabilization or improvement in FVC and/or 6MWT

LUMOXITI® (MOXETUMOMAB PASUDOTOX-TDFK)

Length of Authorization:	Coverage is provided for six months (6 cycles) and may not be renewed
Initiative:	SPC: Oncology agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Hairy Cell Leukemia (HCL)**

- Patient is at least 18 years of age; **AND**
- Patient does not have prior history of severe thrombotic microangiopathy (TMA) or hemolytic uremic syndrome (HUS); **AND**
- Patient does not have severe renal impairment defined as CrCl ≤ 29 mL/min; **AND**
- Must be used as a single agent; **AND**
- Patient has a confirmed diagnosis of Hairy Cell Leukemia or an HCL variant; **AND**
- Patient must have relapsed or refractory disease; **AND**
- Patient has previously failed at least TWO prior systemic therapies, including at least one purine analog (e.g., cladribine, pentostatin, etc.)

CLINICAL CRITERIA FOR RENEWAL

- May **not** be renewed

LUPKYNIS™(VOCLOSPORIN)

Length of Authorization:	6 months initial, 1 year for renewal
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **lupus nephritis**

- Age ≥ 18 years old**; AND**
- International Society of Nephrology/Renal Pathology Society (ISN/RPS) biopsy-proven active Class III or IV lupus nephritis alone or in combination with Class V lupus nephritis**; AND**
- Urine protein to creatinine (UPCR) ratio ≥ 1.5 mg/mg for Class III or IV OR UPCR ≥ 2 mg/mg for Class V; **AND**
- Patient must not have hypersensitivity to any component of the product**; AND**
- Patient must not have concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin); **AND**
- Patient must not have severe hepatic impairment**; AND**
- Patient must concomitantly receive background immunosuppressive therapy, with the exception of cyclophosphamide; **AND**
- Patient had baseline blood pressure < 165/105 mg Hg; **AND**
- Baseline estimated glomerular filtration rate (eGFR) is > 45 mL/min/1.73 m2; **AND**
- Renal function (eGFR) will be assessed at regular intervals thereafter**; AND**
- Lupkynis is prescribed by or in consultation with a rheumatologist or nephrologist

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient must have disease improvement and/or stabilization OR improvement in the slope of decline; **AND**
- Patient has not have experienced any treatment-restricting adverse effects (e.g., hypertension, neurotoxicities, hyperkalemia)

LUTATHERA® (LUTETIUM LU 177 DOTATATE) IV

Length of Authorization:	1 year (4 doses only), may **not** be renewed
Initiative:	SPC: Oncology agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)**

- Patient is at least 18 years old; **AND**
- Patient has a negative pregnancy test (in females); **AND**
- Patient's disease is somatostatin receptor-positive in all tumor lesions (OctreoScan uptake ≥ normal liver); **AND**
- Patient has well-differentiated disease with a Ki67 labeling index score of ≤ 20%; **AND**
- Patient has not received any long-acting somatostatin analogues (e.g., octreotide LAR, pasireotide LAR, lanreotide depot, etc.) within the previous 4 weeks **or** short-acting somatostatin analogues (e.g., octreotide, pasireotide, etc.) within 24 hours prior to therapy; **AND**
- Will be used in combination with a long-acting somatostatin analog (e.g., octreotide LAR, lanreotide depot, etc.) given as a single-injection (between 4–24 hours) following each Lutathera infusion; **AND**
- Patient has progressive locally advanced or metastatic disease; **AND**
- Patient's disease has progressed on long-acting octreotide or lanreotide

Diagnosis is **Carcinoid Tumors**

- Patient is at least 18 years old; **AND**
- Patient has a negative pregnancy test (in females); **AND**
- Patient's disease is somatostatin receptor-positive in all tumor lesions (OctreoScan uptake ≥ normal liver); **AND**
- Patient has well-differentiated disease with a Ki67 labeling index score of ≤ 20%; **AND**
- Patient has not received any long-acting somatostatin analogues (e.g., octreotide LAR, pasireotide LAR, lanreotide depot, etc.) within the previous 4 weeks **or** short-acting somatostatin analogues (e.g., octreotide, pasireotide, etc.) within 24 hours prior to therapy; **AND**
- Will be used in combination with a long-acting somatostatin analog (e.g., octreotide LAR, lanreotide depot, etc.) given as a single-injection (between 4–24 hours) following each Lutathera infusion; **AND**
- Patient's disease has progressed on long-acting octreotide or lanreotide; **AND**
  - Patient has bronchopulmonary/thymic disease; **AND**
    - Used as subsequent therapy for unresectable or metastatic disease; **OR**
    - Used as primary therapy for metastatic disease with clinically significant tumor burden and low grade (typical) histology, evidence of progression, or intermediate grade (atypical) histology or symptomatic disease; **OR**
  - Patient has locally advanced gastrointestinal disease and/or distant metastases; **AND**
    - Patient has progressive disease or clinically significant tumor burden; **OR**
  - Patient's symptoms are poorly controlled; **AND**
    - Used in combination with telotristat for persistent diarrhea; **OR**
      - Used in combination with octreotide LAR or lanreotide for persistent symptoms (i.e., flushing, diarrhea, etc.)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis is **Pheochromocytoma/Paraganglioma**

- Patient is at least 18 years old; **AND**
- Patient has a negative pregnancy test (in females); **AND**
- Patient's disease is somatostatin receptor-positive in all tumor lesions (OctreoScan uptake ≥ normal liver); **AND**
- Patient has well-differentiated disease with a Ki67 labeling index score of ≤ 20%; **AND**
- Patient has not received any long-acting somatostatin analogues (e.g., octreotide LAR, pasireotide LAR, lanreotide depot, etc.) within the previous 4 weeks **or** short-acting somatostatin analogues (e.g., octreotide, pasireotide, etc.) within 24 hours prior to therapy; **AND**
- Will be used in combination with a long-acting somatostatin analog (e.g., octreotide LAR, lanreotide depot, etc.) given as a single-injection (between 4–24 hours) following each Lutathera infusion; **AND**
- Used for treatment of locally unresectable or metastatic disease

CLINICAL CRITERIA FOR RENEWAL

May not be renewed

LUXTURNA® (VORETIGENE NEPARVOVEC-RZYL)

Length of Authorization:	1 dose of Luxturna per eye and may **not** be renewed
Initiative:	SPC: Ophthalmics (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Submission of medical records related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation via direct upload through the PA web portal or by fax.

Diagnosis of **Retinal Dystrophy**

- Patient must be at least 4 years old; **AND**
- Patient has a definitive diagnosis confirming biallelic RPE65 mutation-associated retinal dystrophy; **AND**
- Patient must have viable retinal cells as determined by non-invasive means, such as optical coherence tomography (OCT) and/or ophthalmoscopy indicating **one or more** of the following:
  - An area of retina within the posterior pole of > 100 µm thickness shown on OCT
  - ≥ 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole
  - Remaining visual field within 30 degrees of fixation as measured by an III4e isopter or equivalent; **AND**
- Patient has not had intraocular surgery within six months; **AND**
- Patient must have an adequate washout period, defined as a minimum of 3 months, from retinoid therapies prior to receipt of voretigene

1 injection per eye only; coverage will be provided for one dose of Luxturna per eye and may not be renewed.

LYNPARZA® (OLAPARIB)

Length of Authorization:	6 months, may be renewed First-Line Maintenance Treatment of BRCA-mutated Advanced Ovarian Cancer: may be renewed for up to 2 years of treatment **(Requests for extended treatment beyond two years will be treated on a case-by-case basis. See renewal section)*
Initiative:	SPC: Oncology agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Ovarian Cancer (epithelial ovarian, fallopian tube, or primary peritoneal cancer)**

- Patient must be 18 years or older; **AND**
- Patient has not received prior treatment with a PARP-inhibitor (i.e., olaparib, rucaparib, or talazoparib) prior to initiating therapy; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong or moderate CYP3A inhibitors (e.g., fluconazole, itraconazole), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **OR**
  - Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Used as maintenance treatment; **AND**
  - Patient has stage II-IV carcinosarcoma or clear cell carcinoma; **AND**
    - Patient has deleterious or suspected-deleterious BRCA-mutated disease as detected by any FDA-approved or CLIA-compliant test; **AND**
    - Patient is in complete or partial response after primary therapy; **AND**
      - Used as a single agent; **OR**
      - Used in combination with bevacizumab if used as part of primary therapy for HR deficient disease**; **OR**
  - Patient has stage III-IV high-grade serous or grade 2/3 endometrioid carcinoma; **AND**
    - Patient is in complete or partial response after primary therapy; **AND**
      - Used as a single agent; **AND**
        - Patient has deleterious or suspected-deleterious BRCA-mutated disease as detected by any FDA-approved or CLIA-compliant test; **OR**
      - Used in combination with bevacizumab if used as part of primary therapy for HR deficient disease**; **OR**
  - Patient has recurrent disease; **AND**
    - Patient has deleterious or suspected-deleterious BRCA-mutated disease as detected by any FDA-approved or CLIA-compliant test; **AND**
    - Used as a single agent; **AND**
    - Patient is in complete or partial response after most recent platinum-based chemotherapy (i.e., platinum-sensitive); **AND**
    - Patient has completed two or more lines of previous platinum-based therapy; **OR**
  - Used as subsequent therapy; **AND**
      - Patient has advanced, persistent, or recurrent disease; **AND**
      - Patient has deleterious or suspected-deleterious germline BRCA-mutated disease as detected by any FDA-approved or CLIA-compliant test; **AND**
      - Used as single-agent; **AND**
      - Used after at least two prior chemotherapy regimens

*** Note: HR-deficient disease defined as a deleterious or suspected-deleterious BRCA-mutation with or without genomic instability*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Breast Cancer**

- Patient must be 18 years or older; **AND**
- Patient has not received prior treatment with a PARP-inhibitor (i.e., olaparib, rucaparib, or talazoparib) prior to initiating therapy; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong or moderate CYP3A inhibitors (e.g., fluconazole, itraconazole), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **OR**
  - Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient has deleterious or suspected-deleterious germline BRCA-mutated disease as detected by any FDA-approved or CLIA-compliant test; **AND**
- Used as a single agent for recurrent or metastatic disease; **AND**
  - Patient has HER2-negative disease; **AND**
    - Patient has hormone receptor (HR)-negative disease; **OR**
    - Patient has hormone receptor (HR)-positive disease that is refractory to endocrine therapy or endocrine therapy is considered inappropriate; **OR**
    - Patient has hormone receptor (HR)-positive disease with visceral crisis; **OR**
  - Patient has HER2-positive disease; **AND**
    - Patient has hormone receptor (HR)-negative disease; **OR**
    - Patient has hormone receptor (HR)- positive disease with or without endocrine therapy

Diagnosis of **Pancreatic Adenocarcinoma**

- Patient must be 18 years or older; **AND**
- Patient has not received prior treatment with a PARP-inhibitor (i.e., olaparib, rucaparib, or talazoparib) prior to initiating therapy; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong or moderate CYP3A inhibitors (e.g., fluconazole, itraconazole), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **OR**
  - Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient has deleterious or suspected-deleterious germline BRCA-mutated disease as detected by any FDA-approved or CLIA-compliant test; **AND**
- Used as a single agent for maintenance treatment of metastatic disease; **AND**
- Disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Prostate Cancer**

- Patient must be 18 years or older; **AND**
- Patient has not received prior treatment with a PARP-inhibitor (i.e., olaparib, rucaparib, or talazoparib) prior to initiating therapy; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong or moderate CYP3A inhibitors (e.g., fluconazole, itraconazole), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **OR**
  - Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient has deleterious or suspected-deleterious germline BRCA-mutated disease as detected by any FDA-approved or CLIA-compliant test; **AND**
- Patient does not have a PPP2R2A mutation; **AND**
- Used as a single agent for metastatic castration-resistant disease; **AND**
- Patient has progressed on prior treatment with androgen receptor-directed therapy (e.g., enzalutamide, abiraterone, etc.); **AND**
  - Patient has been treated with taxane-based chemotherapy; **OR**
  - Patient is not fit for taxane-based chemotherapy; **AND**
    - Patient received prior novel hormone therapy; **AND**
    - Patient had no prior docetaxel OR patient received prior docetaxel and has no visceral metastases present; **AND**
- Patient will receive concurrent treatment with a GnRH-analog or has had a bilateral orchiectomy

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., pneumonitis, development of myelodysplastic syndrome/acute myeloid leukemia [MDS/AML], venous thromboembolic events [including pulmonary embolism]);

Ovarian Cancer (First-Line Maintenance Treatment of BRCA-mutated Disease)*

- Patient has **not** received more than 2 years of treatment
- *(Requests for extended treatment beyond two years will be treated on a case-by-case basis)
  - Continue until disease progression, unacceptable toxicity, or completion of 2 years of treatment. Patients with a complete response (no radiological evidence of disease) at 2 years should stop treatment. Patients with evidence of disease at 2 years, who in the opinion of the treating healthcare provider can derive further benefit from continuous treatment, can be treated beyond 2 years

MAKENA® (HYDROXYPROGESTERONE CAPROATE)

Length of Authorization:	Up to 6 months per singleton pregnancy
Initiative:	SPC: Injectable Progestin (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Prevention of preterm birth (delivery at less than 37 weeks, 0 days gestation)
  - Patient is 16 years of age or older; **AND**
  - Patient is currently pregnant with a singleton pregnancy; **AND**
  - Patient must have history of a prior spontaneous singleton preterm birth due to spontaneous preterm labor or premature rupture of membranes; **AND**
  - Confirmation that patient does not have any of the following contraindications:
    - Current or history of thrombosis or thromboembolic disorders; **OR**
    - Known or suspected breast cancer, other hormone-sensitive cancer, or history of these conditions; **OR**
    - Undiagnosed abnormal vaginal bleeding unrelated to pregnancy; **OR**
    - Cholestatic jaundice of pregnancy; **OR**
    - Liver tumors, benign or malignant, or active liver disease; **OR**
    - Uncontrolled hypertension; **AND**

    Therapy must be initiated between 16 weeks, 0 days and 20 weeks, 6 days of gestation and will continue through 36 weeks, 6 days' gestation or delivery, whichever occurs first.
  - ***Note: For Core Formulary, all hydroxyprogesterone caproate products are non-formulary.***

MARGENZA® (MARGETUXIMAB-CMKB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-positive* disease; **AND**
- Used in combination with chemotherapy; **AND**
- Patient has metastatic disease; **AND**
- Patient has previously been treated with at least 2 prior HER2-targeted regimens, at least one of which was used for metastatic disease

***HER2-positive overexpression criteria:**
• Immunohistochemistry (IHC) assay 3+; **OR** • Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number ≥ 4.0 signals/cell; **OR** • Dual-probe in situ hybridization (ISH) assay AND concurrent IHC indicating one of the following: – HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number < 4.0 signals/cell AND concurrent IHC 3+; **OR** – HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 6.0 signals/cell AND concurrent IHC 2+ or 3+; **OR** – HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 4.0 and < 6.0 signals/cell AND concurrent IHC 3+

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet indication-specific relevant criteria, such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in initial criteria; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: left ventricular dysfunction/symptomatic congestive heart failure, infusion related reactions, etc.; **AND**
  - LVEF **absolute** decrease is ≤ 15% from baseline (LVEF results must be within the previous 3 months); **OR**
  - LVEF is >50% (or greater than the institutional lower limit of normal) and **absolute** decrease is < 10% from baseline (LVEF results must be within the previous 3 months)

MARQIBO® (VINCRISTINE SULFATE LIPOSOMAL)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Acute Lymphocytic Leukemia (ALL)**

- Patient is at least 18 years old; **AND**
- Patient does not have any pre-existing demyelinating conditions (e.g., Charcot-Marie-Tooth Syndrome); **AND**
- Used as a single agent; **AND**
- Used for relapsed or refractory disease;
  - Patient's disease is Philadelphia chromosome-negative (Ph-); **OR**
  - Patient's disease is Philadelphia chromosome-positive (Ph+) and refractory to tyrosine kinase inhibitor therapy (e.g., imatinib, dasatinib, nilotinib, ponatinib, etc.)

CLINICAL CRITERIA FOR RENEWAL

- Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: extravasation tissue injury, peripheral motor and sensory neuropathy, central and autonomic neuropathy, myelosuppression (e.g., neutropenia, thrombocytopenia, or anemia), tumor lysis syndrome, constipation and bowel obstruction, severe fatigue, elevated liver function tests (ALT, AST, and bilirubin), etc.

MEKINIST® (TRAMETINIB)

Length of Authorization:	6 months, may be renewed Coverage for the adjuvant treatment of melanoma is up to a maximum of 1 year of therapy.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cutaneous Melanoma**

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib, etc.) unless otherwise specified; **AND**
- Patient has BRAF V600 mutation-positive disease detected by an FDA approved or CLIA compliant test; **AND**
  - Used in combination with dabrafenib as adjuvant therapy; **AND**
    - Patient has lymph node involvement following complete resection, complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; **OR**
    - Patient has clinical satellite/in-transit metastases or local satellite/in-transit recurrence with no evidence of disease (NED) after complete excision to clear margins; **OR**
  - Used as a single-agent therapy in BRAF-inhibitor treatment-naïve patients with unresectable or metastatic disease; **OR**
  - Used in combination with dabrafenib in patients with unresectable or metastatic** disease; **AND**
    - Used as initial or subsequent therapy; **OR**
    - Used as re-induction therapy for patients who experience disease control (i.e., complete response, partial response, or stable disease) from prior MEK inhibitor therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation

***Metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease*

Diagnosis of **Uveal Melanoma**

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib, etc.) unless otherwise specified; **AND**
- Used as a single agent for treatment of distant metastatic disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Anaplastic Thyroid Cancer**

- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient is at least 18 years of age; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib, etc.); **AND**
- Patient has BRAF V600E mutation-positive disease; **AND**
- Used in combination with dabrafenib; **AND**
  - Patient has locally advanced disease with no satisfactory locoregional treatment options; **OR**
  - Patient has metastatic disease

Diagnosis of **Non-Small Cell Lung Cancer**

- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient is at least 18 years of age; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib, etc.); **AND**
- Patient has BRAF V600E mutation-positive disease as detected by an FDA approved or CLIA compliant test; **AND**
- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Used in combination with dabrafenib (Tafinlar)

Diagnosis of **Central Nervous System (CNS) Cancers**

- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient is at least 18 years of age; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib, etc.); **AND**
- Patient has BRAF V600E mutation-positive disease; **AND**
  - Used in combination with dabrafenib; **AND**
    - Patient has pilocytic astrocytoma, pleomorphic xanthoastrocytoma (PXA), OR ganglioglioma; **AND**
      - Used as adjuvant treatment for incomplete resection, biopsy, or surgically inaccessible location; **OR**
    - Patient has recurrent or progressive low grade glioma with prior fractionated external beam radiation therapy (EBRT); **OR**
    - Patient has recurrent anaplastic glioma or glioblastoma; **OR**
- Used for brain metastases in patients with BRAF V600E mutation-positive melanoma; **AND**
  - Used in combination with dabrafenib; **AND**
    - Used as primary treatment in patients with small asymptomatic brain metastases; **OR**
    - Patient has recurrent limited brain metastases; **OR**
    - Used for relapsed limited brain metastases with stable systemic disease or reasonable systemic treatment options; **OR**
    - Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Ovarian Cancer (Epithelial Ovarian /Fallopian Tube /Primary Peritoneal)**

- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient is at least 18 years of age; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib, etc.); **AND**
- Patient has persistent or recurrent low-grade serous carcinoma; **AND**
- Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **AND**
- Used as a single agent

Diagnosis of **Hepatobiliary Cancers (Gallbladder Cancer, Intra/Extra-Hepatic Cholangiocarcinoma)**

- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient is at least 18 years of age; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib, etc.); **AND**
- Used in combination with dabrafenib; **AND**
- Used as subsequent therapy for progression on or after systemic treatment for unresectable or metastatic BRAF-V600E mutated disease

Diagnosis of **Histiocytic Neoplasms**

- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient is at least 18 years of age; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib); **AND**
- Used as single agent therapy; **AND**
- Patient has a MAP kinase pathway mutation, or no detectable mutation, or testing not available; **AND**
- Patient has one of the following:
  - Patient relapsed/refractory or symptomatic Erdheim-Chester disease; **OR**
  - Rosai-Dorfman disease; **AND**
    - Patient has symptomatic unifocal unresectable (bulky/site of disease) or symptomatic multifocal disease; **OR**
    - Relapsed or refractory disease; **OR**
  - Langerhans cell histiocytosis (LCH); **AND**
    - Patient has multisystem disease with symptomatic or impending organ dysfunction; **OR**
    - Patient has pulmonary disease; **OR**
    - Patient has multifocal single system bone disease that is not responsive to treatment with a bisphosphonate and > 2 lesions; **OR**
    - Patient has CNS lesions; **OR**
    - Patient has relapsed or refractory disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: interstitial lung disease/pneumonitis, cardiomyopathy, new primary malignancies, severe hemorrhagic events, colitis/gastrointestinal perforation, venous thromboembolism, ocular toxicities (e.g., persistent retinal pigment epithelial detachment [RPED], retinal vein occlusion [RVO], etc.), serious skin toxicities (e.g., Stevens-Johnson syndrome [SJS], drug reaction with eosinophilia and systemic symptoms [DRESS], etc.), serious febrile reactions, hyperglycemia, etc.; **AND**
- Left ventricular ejection fraction (LVEF) has not had an **absolute** decrease of ≥ 10% from baseline and is not below the lower limit of normal (LLN) *(LVEF results must be within the previous 3 months)*; **AND**

Adjuvant treatment of Melanoma

- Treatment has not exceeded 1 year of therapy

Cutaneous Melanoma (re-induction therapy)

- See initial criteria. Used as re-induction therapy

MEKTOVI® (BINIMETINIB)

Length of Authorization:	6 months, eligible for renewal Coverage for the adjuvant treatment of melanoma is up to a maximum of 1 year of therapy
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cutaneous Melanoma**

- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 2–3 months) during treatment; **AND**
- Patient is at least 18 years of age; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, dabrafenib, cobimetinib, trametinib) unless otherwise specified; **AND**
- Patient has BRAF V600 mutation-positive disease as detected by an FDA approved or CLIA compliant test; **AND**
  - Patient has unresectable or metastatic** disease; **AND**
    - Used as in combination with encorafenib; **AND**
      - Used as initial therapy or subsequent therapy; **OR**
      - Used as re-induction therapy for patients who experience disease control (i.e., complete response, partial response, or stable disease) from prior MEK inhibitor therapy, but who subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**
  - Used as adjuvant therapy in combination with encorafenib in patients with unacceptable toxicities to dabrafenib/trametinib; **AND**
    - Patient has lymph node involvement following complete resection, complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; **OR**
    - Patient has clinical satellite/in-transit metastases or local satellite/in-transit recurrence with no evidence of disease (NED) after complete excision to clear margins

***Metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease*

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: interstitial lung disease/pneumonitis, cardiomyopathy, severe hemorrhagic events, venous thromboembolism, ocular toxicities (e.g., serous retinopathy, retinal vein occlusion [RVO], uveitis), rhabdomyolysis, hepatotoxicity, cardiomyopathy, etc.; **AND**
- Left ventricular ejection fraction (LVEF) has not had an **absolute** decrease of ≥ 10% from baseline and is not below the lower limit of normal (LLN) *(LVEF results must be within the previous 3 months)*; **AND**

Adjuvant treatment of Melanoma

- Treatment has not exceeded 1 year of therapy

Cutaneous Melanoma (re-induction therapy)

- Refer to initial criteria (see Cutaneous Melanoma; used as re-induction therapy)

MEPSEVII™ (VESTRONIDASE ALFA-VJBK)

Length of Authorization:	1 year, eligible for renewal
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Mucopolysaccharidosis VII (MPS VII; Sly syndrome)**

- Patient has a definitive diagnosis of MPS VII confirmed by BOTH of the following:
  - Beta-glucuronidase enzyme deficiency in peripheral blood leukocytes; **AND**
  - Detection of pathogenic mutations in the *GUSB* gene by molecular genetic testing; **AND**
- Patient aged 5 months or older; **AND**
- Documented baseline value for one or more of the following: six-minute walk test (6MWT), motor function [i.e., Bruininks-Oseretsky Test of Motor Proficiency (BOT-2)], liver and/or spleen volume, urinary excretion of glycosaminoglycans (GAGs) such as chondroitin sulfate and dermatan sulfate, skeletal involvement (i.e. Z-score), pulmonary function tests, shoulder flexion, visual acuity, etc.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., anaphylaxis and severe allergic reactions); **AND**
- Patient has responded to therapy compared to pretreatment baseline in one or more of the following:
  - Stability or improvement in 6MWT shoulder flexion, visual acuity, and/or other motor functions
  - Reduction in liver and/or spleen volume
  - Reduction in urinary excretion of GAGs
  - Stability of skeletal disease (i.e. improvement in Z-score)
  - Stability or improvement in pulmonary function tests.

METASTRON™ (STRONTIUM-89 CHLORIDE)

Length of Authorization:	1 treatment course and may be renewed, one-time only, after 90 days
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Pain related to metastatic bone lesions**

- Patient is at least 18 years old; **AND**
- Patient has not had a treatment course of strontium-89 chloride within the previous 90 days; **AND**
- Patient will not use in combination with or has not had a treatment course of Samarium-Sm-153 Lexidronam within the previous 60 days; **AND**
- Women of child-bearing age must have a negative pregnancy test prior to treatment; **AND**
- Lactating women should discontinue breast feeding at least 6 weeks prior to administration; **AND**
- Patients of reproductive potential will use effective contraception during treatment with therapy and for at least six months after the last dose; **AND**
- Patient does not have significant bone marrow suppression (i.e., neutropenia, leukopenia, thrombocytopenia, etc.); **AND**
- Patient does not have disseminated intravascular coagulation; **AND**
- Used for palliative treatment of metastatic skeletal bone pain; **AND**
- Patient has had a positive (enhancement) radionuclide bone scan confirming osteoblastic metastatic bone lesions; **AND**
- Therapy will not be used for spinal cord compression pain; **AND**
- Patient has failed other conventional treatments for bone pain due to skeletal metastases (e.g., chemotherapy, hormonal therapy, external beam radiation, opioid analgesics, etc.); **AND**
- Patient has a life-expectancy of at least 6 months

CLINICAL CRITERIA FOR RENEWAL

- Patient had an inadequate response or recurrence of bone pain after the initial dose; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe leukopenia, severe thrombocytopenia, severe neutropenia); **AND**
- Patient has experienced hematological recovery since administration of the initial dose

MIFEPREX® (MIFEPRISTONE)

Length of Authorization:	1 time
Initiative:	MNC: Miscellaneous Pa required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

If Under the Pharmacy Benefit: Abortifacients Prior Authorization:

- Must have:
  - Intrauterine pregnancy
  - Must be ≤ 70 days' gestation
- Must **not** have
  - A suspected or confirmed ectopic pregnancy (not effective)

FYI - Mifeprex is only available through a restricted program under a REMS called MIFEPREX REMS Program because of the risks of serious complications

- Requirements of the program:
  - Prescribers must be certified with the program by completing the Prescriber Agreement Form
  - Patients must sign a Patient Agreement Form
  - Mifeprex must be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices and hospitals by or under the supervision of a certified prescriber
  - Further information is available at 1-877-4 Early Option (1-877-432-7596)

MONJUVI® (TAFASITAMAB-CXIX)

Length of Authorization:	6 months, eligible for renewal Combined use with lenalidomide must not exceed a maximum of 12 cycles; however, continued maintenance tafasitamab monotherapy may be renewed until disease progression or unacceptable toxicity.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Diffuse Large B-Cell Lymphoma (DLBCL)**

- Patient is 18 years of age or older; **AND**
- Patient has not received prior therapy with immunomodulatory imide (IMiD-class) agents (e.g., lenalidomide); **AND**
- Patient has not received prior therapy with CD19-directed therapy (e.g., axicabtagene, tisagenlecleucel) **or** patient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**
- Therapy will be initiated in combination with lenalidomide (**Note**: combination therapy with lenalidomide use is for up to 12 cycles only); **AND**
- Patient is ineligible for stem cell transplant; **AND**
  - Patient has diffuse large B-cell lymphoma (DLBCL); **AND**
    - Used as subsequent therapy for partial response, no response, relapsed, progressive, or refractory disease; **OR**
  - Patient has DLBCL without translocations of MYC and BCL2 and/or BCL6 transformed from grade 1-2 follicular lymphoma OR DLBCL transformed from nodal marginal zone lymphoma; **AND**
    - Patient received multiple lines of prior therapies, including two or more prior lines of chemoimmunotherapy for indolent or transformed disease; **OR**
    - Patient received minimal or no chemoimmunotherapy prior to histologic transformation with no response or progressive disease after chemoimmunotherapy, which must have included an anthracycline or anthracenedione-based regimen, unless contraindicated

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe infusion-related reactions, severe thrombocytopenia, severe neutropenia, severe infection, etc.; **AND**
- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Combination therapy with lenalidomide may not exceed a maximum of 12 cycles (continued tafasitamab single-agent maintenance therapy may be continued until disease progression or unacceptable toxicity)

MONOFERRIC™ (FERRIC DERISOMALTOSE)

Length of Authorization:	Coverage is provided for 35 days.
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR APPROVAL

Diagnosis of **Iron Deficiency Anemia in Non-Dialysis-Dependent Chronic Kidney Disease (NDD-CKD)**

- Patient age 18 years or older; **AND**
- Laboratory values must be obtained within 28 days prior to the anticipated date of administration; **AND**
- Other causes of anemia (e.g., blood loss, vitamin deficiency) have been ruled out; **AND**
- The patient does not have a history of allergic reaction to any intravenous iron product; **AND**
- Other supplemental iron is to be discontinued prior to administration of ferric derisomaltose; **AND**
- Patient must not be receiving hemodialysis; **AND**
- Patient has chronic renal impairment with eGFR between 15-59 mL/min; **AND**
- Patient has iron-deficiency anemia with a Hemoglobin (Hb) ≤ 11 g/dL; **AND**:
  - Ferritin ≤ 100 ng/mL; **OR**
  - Ferritin ≤ 300 ng/mL when transferrin saturation (TSAT) ≤ 30%

Diagnosis of **Iron Deficiency Anemia in Patients Intolerant to or who have had unsatisfactory response to oral iron**

- Patient age 18 years or older; **AND**
- Laboratory values must be obtained within 28 days prior to the anticipated date of administration; **AND**
- Other causes of anemia (e.g., blood loss, vitamin deficiency) have been ruled out; **AND**
- The patient does not have a history of allergic reaction to any intravenous iron product; **AND**
- Other supplemental iron is to be discontinued prior to administration of ferric derisomaltose; **AND**
- Patient had an intolerance or inadequate response to a minimum of 14 days of oral iron; **AND**
- Patient has iron-deficiency anemia with a Hemoglobin (Hb) ≤ 11 g/dL; **AND**:
  - Ferritin < 100 ng/mL; **OR**
  - Transferrin saturation (TSAT) < 20%

CLINICAL CRITERIA FOR RENEWAL

Refer to initial criteria

MULPLETA® (LUSUTROMBOPAG)

Length of Authorization:	Coverage is provided for one 7-day course of therapy and may not be renewed.
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR APPROVAL

Diagnosis of **Thrombocytopenia due to Chronic Liver Disease (CLD)**

- Patient is 18 years of age or older; **AND**
- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., romiplostim, eltrombopag, avatrombopag, etc.) or fostamtinib; **AND**
- Patient does **not** have Child-Pugh Class-C liver disease; **AND**
- Laboratory values are current (i.e., drawn within the previous 28 days); **AND**
- Lusutrombopag is not being used to attempt to normalize platelet counts; **AND**
- Patient is scheduled to undergo a procedure with a risk of bleeding which would necessitate a platelet transfusion; **AND**
- Patient will not be undergoing any of the following procedures:
  - Craniotomy
  - Thoracotomy
  - Laparotomy
  - Open-heart surgery
  - Organ resection; **AND**
- The patient is at increased risk for bleeding as indicated by platelet count of less than $< 50 \times 10^9/L$

CLINICAL CRITERIA FOR RENEWAL

May **not** be renewed

MULTIPLE SCLEROSIS THERAPY

Length of Authorization:	• 2 years, may be renewed • Mavenclad: Patient has not exceeded a total of 2 treatment courses or 4 cycles in a 2-year period; • Tysabri for Crohn's disease: Initial approval is for 12 weeks; renewal is for 6 months
Initiative:	SPC: Multiple Sclerosis Therapy (IE 2462 / NCPDP 75)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL OF ALL MEDICATIONS

Diagnosis of **relapsing form of multiple sclerosis** [i.e., relapsing-remitting disease (RRMS), active secondary progressive disease (SPMS), or clinically isolated syndrome (CIS – all meds except for Lemtrada®)]

- Patient is at least 18 years of age (unless specified elsewhere); **AND**
- Diagnosis confirmed by laboratory report (i.e., magnetic resonance imaging [MRI]); **AND**
- Must be used as single agent therapy.

DRUG-SPECIFIC CRITERIA IN ADDITION TO INITIAL CRITERIA ABOVE

AUBAGIO®

In addition to the criteria under initial approval:

- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient is not concurrently using Arava® (*leflunomide*); **AND**
- Patient does not have severe hepatic impairment; **AND**
- Females of reproductive potential must have a negative pregnancy test before initiation of therapy and use effective contraception while on therapy

In addition to the above criteria:

For Standard, Precision, and Enhanced Formularies

- Patient must have a **documented** failure, contraindication, intolerance, or ineffective response with a minimum **three**-month trial of Avonex®, Betaseron®, Copaxone®, Gilenya®, Kesimpta, glatiramer acetate, Mayzent®, Plegridy®, dimethyl fumarate, or Vumerity®; **OR**
- Patient is continuing treatment with requested medication

For Core Formulary

- Patient must have a documented failure, contraindication, intolerance, or ineffective response with a minimum of a three-month trial through **two** preferred agents: Avonex®, Betaseron®, dimethyl fumarate, Gilenya®, glatiramer acetate, Mayzent®, and Plegridy®.

DRUG-SPECIFIC CRITERIA IN ADDITION TO CRITERIA ABOVE *(CONTINUED)*

BAFIERTAM™

In addition to the criteria under initial approval:

- Patient is at least 18 years of age; **AND**
- Will not be given concomitantly with other fumarate class drugs (e.g., dimethyl fumarate, diroximel fumarate); **AND**
- Patient baseline lymphocyte and liver function tests were obtained prior to initiation of therapy and will continue to be monitored periodically while on therapy

In addition to the criteria above:

FOR STANDARD, PRECISION, AND ENHANCED FORMULARIES

- Patient must have a documented failure, contraindication, intolerance, or ineffective response with a minimum **three**-month trial of Avonex®, Betaseron®, Copaxone®, Gilenya®, glatiramer acetate, Kesimpta®, Mayzent®, Plegridy®, dimethyl fumarate, or Vumerity®; **OR**
- Patient is continuing treatment with the requested medication

FOR CORE FORMULARY

- Patient must have a documented failure, contraindication, intolerance, or ineffective response with a minimum three-month trial through **two** preferred agents: Avonex®, Betaseron®, dimethyl fumarate, Gilenya®, glatiramer acetate, Mayzent®, and Plegridy®

COPAXONE®

In addition to the criteria under initial approval:

FOR CORE FORMULARY

- Patient must have a documented failure, contraindication, intolerance, or ineffective response with a minimum three-month trial through **two** preferred agents: Avonex®, Betaseron®, dimethyl fumarate, Gilenya®, glatiramer acetate, Mayzent®, and Plegridy®

EXTAVIA®, REBIF®

In addition to the criteria under initial approval:

FOR STANDARD, PRECISION, AND ENHANCED FORMULARIES

- Patient must have a **documented** failure, contraindication, intolerance, or ineffective response with a minimum of **three**-month trial of Avonex®, Betaseron®, Copaxone®, Gilenya®, glatiramer acetate, Kesimpta®, Mayzent®, Plegridy®, dimethyl fumarate, or Vumerity®; **AND**
- For Extavia® patient must have a **documented** failure, contraindication, intolerance, or ineffective response with a minimum of **three**-month trial of Betaseron®; **OR**
- Patient is continuing treatment with requested medication.

FOR CORE FORMULARY

- For Rebif®, patient must have a documented failure, contraindication, intolerance, or ineffective response with a minimum of a three-month trial of **two** preferred agents: Avonex®, Betaseron®, dimethyl fumarate, Gilenya®, glatiramer acetate, Mayzent®, and Plegridy®; **AND**
- For Extavia®, patient must have a documented failure, contraindication, intolerance, or ineffective response with a minimum of three-month trial of Betaseron® **and** one other preferred agent: Avonex®, dimethyl fumarate, Gilenya®, glatiramer acetate, Mayzent®, and Plegridy®

DRUG-SPECIFIC CRITERIA IN ADDITION TO CRITERIA ABOVE *(CONTINUED)*

GILENYA®

In addition to the criteria under initial approval:

- Patient is 10 years of age or older; **AND**
- Patient has been tested for antibodies to the varicella zoster virus (VZV) or has received immunization for VZV one month prior to beginning therapy; **AND**
- Patient does not have a prolonged QTc interval at baseline (≥ 500 msec); **AND**
- Patient must not have any of the following contraindications to Gilenya®:
  - Myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure with hospitalization, or Class III/IV heart failure in the previous 6 months.
  - History or presence of Mobitz Type II second- or third-degree atrioventricular block or sick sinus syndrome (unless patient has a functioning pacemaker)
  - Cardiac arrhythmias requiring treatment with Class Ia (e.g., quinidine, procainamide, disopyramide) or Class III (e.g., amiodarone, dronedarone, sotalol, dofetilide, ibutilide) anti-arrhythmic drugs; **AND**
- Must not be administered concurrently with live vaccines and for at least 2 months after treatment; **AND**
- Patient will not be on concomitant therapy with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented:
  - Drugs that prolong the QT-interval (e.g., fluoroquinolone or macrolide antibiotics, venlafaxine, fluoxetine, quetiapine, ziprasidone, sumatriptan, zolmitriptan)
  - Ketoconazole
  - Drugs that slow the heart rate or AV conduction (e.g., beta blockers, digoxin, or heart rate-slowing calcium channel blockers such as diltiazem or verapamil)
  - Other antineoplastic, immunosuppressive or immunomodulating drugs (note: if there is a history of prior use of these drugs, consider possible unintended additive immunosuppressive effects); **AND**
- Patient does not have an active infection, including clinically important localized infections**; AND**
- Patient has had a baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment and will be re-evaluated during treatment if changes in vision occur

GLATOPA®

In addition to the criteria under initial approval:

FOR STANDARD, PRECISION, AND ENHANCED FORMULARIES

- Patient must have tried both Copaxone® and generic glatiramer.

FOR CORE FORMULARY

- Patient must have tried generic glatiramer.

DRUG-SPECIFIC CRITERIA IN ADDITION TO CRITERIA ABOVE *(CONTINUED)*

KESIMPTA®

In addition to the criteria under initial approval:

- Patient is at least 18 years of age; **AND**
- Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment and confirmed negative for active HBV; **AND**
- Patient serum immunoglobulin baseline has been measured prior to the start of therapy; **AND**
- Patient has not received any live or live-attenuated vaccinations in the 4 weeks prior to the start of therapy; **AND**
- Will not be administered concurrently with live vaccines; **AND**
- Patient does not have an active infection, including clinically important localized infections.

In addition to the above criteria:

FOR CORE FORMULARY

- Patient must have a documented failure, contraindication, intolerance, or ineffective response with a minimum of a three-month trial through **two** preferred agents: Avonex®, Betaseron®, dimethyl fumarate, Gilenya®, glatiramer acetate, Mayzent®, and Plegridy®

LEMTRADA®

In addition to the criteria under initial approval:

- Patient has been evaluated and screened for the presence of varicella zoster virus (VZV) and vaccinated, if required, prior to initiating treatment; **AND**
- Patient has a baseline electrocardiogram (ECG); **AND**
- Patient does not have human immunodeficiency virus infection; **AND**
- Patient has been evaluated and screened for the presence of tuberculosis (TB) prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**
- Patient does not have an active infection; **AND**
- Must not be administered concurrently, or within 6 weeks prior to treatment, with live vaccines; **AND**
- Patient has received a baseline skin exam for melanoma and will receive yearly skin exams; **AND**
- Patient has a baseline urine protein to creatinine ratio **and** thyroid-stimulating hormone (TSH) level prior to initiation of treatment and will receive ongoing laboratory monitoring during treatment; **AND**
- Patient will receive anti-viral prophylaxis for herpetic viral infections initiated on the first day of treatment and continued for two months following treatment (or until the CD4+ lymphocyte count is ≥ 200 cells/mcL); **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the LEMTRADA REMS program; **AND**
- Must be used as a single agent

DRUG-SPECIFIC CRITERIA IN ADDITION TO CRITERIA ABOVE *(CONTINUED)*

MAVENCLAD®

In addition to the criteria under initial approval:

- Patient weight is at least 40 kg (88 lbs.); **AND**
- Patient has been tested for the presence of antibodies to the varicella zoster virus (VZV) or has received vaccination for VZV 4-6 weeks prior to beginning therapy; **AND**
- Patient has a baseline magnetic resonance imaging (MRI) before initiating the first treatment course (within 3 months prior to start of therapy); **AND**
- Patient must not have any of the following contraindications to cladribine:
  - Patient does not have a current diagnosis of malignancy; **AND**
  - Women of child-bearing age must have a negative pregnancy test prior to treatment
  - Patients of reproductive potential must use effective contraception while on treatment and for at least six months after the last dose
  - Patient does not have an infection with the human immunodeficiency virus (HIV)
  - Patient does not have an active infection, including clinically important localized infections
  - Lactating women should discontinue breast feeding on treatment day to and for 10 days after the last administered dose; **AND**
- Will not be used in combination with other antineoplastic, immunosuppressive, or immunomodulating drugs (**Note:** if there is a history of prior use of these drugs, consider possible unintended additive immunosuppressive effects); **AND**
- Will not be used in combination with antiviral and antiretroviral drugs (e.g., lamivudine, zalcitabine, ribavirin, stavudine, zidovudine); **AND**
- Will not be used in combination with potent ENT1, CNT3, or BCRP transporter inhibitors (e.g., ritonavir, eltrombopag, curcumin, cyclosporine, dilazep, nifedipine, nimodipine, cilostazol, sulindac, dipyridamole, reserpine), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Live vaccines must not be administered concurrently or 4-6 weeks prior to beginning therapy; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Patient has been evaluated and screened for the presence of hepatitis B and hepatitis C virus (HBV/HCV) prior to initiating each treatment course
- RRMS only: Patient had at least 1 relapse in the previous 12 months

In addition to the above criteria:

FOR STANDARD, PRECISION, AND ENHANCED FORMULARIES

- Patient must have a documented failure, contraindication, intolerance, or ineffective response with a minimum of **three**-month trial of **two** of the following: Avonex®, Betaseron®, Copaxone®, Gilenya®, glatiramer acetate, Kesimpta®, Mayzent®, Plegridy®, dimethyl fumarate, or Vumerity®; **OR**
- Patient is continuing treatment with the requested medication**.**

FOR CORE FORMULARY

- Patient must have a documented failure, contraindication, intolerance, or ineffective response with a minimum of a three-month trial through **two** preferred agents: Avonex®, Betaseron®, dimethyl fumarate, Gilenya®, glatiramer acetate, Mayzent®, and Plegridy®

Note: Excludes use in clinically isolated syndrome (CIS)

DRUG-SPECIFIC CRITERIA IN ADDITION TO CRITERIA ABOVE *(CONTINUED)*

MAYZENT®

In addition to the criteria under initial approval:

- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Patient will not be initiating therapy after previous treatment with alemtuzumab; **AND**
- Patient has been tested for the presence of antibodies to the varicella zoster virus (VZV) or has received vaccination for VZV 4 weeks prior to beginning therapy; **AND**
- Patient must not have any of the following contraindications to siponimod:
  - A CYP2C9*3/*3 genotype
  - Myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure with hospitalization, or Class III/IV heart failure within the previous six months
  - History or presence of Mobitz Type II second or third-degree atrioventricular block or sick sinus syndrome (unless patient has a functioning pacemaker); **AND**
- Must be prescribed by, or in consultation with, a specialist in cardiology in patients with a pre-existing cardiac condition and/or cardiovascular disease (i.e., conduction abnormalities, arrhythmias requiring treatment, heart disease, heart failure, history of cardiac arrest or myocardial infarction, cerebrovascular disease, uncontrolled hypertension, or sinoatrial heart block); **AND**
- Patient CYP2C9 variant status has been tested to determine genotyping **(required for dosing)**; **AND**
- Patient will not be on concomitant therapy with any of the following:
  - Moderate or strong CYP3A4 inducers (e.g., modafinil, efavirenz) in patients with a CYP2C9*1/*3 and CYP2C9*2/*3 genotypes
  - Drug regimens that contain moderate CYP2C9/CYP3A4 dual inhibitors (e.g., fluconazole) or in combination with a moderate CYP2C9 inhibitor plus a moderate-to-strong CYP3A4 inhibitor
  - Drug regimens that contain moderate CYP2C9/strong CYP3A4 dual inducer (e.g., rifampin or carbamazepine) or a moderate CYP2C9 inducer plus a strong CYP3A4 inducer; **AND**
- Patient will not be on concomitant therapy with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented:
  - Moderate CYP2C9 inhibitors (e.g., amiodarone, fluvoxamine, miconazole)
  - Moderate CYP2C9 inducers (e.g., carbamazepine, enzalutamide, rifampin)
  - Other antineoplastic, immunosuppressive or immunomodulating drugs (**Note**: if there is a history of prior use of these drugs, consider possible unintended additive immunosuppressive effects)
  - Drugs that prolong the QT-interval (e.g., fluoroquinolone or macrolide antibiotics, venlafaxine, fluoxetine, quetiapine, ziprasidone, sumatriptan, zolmitriptan)
  - Drugs that may decrease heart rate (e.g., ivabradine, digoxin, verapamil, diltiazem, beta-blockers); **AND**
- Must not be administered concurrently with live vaccines and for at least 4 weeks after treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient has had a baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment and will be re-evaluated during treatment if changes in vision occur.

DRUG-SPECIFIC CRITERIA IN ADDITION TO CRITERIA ABOVE *(CONTINUED)*

OCREVUS®

In addition to the criteria under initial approval:

- Patient is 18 years or older (**unless otherwise specified**); **AND**
- Patient has been screened for the presence of Hepatitis B virus (HBV) prior to initiating treatment **and** does not have active disease (i.e., positive HBsAg and anti-HBV tests); **AND**
- Patient has baseline serum immunoglobulins assessed; **AND**
- Patient will not receive live vaccines concurrently with ocrelizumab; **AND**
- Patient does not have an active infection; **AND**
- Patient must have a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (e.g., MRI); **AND**
- Must be used as single agent therapy; **AND**
  - Patient has a diagnosis of a relapsing form of MS [i.e., relapsing-remitting MS (RRMS)*, active secondary progressive disease (SPMS), or clinically isolated syndrome (CIS)]; **OR**
  - Patient has a diagnosis of primary progressive MS (PPMS); **AND**
    - Patient less than 65 years of age; **AND**
    - Patient has an expanded disability status scale (EDSS) score of ≤ 6.5

PONVORY®

In addition to the criteria under initial approval:

- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Patient will not be initiating therapy after previous treatment with alemtuzumab; **AND**
- Patient has been tested for the presence of antibodies to the varicella zoster virus (VZV) or has received vaccination for VZV 4 weeks prior to beginning therapy; **AND**
- Patients has had a baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment; **AND**
- Patient has a baseline heart rate (HR) of greater than 55 beats per minute (bpm); **AND**
- Patient does not have moderate or severe hepatic impairment (i.e., Child-Pugh class B or C); **AND**
- Patient must not have any of the following contraindications to ponesimod:
  - Myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure with hospitalization, or Class III/IV heart failure within the previous six months
  - History or presence of Mobitz Type II second or third-degree atrioventricular block, sick sinus syndrome, or sinoatrial block (unless treated with a functioning pacemaker); **AND**
- Must be prescribed by or in consultation with a specialist in cardiology in patients with a pre-existing cardiac condition and/or cardiovascular disease (i.e., conduction abnormalities, arrhythmias requiring treatment, heart disease, heart failure, history of cardiac arrest or myocardial infarction, cerebrovascular disease, uncontrolled hypertension, or sinoatrial heart block), syncope, bradycardia, severe untreated sleep apnea, or in patients receiving therapies that decrease heart rate; **AND**

DRUG-SPECIFIC CRITERIA IN ADDITION TO CRITERIA ABOVE *(CONTINUED)*

PONVORY® *(CONTINUED)*

- Patient will not be on concomitant therapy with any of the following:
  - Coadministration with strong CYP3A4 and UGT1A1 inducers (e.g., rifampin, phenytoin, carbamazepine)
  - Drugs that prolong the QT-interval with known arrhythmogenic properties (e.g., verapamil, diltiazem) or drugs that may decrease heart rate (e.g., digoxin)
  - Other antineoplastic, immunosuppressive, or immunomodulating drugs (**Note**: if there is a history of prior use of these drugs, consider possible unintended additive immunosuppressive effects); **AND**
- Must not be administered concurrently with live vaccines during and at least 4 weeks prior to and 1 to 2 weeks after treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections.

In addition to the above criteria:

For Standard, Precision, and Enhanced Formularies

- Patient must have a **documented** failure, contraindication, intolerance, or ineffective response with a minimum **three**-month trial of Avonex®, Betaseron®, Copaxone®, Gilenya®, Kesimpta, glatiramer acetate, Mayzent®, Plegridy®, dimethyl fumarate, or Vumerity®; **OR**
- Patient is continuing treatment with requested medication

For Core Formulary

- Patient must have a documented failure, contraindication, intolerance, or ineffective response with a minimum of a three-month trial through **two** preferred agents: Avonex®, Betaseron®, dimethyl fumarate, Gilenya®, glatiramer acetate, Mayzent®, and Plegridy®.

TECFIDERA® AND DIMETHYL FUMARATE

In addition to the criteria under initial approval:

- Will not be given concomitantly with other fumarate class drugs (e.g., diroximel fumarate monomethyl fumarate); **AND**
- Patient has had a baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment and will be re-evaluated during treatment if changes in vision occur

- **Note**: Brand name Tecfidera is non-formulary for all formularies. **NO GRANDFATHERING.**

TYSABRI®

Diagnosis of **MS**

- Prescriber and patient must be enrolled in and meet the conditions of the TOUCH program; **AND**
- Documented negative JCV antibody ELISA test within the past 6 months **§**; **AND**
- Not used in combination with antineoplastic, immunosuppressant, or immunomodulating agents; **AND**
- Patient must not have a systemic medical condition resulting in significantly compromised immune system function

DRUG-SPECIFIC CRITERIA IN ADDITION TO CRITERIA ABOVE *(CONTINUED)*

TYSABRI® *(CONTINUED)*

In addition to the above criteria:

FOR STANDARD, PRECISION, AND ENHANCED FORMULARIES

- Patient must have a **documented** failure, contraindication, intolerance, or ineffective response with a minimum of **three**-month trial of Avonex®, Copaxone®, Betaseron®, Gilenya®, glatiramer acetate, Kesimpta®, Mayzent®, Plegridy®, dimethyl fumarate, or Vumerity®; **OR**
- Patient is continuing treatment with requested medication.

FOR CORE FORMULARY:

- Patient must have a documented failure, contraindication, intolerance, or ineffective response with a minimum of a three-month trial through **two** preferred agents: Avonex®, Betaseron®, dimethyl fumarate, Gilenya®, glatiramer acetate, Mayzent®, and Plegridy®

Diagnosis of **Crohn's disease**

- Patient is at least 18 years of age; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the TOUCH program; **AND**
- Documented negative JCV antibody ELISA test within the past 6 months **§**; **AND**
- Not used in combination with antineoplastic, immunosuppressant, or immunomodulating agents; **AND**
- Patient must not have a systemic medical condition resulting in significantly compromised immune system function; **AND**
- Patient has moderate to severe active disease; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented trial and failure on **one** oral immunosuppressive therapy for at least 3 months, unless use is contraindicated, such as corticosteroids, methotrexate, azathioprine, and/or 6-mercaptopurine; **AND**
- Documented trial and failure on **one** TNF-Inhibitor therapy for at least 3 months, unless contraindicated, such as infliximab, certolizumab, or adalimumab; **AND**
- Used as single agent therapy [Not used concurrently with another biologic drug or immunosuppressant (e.g., 6-mercaptopurine, azathioprine, cyclosporine, methotrexate) used for Crohn's disease].

§ Risk factors for the development of Progressive Multifocal Leukoencephalopathy (PML) [1,13,14]

- Presence of anti-JCV antibodies. Patients who are anti-JCV antibody positive have a higher risk for developing PML.
- Prior treatment with an immunosuppressant (e.g., mitoxantrone, azathioprine, methotrexate, cyclophosphamide, mycophenolate mofetil)
- Longer treatment duration, especially beyond 2 years
- Elevated levels of anti-JCV antibody response index (i.e., index > 0.9).
  - In those using natalizumab for 25–36 months with no prior use of immunosuppressants, the PML risk is 0.2 per 1,000 in those with an index of 0.9 or less, 0.3 per 1,000 in those with an index of 0.9–1.5, and 3 per 1,000 in those with an index greater than 1.5.

DRUG-SPECIFIC CRITERIA IN ADDITION TO CRITERIA ABOVE *(CONTINUED)*

VUMERITY®

In addition to the criteria under initial approval:

- Will not be given concomitantly with other fumarate class drugs (e.g., dimethyl fumarate, monomethyl fumarate); **AND**
- Patient does not have moderate to severe renal impairment (i.e., GFR ≥ 45 mL/min/1.73 m^2)**; AND**
- Patient baseline lymphocyte and liver function tests were obtained prior to initiation of therapy and will continue to be monitored periodically while on therapy.

In addition to the above criteria:

FOR CORE FORMULARY

- Patient must have a documented failure, contraindication, intolerance, or ineffective response with a minimum of a three-month trial through **two** preferred agents: Avonex®, Betaseron®, dimethyl fumarate, Gilenya®, glatiramer acetate, Mayzent®, and Plegridy®

ZEPOSIA® FOR MULTIPLE SCLEROSIS

In addition to the criteria under initial approval for multiple sclerosis:

- Patient is at least 18 years old; **AND**
- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Patient will not be initiating therapy after previous treatment with alemtuzumab; **AND**
- Patient has been tested for the presence of antibodies to the varicella zoster virus (VZV) or has received vaccination for VZV 4 weeks prior to beginning therapy; **AND**
- Patients with diabetes mellitus or a history of uveitis have had a baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment; **AND**
- Patient must not have any of the following contraindications to ozanimod:
  - Severe, untreated sleep apnea
  - Concomitant use with MAO-inhibitors (e.g., selegiline, phenelzine, linezolid)
  - Myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure with hospitalization, or Class III/IV heart failure within the previous six months
  - History or presence of Mobitz Type II second or third-degree atrioventricular block, sick sinus syndrome, or sinoatrial block (unless treated with a functioning pacemaker); **AND**
- Must be prescribed by, or in consultation with, a specialist in cardiology in patients with a pre-existing cardiac condition and/or cardiovascular disease (i.e., conduction abnormalities, arrhythmias requiring treatment, heart disease, heart failure, history of cardiac arrest or myocardial infarction, cerebrovascular disease, uncontrolled hypertension, or sinoatrial heart block); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP2C8 inducers (e.g., rifampin); **AND**
  - Coadministration with strong CYP2C8 inhibitors (e.g., gemfibrozil); **AND**

DRUG-SPECIFIC CRITERIA IN ADDITION TO CRITERIA ABOVE *(CONTINUED)*

ZEPOSIA® FOR MULTIPLE SCLEROSIS (*CONTINUED*)

- Patient will avoid concomitant therapy with all of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented:
  - Coadministration with anti-arrhythmic drugs, drugs that prolong the QT-interval, or drugs that may decrease the heart rate (e.g., quinidine, procainamide, amiodarone, sotalol, combination use of a beta blocker and calcium channel blocker, fluoroquinolone or macrolide antibiotics, venlafaxine, fluoxetine, quetiapine, ziprasidone, sumatriptan, zolmitriptan); **AND**
  - Coadministration with adrenergic or serotonergic drugs that can increase norepinephrine or serotonin (e.g., opioid drugs, selective serotonin reuptake inhibitors (SSRIs), selective norepinephrine reuptake inhibitors (SNRIs), tricyclics, tyramine); **AND**
  - Coadministration with foods containing very large amounts (i.e., > 150 mg) of tyramine (e.g., aged, fermented, cured, smoked, and pickled foods); **AND**
  - Coadministration with other antineoplastic, immunosuppressive or immunomodulating drugs (**Note**: if there is a history of prior use of these drugs, consider possible unintended additive immunosuppressive effects); **AND**
- Must not be administered concurrently with live vaccines during and at least 4 weeks prior to and 12 weeks after treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections

In addition to the above criteria:

FOR STANDARD AND ENHANCED FORMULARIES

- Patient must have a documented failure, contraindication, intolerance, or ineffective response with a minimum of three-month trial of one of the following: Avonex®, Betaseron®, Copaxone®, Gilenya®, glatiramer acetate, Kesimpta®, Mayzent®, Plegridy®, dimethyl fumarate, or Vumerity®; **OR**
- Patient is continuing treatment with the requested medication.

ZEPOSIA® FOR ULCERATIVE COLITIS

For a Diagnosis of **Ulcerative Colitis**

- Patient is at least 18 years of age; **AND**
- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Patient will not be initiating therapy after previous treatment with alemtuzumab; **AND**
- Patient has been tested for the presence of antibodies to the varicella zoster virus (VZV) or has received vaccination for VZV 4 weeks prior to beginning therapy; **AND**
- Patients with diabetes mellitus or a history of uveitis have had a baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment; **AND**
- Patient must not have any of the following contraindications to ozanimod:
  - Severe, untreated sleep apnea
  - Concomitant use with MAO-inhibitors (e.g., selegiline, phenelzine, linezolid)
  - Myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure with hospitalization, or Class III/IV heart failure within the previous six months
  - History or presence of Mobitz Type II second or third-degree atrioventricular block, sick sinus syndrome, or sinoatrial block (unless treated with a functioning pacemaker); **AND**

DRUG-SPECIFIC CRITERIA IN ADDITION TO CRITERIA ABOVE *(CONTINUED)*

ZEPOSIA® FOR ULCERATIVE COLITIS (CONTINUED)

- Must be prescribed by or in consultation with a specialist in cardiology in patients with a pre-existing cardiac condition and/or cardiovascular disease (e.g., conduction abnormalities, arrhythmias requiring treatment, heart disease, heart failure, history of cardiac arrest or myocardial infarction, cerebrovascular disease, uncontrolled hypertension, or sinoatrial heart block); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP2C8 inducers (e.g., rifampin); **AND**
  - Coadministration with strong CYP2C8 inhibitors (e.g., gemfibrozil); **AND**
- Patient will avoid concomitant therapy with all of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented:
  - Coadministration with anti-arrhythmic drugs, drugs that prolong the QT-interval, or drugs that may decrease the heart rate (e.g., quinidine, procainamide, amiodarone, sotalol, combination use of a beta blocker and calcium channel blocker, fluoroquinolone or macrolide antibiotics, venlafaxine, fluoxetine, quetiapine, ziprasidone, sumatriptan, zolmitriptan); **AND**
  - Coadministration with adrenergic or serotonergic drugs that can increase norepinephrine or serotonin (e.g., opioid drugs, selective serotonin reuptake inhibitors (SSRIs), selective norepinephrine reuptake inhibitors (SNRIs), tricyclics, tyramine); **AND**
  - Coadministration with foods containing very large amounts (i.e., > 150 mg) of tyramine (e.g., aged, fermented, cured, smoked, and pickled foods); **AND**
  - Coadministration with other antineoplastic, immunosuppressive or immunomodulating drugs (**Note**: if there is a history of prior use of these drugs, consider possible unintended additive immunosuppressive effects); **AND**
- Must not be administered concurrently with live vaccines during and at least 4 weeks prior to and 12 weeks after treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Used as single agent therapy or in combination with oral aminosalicylates (e.g., mesalamine, sulfasalazine, balsalazide) and/or corticosteroids; **AND**
- Documented moderate to severe disease; **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of oral aminosalicylates (e.g., mesalamine, sulfasalazine, balsalazide), corticosteroids, immunomodulators (e.g., 6-mercaptopurine, azathioprine), or a biologic (e.g., TNF blocker and/or vedolizumab)

DRUG-SPECIFIC CRITERIA IN ADDITION TO CRITERIA ABOVE *(CONTINUED)*

ADDITIONAL INFORMATION ON MS DIAGNOSIS CRITERIA

<table>
<tr><th colspan="2">Definitive diagnosis of MS with a relapsing-remitting course is based upon BOTH dissemination in time and space. Unless contraindicated, MRI should be obtained (even if criteria are met).</th></tr>
<tr><th>Dissemination in time
(Development/appearance of new CNS lesions over time)</th><th>Dissemination in space
(Development of lesions in distinct anatomical locations within the CNS; multifocal)</th></tr>
<tr><td>• ≥ 2 clinical attacks; OR
• 1 clinical attack and one of the following:
– MRI indicating simultaneous presence of gadolinium-enhancing and non-enhancing lesions at any time or by a new T2-hyperintense or gadolinium-enhancing lesion on follow-up MRI compared to baseline scan
– CSF-specific oligoclonal bands</td><td>• ≥ 2 lesions; OR
• 1 lesion and one of the following:
– Clear-cut historical evidence of a previous attack involving a lesion in a distinct anatomical location
– MRI indicating ≥ 1 T2-hyperintense lesions characteristic of MS in ≥ 2 of 4 areas of the CNS (periventricular, cortical or juxtacortical, infratentorial, or spinal cord)</td></tr>
<tr><th colspan="2">Active secondary progressive MS (SPMS) is defined as the following:</th></tr>
<tr><td colspan="2">• Expanded Disability Status Scale (EDSS) score > 3.0; AND
• Disease is progressive ≥ 3 months following an initial relapsing-remitting course (i.e., EDSS score increase by 1.0 in patients with EDSS ≤5.5 or increase by 0.5 in patients with EDSS ≥ 6); AND
– ≥ 1 relapse within the previous 2 years; OR
– Patient has gadolinium-enhancing activity or new or unequivocally enlarging T2 contrast-enhancing lesions as evidenced by MRI</td></tr>
<tr><th colspan="2">Definitive diagnosis of MS with a primary progressive course is based upon the following:</th></tr>
<tr><td colspan="2">• 1 year of disability progression independent of clinical relapse; AND
• Two of the following:
– ≥ 1 T2-hyperintense lesion characteristic of MS in one or more of the following regions of the CNS (periventricular, cortical or juxtacortical, or infratentorial)
– ≥ 2 T2-hyperintense lesions in the spinal cord
– Presence of CSF-specific oligoclonal bands</td></tr>
<tr><th colspan="2">Definitive diagnosis of CIS is based upon all of the following:</th></tr>
<tr><td colspan="2">• A monophasic clinical episode with patient-reported symptoms and objective findings reflecting a focal or multifocal inflammatory demyelinating event in the CNS
• Neurologic symptom duration of at least 24 hours, with or without recovery
• Absence of fever or infection
• Resembles a typical MS relapse (attack and exacerbation) but occurs in a patient not known to have MS</td></tr>
</table>

CLINICAL CRITERIA FOR RENEWAL

- Continuous monitoring of response to therapy indicates a beneficial response* [manifestations of MS disease activity include, but are not limited to, an increase in annualized relapse rate (ARR), development of new/worsening T2 hyperintensities or enhancing lesions on brain/spinal MRI, and progression of sustained impairment as evidenced by expanded disability status scale (EDSS), timed 25-foot walk (T25-FW), 9-hole peg test (9-HPT)]; **AND**

***Note**: Inadequate response, in those who have been adherent and receiving therapy for sufficient time to realize the full treatment effect, is defined as ≥ 1 relapse, ≥ 2 unequivocally new MRI-detected lesions, or increased disability on examination over a one-year period

- Zeposia for Ulcerative colitis: Disease response as indicated by improvement in signs and symptoms compared to baseline, such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score or the Mayo Score].
- Absence of unacceptable toxicity from the drug
  - **Examples for Aubagio®**: increase in serum transaminases (ALT), severe hepatic injury, severe hypersensitivity and skin reactions, peripheral neuropathy, uncontrolled hypertension, bone marrow suppression (e.g., neutropenia, lymphopenia, thrombocytopenia), serious infections, interstitial lung disease/acute interstitial pneumonitis, drug reaction with eosinophilia and systemic symptoms (DRESS),etc.
  - **Examples for Bafiertam™**: anaphylaxis and angioedema, prolonged (more than 6 months) lymphopenia (<0.5 x 10^9/L), serious flushing reactions, progressive multifocal leukoencephalopathy (PML), liver injury, herpes zoster or other serious infections, etc.
  - **Examples for Gilenya®**: macular edema; severe hepatic injury; bradyarrhythmia; atrioventricular (AV) blocks; active serious infection; decreased respiratory function; Progressive multifocal leukoencephalopathy (PML); Posterior reversible encephalopathy syndrome (PRES); cutaneous malignancies (e.g., basal cell carcinoma, melanoma), lymphomas, uncontrolled hypertension, hypersensitivity reactions, etc.
  - **Examples for Lemtrada®**: immune thrombocytopenia, glomerular nephropathies, thyroid disorders, autoimmune conditions, severe infusion reactions including anaphylaxis, ischemic or hemorrhagic strokes, malignancies (e.g., thyroid cancer, melanoma, lymphoproliferative disorders/lymphoma), progressive multifocal encephalopathy, thrombotic thrombocytopenic purpura, hemophagocytic lymphohistiocytosis, acquired hemophilia A, etc.
  - **Examples for Kesimpta®**: Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: serious or opportunistic infections, HBV reactivation, progressive multifocal leukoencephalopathy (PML), serious injection site reactions, prolonged hypogammaglobinemia, etc.
  - **Examples for Mavenclad®**: lymphopenias, severe hepatic injury, active serious infection, progressive multifocal leukoencephalopathy (PML), new onset malignancies, graft-versus-host-disease with blood transfusions, thrombocytopenia, neutropenia, pancytopenia, severe hypersensitivity reactions, acute cardiac failure, etc.;
  - **Examples for Mayzent®**: macular edema; severe hepatic injury; bradyarrhythmia; atrioventricular (AV) conduction delays; active serious infection; decreased respiratory function; Progressive multifocal leukoencephalopathy (PML); Posterior reversible encephalopathy syndrome (PRES); uncontrolled hypertension; etc.
  - **Examples for Ocrevus®**: severe infusion reactions, severe infections, malignancy, hypogammaglobulinemia, etc.
  - **Examples for Ponvory®**: active serious infection, bradyarrhythmia, atrioventricular (AV) blocks, decreased respiratory function, severe hepatic injury, uncontrolled hypertension, cutaneous malignancies, macular edema, progressive multifocal leukoencephalopathy (PML), posterior reversible encephalopathy syndrome (PRES), etc.

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

- **Examples for Tecfidera® and generic dimethyl fumarate**: anaphylaxis and angioedema, prolonged (more than 6 months) lymphopenia (<0.5 x 10^9/L), serious flushing reactions, progressive multifocal leukoencephalopathy (PML), liver injury, herpes zoster or other serious infections, etc.
- **Examples for Tysabri®**: hypersensitivity reactions/antibody formation, hepatotoxicity, signs or symptoms of progressive multifocal leukoencephalopathy (PML), herpes infections (including herpes encephalitis and meningitis and acute retinal necrosis), immunosuppression, infections (including pneumonias, pneumocystis carinii pneumonia, pulmonary mycobacterium avium intracellulare, bronchopulmonary aspergillosis, herpes, urinary tract infections, gastroenteritis, vaginal infections, tooth infections, tonsillitis, etc.), thrombocytopenia, etc.
- **Examples for Copaxone® and glatiramer acetate**: Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: immediate post-injection site reactions, lipoatrophy and skin necrosis, chest pain, hepatic injury, etc.
- **Examples for Betaseron®:** Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: increase in serum transaminases (ALT) or severe hepatic injury, leukopenia, depression and suicidal ideation, seizures, anaphylaxis, injection site necrosis and reactions, drug-induced lupus erythematosus, thrombotic microangiopathy, congestive heart failure, etc.
- **Examples for Extavia®:** Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: increase in serum transaminases or severe hepatic injury, leukopenia, depression and suicidal ideation, seizures, anaphylaxis, injection site necrosis and reactions, drug-induced lupus erythematosus, thrombotic microangiopathy, congestive heart failure, etc.
- **Examples for Avonex® Glatopa®, Plegridy®, and Rebif®**: increase in serum transaminases (ALT) or severe hepatic injury, depression and other severe psychiatric symptoms (suicidal ideation or psychosis), anaphylaxis or other allergic reactions, seizures, congestive heart failure, decreased blood counts (thrombocytopenia, pancytopenia, etc.), thrombotic microangiopathy, autoimmune disorders (idiopathic thrombocytopenia, hyper- and hypothyroidism, autoimmune hepatitis, etc.), etc.
- **Examples for Vumerity®**: anaphylaxis and angioedema; prolonged (more than 6 months) lymphopenia (< 0.5 x 10^9/L), serious flushing reactions, progressive multifocal leukoencephalopathy (PML), liver injury, herpes zoster and other serious opportunistic infections, etc.
- **Tysabri®**: Documented negative JCV antibody ELISA test within the past 6 months.
- **Examples for Zeposia®**: macular edema, severe hepatic injury, bradyarrhythmia, atrioventricular (AV) delays, active serious infection, decreased respiratory function, progressive multifocal leukoencephalopathy (PML), posterior reversible encephalopathy syndrome (PRES), uncontrolled hypertension, etc.

Additional monitoring for **Lemtrada®**:

- Patient is receiving ongoing monitoring for presence of TB or other active infections; **AND**
- Patient is receiving ongoing laboratory monitoring (e.g., TSH levels, urine protein to creatinine ratio) and physical examinations (melanoma exam, malignancies, infection) as indicated.

Additional information for **Mavenclad®**:

- Patient has not exceeded a total of 2 treatment courses or 4 cycles in a 2-year period.

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

Additional monitoring for **Ponvory®**:

- Patient has had an ophthalmic re-evaluation if changes in vision have been experienced; **AND**
- Patient has periodic skin examinations for cutaneous malignancies during therapy

Additional information for **Tysabri®**:

- Infusion reactions or breakthrough disease activity may indicate neutralizing natalizumab antibodies. Therapy should be discontinued in patients who have persistent neutralizing antibodies to natalizumab.

Additional information for **Ocrevus®**:

- Patient has not received a dose of ocrelizumab within the past 5 months
  - For a diagnosis of PPMS
  - Patient continues to be ambulatory, defined as an EDSS score of < 7.5

Additional monitoring for **Zeposia**:

- Patient has had an ophthalmic re-evaluation if changes in vision have been experienced

Crohn's Disease (**Tysabri®**):

- Initial renewal only:
  - Clinical response and remission of disease is seen by 12 weeks
- Second renewal only:
  - Patient has been tapered off of oral corticosteroids within six months of starting Tysabri; **AND**
  - Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra intestinal complications, tapering or discontinuation of corticosteroid therapy, use of anti-diarrheal drugs, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score.].
- All subsequent renewals:
  - Patient does not require additional steroid use that exceeds three months in a calendar year to control their Crohn's disease; **AND**
  - Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra intestinal complications, tapering or discontinuation of corticosteroid therapy, use of anti-diarrheal drugs, and/or an improvement on a disease activity scoring tool (e.g., an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score).

MULTIPLE SCLEROSIS THERAPY: AMPYRA®(DALFAMPRIDINE)

Length of Authorization:	6 Months initial, 2-year renewals
Initiative:	SPC: Multiple Sclerosis Therapy (IE 2462 / NCPDP 75)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Sclerosis (MS)**

- Patient is 18 years of age or older; **AND**
- Patient has no past medical history of seizures; **AND**
- Patient's creatinine clearance, determined within the last 6 months, is ≥ 50 mL/min; **AND**
- Patient will avoid concomitant use with OCT2 inhibitors (i.e., cimetidine), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient is currently on disease modifying therapy for MS (i.e., interferon beta-1a, interferon beta-1b, peginterferon beta-1a, glatiramer, teriflunomide, fingolimod, dimethyl fumarate, natalizumab, alemtuzumab, daclizumab, ocrelizumab, etc.); **AND**
- Confirmed diagnosis of MS as documented by laboratory report (i.e., MRI); **AND**
- Expanded Disability Status Score (EDSS) ≥ 2.5 and ≤ 7; **AND**
- Baseline timed 25 feet walk (T25W) between 8 and 45 seconds

CLINICAL CRITERIA FOR RENEWAL

- Patient has 20% improvement from baseline in timed 25 feet walk (T25W); **AND**
- Absence of unacceptable toxicity from the drug (e.g., seizures, renal impairment, anaphylaxis)

CORE FORMULARY CRITERIA

Diagnosis of **Multiple Sclerosis (MS)**

- Patient is 18 years of age or older; **AND**
- Patient has no past medical history of seizures; **AND**
- Patient's creatinine clearance, determined within the last 6 months, is ≥ 50 mL/min; **AND**
- Patient will avoid concomitant use with OCT2 inhibitors (i.e., cimetidine), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient is currently on disease modifying therapy for MS (i.e., interferon beta-1a, interferon beta-1b, peginterferon beta-1a, glatiramer, teriflunomide, fingolimod, dimethyl fumarate, natalizumab, alemtuzumab, daclizumab, ocrelizumab, etc.); **AND**
- Confirmed diagnosis of MS as documented by laboratory report (i.e., MRI); **AND**
- Expanded Disability Status Score (EDSS) ≥ 2.5 and ≤ 7; **AND**
- Baseline timed 25 feet walk (T25W) between 8 and 45 seconds
- **Core:** For brand Ampyra, patient must have a contraindication or intolerance to a trial dalfampridine ER

CLINICAL CRITERIA FOR RENEWAL

- Patient has 20% improvement from baseline in timed 25 feet walk (T25W); **AND**
- Absence of unacceptable toxicity from the drug (e.g., seizures, renal impairment, anaphylaxis)

MYALEPT® (METRELEPTIN)

Length of Authorization:	6 months, eligible for renewal
Initiative:	SPC: Growth Hormone (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **generalized lipodystrophy (congenital or acquired)**

- Patient is at least 1 year of age or older; **AND**
- Both patient and prescriber are enrolled in the MYALEPT REMS program; **AND**
- Patient has a diagnosis of diabetes or hypertriglyceridemia associated with their lipodystrophy as indicated by one or more of the following:
  - Fasting triglycerides > 200 mg/dL
  - Post-prandial triglycerides > 500 mg/dL [when fasting is clinically not indicated (i.e. in infants)]
  - Fasting plasma glucose ≥ 126 mg/dL
  - Random plasma glucose ≥ 200 mg/dL and symptoms of hyperglycemia (polyuria, polydipsia, etc.)
  - Plasma glucose ≥ 200 mg/dL 2 hours after 75 g glucose load
  - HbA1c ≥ 6.5%; **AND**
- Confirmation the patient is receiving a low-fat diet; **AND**
- Documented baseline HbA1c, fasting triglycerides, and fasting plasma glucose; **AND**
- If patient has a diagnosis of diabetes, then a documented failure, contraindication, or ineffective response to an adequate (i.e., three month) trial with at least two (2) previous anti-diabetic therapies such as alpha-glucosidase inhibitors, insulins, amylin analogs, metformin, GLP-1 agonist (incretin mimetics), sulfonylureas, meglitinides, DPP-IV inhibitors, SGLT2 inhibitors, or thiazolidinediones (TZD); **AND**
- If patient has a diagnosis of hypertriglyceridemia, then a documented failure, contraindication, or ineffective response to a minimum three (3) month trial with a fibrate (e.g., gemfibrozil, fenofibrate, fenofibric acid, etc.) or the combination of a fibrate and a statin (e.g., atorvastatin, fluvastatin, pitavastatin, pravastatin, rosuvastatin, simvastatin, etc.); **AND**
- Will NOT be used in patients with any of the following conditions:
  - Partial lipodystrophy
  - HIV-related lipodystrophy
  - Liver disease or non-alcoholic steatohepatitis (NASH)
  - General obesity that is not associated with congenital leptin deficiency
  - Metabolic disease without concurrent evidence of congenital or acquired generalized lipodystrophy

CLINICAL CRITERIA FOR RENEWAL

- Disease response as indicated by improvement in HbA1c, **or** fasting triglycerides, **or** fasting glucose compared to baseline; **AND**
- Confirmation that the patient does not possess circulating neutralizing anti-metreleptin antibodies. The prescribing physician should test patients who develop severe infections or show signs suspicious for loss of efficacy during treatment (i.e., sudden increase in dose); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hypersensitivity reactions (e.g., anaphylaxis, urticaria or generalized rash), autoimmunity, hypoglycemia with concomitant use with insulin and insulin secretagogues, T-cell lymphoma, benzyl alcohol toxicity, etc.

MYFEMBREE® (RELUGOLIX/ESTRADIOL/NORETHINDRONE ACETATE) ORIAHNN® (ELAGOLIX/ESTRADIOL/NORETHINDRONE ACETATE; ELAGOLIX)

Length of Authorization:	Initial: 1 year Renewal: 1 year (maximum duration is 24 months total).
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CRITERIA FOR INITIAL APPROVAL

- Patient is 18 years of age or older; **AND**
- Patient is premenopausal; **AND**
- Patient has heavy menstrual bleeding associated with uterine leiomyomas (fibroids); **AND**
- Patient is not at high risk of an arterial, venous thrombotic, or thromboembolic disorder; **AND**
- Pregnancy is excluded prior to initiating treatment; **AND**
- Patient will use effective non-hormonal contraception during treatment with either product and for 28 days after stopping Oriahnn® therapy or for 7 days after stopping Myfembree® therapy; **AND**
- Patient does not have current or a history of breast cancer or other hormonally-sensitive malignancies; **AND**
- Patient does not have known liver impairment or disease; **AND**
- Patient does not have undiagnosed abnormal uterine bleeding; **AND**
- For Oriahnn®: Patient is not on concomitant organic anion transport polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine, gemfibrozil, rifampin); **AND**
- For Oriahnn® and Myfembree®: Patient has failed an adequate trial of one of the following therapies:
  - Combined hormonal contraceptives **or** progestins (including oral or transdermal formulations, vaginal ring, intrauterine device, or injections), **OR**
  - Tranexamic acid

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet the initial criteria; **AND**
- Provide verbal attestation that the patient does not have osteoporosis and provide the Z score (patient should not have a Z score less than -1.5 at spine and femur [total hip] for Oriahnn® or patient should not have a Z score of less than -2.0 at the lumbar spine, total hip, or femoral neck for Myfembree®); **AND**
- Patient is considered to have clinically meaningful response to treatment; **AND**
- Patient is not experiencing any treatment-limiting adverse reactions of the medication.

MYLOTARG™ (GEMTUZUMAB OZOGAMICIN)

Length of Authorization:

Newly-Diagnosed AML

- De novo disease in combination with daunorubicin and cytarabine: coverage will be provided for 6 months consisting of 3 cycles (1 induction and 2 consolidation) and may not be renewed.
- De novo disease in combination with daunorubicin and cytarabine (pediatric): coverage will be provided for 6 months consisting of 2 cycles (1 induction and 1 consolidation) and may not be renewed.
- Single-agent use: Coverage will be provided for 6 months and may be renewed. Coverage is provided for 1 cycle of induction and up to a maximum of 8 cycles of continuation.

Post-Remission Therapy for AML

- Coverage will be provided for 6 months consisting of 2 cycles (2 doses) and may not be renewed.

Relapsed or Refractory AML

- Coverage will be provided for 6 months consisting of one cycle (3 doses) and may not be renewed.

Acute Promyelocytic Leukemia

- Induction/Consolidation Therapy: Coverage will be provided for 6 months and may be renewed. Coverage is provided for 1 cycle of induction therapy followed by consolidation therapy until 28 weeks from complete
- Therapy after first relapse: Coverage will be provided for 6 months and may be renewed until bone marrow confirmation of remission.

Initiative: SPC: Oncology Agents (IE 2462 / NCPDP 75 – HICL, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Acute Myeloid Leukemia (AML)**

- Patient is at least 18 years of age, (unless otherwise noted); **AND**
- Patient has not previously received gemtuzumab ozogamicin; **AND**
- Baseline electrocardiogram (ECG) obtained in patients with a history of or predisposition for QTc prolongation; **AND**
- Patient has CD33-positive disease; **AND**
- Patient has newly diagnosed disease; **AND**
  - Used in combination with daunorubicin and cytarabine; **AND**
    - Patient has de novo disease; **AND**
      - Patient is 1 month of age or older; **OR**
    - Patient has favorable-risk cytogenetics or intermediate-risk disease; **OR**
  - Used as a single agent; **OR**
- Used as post-remission therapy; **AND**
  - Used in combination with daunorubicin and intermediate-dose cytarabine; **AND**
    - Patient is ≥ 60 years old and obtained a complete response to previous intensive therapy; **OR**
    - Patient is < 60 years old; **AND**
      - Patient has core binding factor (CBF) cytogenetic translocations and minimal residual disease (MRD) negative; **OR**
      - Patient has intermediate-risk cytogenetics and/or molecular abnormalities, including MRD positive; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

  - Used in combination with high-dose cytarabine; **AND**
    - Patient is < 60 years old with CBF cytogenetic translocations and MRD negative; **OR**
- Patient has relapsed or refractory disease; **AND**
  - Used as a single agent; **AND**
    - Patient is 2 years of age or older; **OR**
  - Used as a component of repeating the initial successful induction regimen if late relapse (≥ 12 months since induction regimen); **OR**
- Patient has acute promyelocytic leukemia; **AND**
  - Used as induction and consolidation therapy in patients with low-risk disease (white blood cell count ≤ 10 X 10^9/L); **AND**
    - Used in combination with tretinoin (ATRA); **AND**
    - Arsenic is not available or is contraindicated; **OR**
  - Used as induction and consolidation therapy in patients with high-risk disease (white blood cell count > 10 x 10^9/L); **AND**
    - Used in combination with ATRA and/or arsenic trioxide (ATO); **OR**
    - Used as a substitute for an anthracycline in patients who have prolonged QTc interval as their sole comorbidity; **OR**
  - Used for first relapse (morphologic or molecular) in combination with ATO; **AND**
    - Used forlate relapse (≥ 6 months) of initial response after an ATO-containing regimen; **OR**
    - Used for early relapse (< 6 months) after an ATRA + anthracycline-containing regimen; **OR**
    - Patient is ATO-naïve

CLINICAL CRITERIA FOR RENEWAL

- Disease stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infusion-related reactions, hemorrhage, hepatotoxicity including hepatic veno-occlusive disease (VOD)/sinusoidal obstruction syndrome (SOS), QT interval prolongation, etc.; **AND**
  - Patients receiving single-agent treatment for newly-diagnosed AML have not exceeded the maximum of 8 cycles of continuation (adult only); **OR**
  - Patients receiving therapy for first relapse of acute promyelocytic leukemia (APL): Therapy will be discontinued once there is bone marrow confirmation of remission

Note: treatment of newly diagnosed de novo AML, relapsed or refractory AML, and post-remission therapy for AML are not renewable.

MYOBLOC® (RIMABOTULINUMTOXINB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Botulinum toxin (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Note: For any cosmetic purpose, refer to "Cosmetic Agents – Benefit Builder" section

For all shared FDA approved indications with Dysport®, the patient must have a documented failure, contraindication, or intolerance to Dysport® prior to the consideration of Myobloc®

Note: For Core Formulary, all botulinum toxin products are non-formulary.

Diagnosis of **Cervical Dystonia**:

- Patient is 18 years of age or older; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, onabotulinumtoxinA); **AND**
- Patient has a history of recurrent involuntary contraction of one or more muscles in the neck; **AND**
  - Patient has sustained head tilt; **OR**
  - Abnormal posturing with limited range of motion in neck
- ***Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Dysport®***

Diagnosis of **Chronic Sialorrhea:**

- Patient is 18 years of age or older; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (i.e., abobotulinumtoxinA, incobotulinumtoxinA, onabotulinumtoxinA); **AND**
  - Patient has a history of troublesome sialorrhea for at least a 3-month period

Diagnosis of **Upper Limb Spasticity:**

- Patient is 18 years of age or older; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, onabotulinumtoxinA); **AND**
- ***Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Dysport***

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

Diagnosis of **Prophylaxis for Chronic Migraines:**

- Patient is 18 years of age or older; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, onabotulinumtoxinA); **AND**
- Not used in combination with calcitonin gene-related peptide (CGRP) inhibitors (e.g., eptinezumab, erenumab, galcanezumab, fremanezumab) (*NOTE: This does not include CGRP inhibitors used for acute treatment [i.e., ubrogepant])*; **AND**
- Patient is utilizing prophylactic intervention modalities (e.g., pharmacotherapy, behavioral therapy, or physical therapy); **AND**
- Patient has 15 or more headache (tension-type-like and/or migraine-like) days per month for at least 3 months; **AND**
  - Patient has had at least five attacks with features consistent with migraine (with and/or without aura)§; **AND**
  - On at least 8 days per month for at least 3 months
    - Headaches have characteristics and symptoms consistent with migraine; **OR**
    - Patient suspected migraines are relieved by a triptan or ergot derivative medication; **AND**
- Patient has failed at least an 8-week trial of any two oral medications (16 weeks total) for the prevention of migraines, such as (not all inclusive):
  - Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline)
  - Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol)
  - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan)
  - Anti-epileptics (e.g., divalproex, valproate, topiramate)
  - Calcium channel blockers (e.g., verapamil)

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

Migraine Features
Migraine without aura • At least five attacks have the following: – Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated) – Headache has at least two of the following characteristics: • Unilateral location • Pulsating quality • Moderate or severe pain intensity • Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs); **AND** – During headache, at least one of the following: • Nausea and/or vomiting • Photophobia and phonophobia
Migraine with aura • At least two attacks have the following: – One or more of the following fully reversible aura symptoms: • Visual • Sensory • Speech and/or language • Motor • Brainstem • Retinal; **AND** – At least three of the following characteristics: • At least one aura symptom spreads gradually over ≥ 5 minutes • Two or more symptoms occur in succession • Each individual aura symptom lasts 5 to 60 minutes • At least one aura symptom is unilateral • At least one aura symptom is positive (e.g., scintillations and pins and needles) • The aura is accompanied, or followed within 60 minutes, by headache

Diagnosis of **Severe Primary Axillary Hyperhidrosis**

- Patient is 18 years of age or older; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, onabotulinumtoxinA); **AND**
- Patient has tried and failed ≥ 1-month trial of a topical agent (e.g., aluminum chloride, glycopyrronium); **AND**
  - Patient has history of medical complications such as skin infections or significant functional impairments; **OR**
  - Patient has had a significant burden of disease or impact to activities of daily living due to condition (e.g., impairment in work performance/productivity, frequent change of clothing, difficulty in relationships and/or social gatherings)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of a toxin spread effect (i.e., asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, breathing difficulties, etc.), serious hypersensitivity reaction, etc.; **AND**
- Disease response as evidenced by:
  - **Cervical dystonia**:
    - Improvement in the severity and frequency of pain; **AND**
    - Improvement of abnormal head positioning
  - **Upper Limb Spasticity**
    - Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (e.g., Ashworth Scale, Physician Global Assessment, Clinical Global Impression [CGI])
  - **Prophylaxis of chronic migraines**
    - Not used in combination with calcitonin gene-related peptide (CGRP) inhibitors (e.g., erenumab); **AND**
    - Significant decrease in the number, frequency, and/or intensity of headaches; **AND**
    - Improvement in function; **AND**
    - Patient continues to utilize prophylactic intervention modalities (e.g., pharmacotherapy, behavioral therapy, physical therapy)
  - **Chronic sialorrhea**
    - Significant decrease in saliva production
  - **Severe primary axillary hyperhidrosis**
    - Significant reduction in spontaneous axillary sweat production; **AND**
    - Patient has a significant improvement in activities of daily living

DOSAGE AND ADMINISTRATION

- When initiating treatment, the lowest recommended dose should be used.
- Unless otherwise stated, re-treatment should occur no sooner than 12 weeks from the prior injection.

NOTE: For denials due to quantity requests over the FDA limit, please **use the following initiative and reason code:**

- SPC: Botulinum Toxin
- DCDD: Denial: Does not Meet FDA criteria for Diagnosis and Dose

Indication	Dose
Cervical Dystonia	**Initial dose:** 500 units divided among the affected muscles. **Re-treatment:** 250–1000 units every 12–16 weeks or longer as necessary.
Upper Limb Spasticity	**Initial dose:** 500–1000 units based on muscles affected, severity of muscle spasticity, prior response and adverse reaction history. **Re-treatment:** 500–1000 units every 12–16 weeks or longer, as necessary.
Chronic Migraine Prophylaxis	Up to 240 units divided among the affected muscles every 12 weeks.
Sialorrhea	Up to 450 units divided among the affected muscles every 12 weeks.
Chronic Anal Fissure	Up to 150 units divided among the affected muscles every 12 weeks.
Lower Limb Spasticity	**Adults**: Up to 1500 units divided among the affected muscles every 12 weeks **Pediatrics:** Up to 10–15 units/kg per limb divided among gastrocnemius-soleus complex muscles every 12 weeks. Maximum dose per treatment session is 1000 units total.
Blepharospasms	Up to 180 units per affected eye every 12 weeks.
Neurogenic detrusor overactivity; OAB	Up to 750 units divided among the affected muscles every 12 weeks.
Severe Primary Axillary Hyperhidrosis	Up to 200 units per axilla not more often than every 12 weeks.
Hemifacial Spasms	Up to 220 units per treatment session based on sites and severity of the spasm. Subsequent injections administered upon recurrence of spasm, every 12 weeks, if needed.
Ventral Hernia	500 units divided among abdominal muscles, injected 2–4 weeks prior to AWR surgery. *May not be renewed.*

Max Units (per dose and over time):

Indication	# vials to build in FirstTrax℠	Per # days
Cervical Dystonia	2 (500-unit vial)	84
Upper Limb Spasticity	2 (500-unit vial)	84
Chronic Migraine Prophylaxis	1 (300-unit vial)	84
Sialorrhea	1 (500-unit vial)	84
Chronic Anal Fissure	1 (300-unit vial)	84
Blepharospasms	1 (500-unit vial)	84
Lower Limb Spasticity	3 (500-unit vial)	84
Lower Limb Spasticity (Pediatric)	2 (500-unit vial)	84
Neurogenic Detrusor Overactivity/OAB	2 (500-unit vial)	84
Severe Primary Axillary Hyperhidrosis	1 (500-unit vial)	84
Hemifacial Spasms	1 (300-unit vial)	84
Ventral Hernia	1 (500-unit vial)	N/A

Available in 300 unit and 500 unit single-use vials.

* The plan may only allow for a max of 30 days to be billed at a time; no days' supply override needs to be placed to allow these to pay. The pharmacy may process as the 30 days. These limitations will not allow the member to fill more than the allotted vials per max days' supply (i.e., 84, 112, or 168).

NAGLAZYME® (GALSULFASE)

Length of Authorization:	1 Year, may be renewed
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Mucopolysaccharidosis VI (MPS VI; Maroteaux-Lamy syndrome)**

- Patient aged 5 years or older; **AND**
- Patient has a definitive diagnosis of MPS VI confirmed by the following:
  - Detection of pathogenic mutations in the *ARSB* gene by molecular genetic testing; **OR**
  - Arylsulfatase B (ASB) enzyme activity of <10% of the lower limit of normal in cultured fibroblasts or isolated leukocytes; **AND**
    - Patient has normal enzyme activity of a different sulfatase (excluding patients with Multiple Sulfatase Deficiency [MSD]); **AND**
    - Patient has an elevated urinary glycosaminoglycan (uGAG) level (i.e. dermatan sulfate or chondroitin sulfate) defined as being above the upper limit of normal by the reference laboratory; **AND**
- Documented baseline 12-minute walk test (12-MWT), 3-minute stair climb test, and/or pulmonary function tests (e.g., FEV1, etc.); **AND**
- Documented baseline value for urinary glycosaminoglycan (uGAG)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., anaphylaxis and hypersensitivity reactions, immune-mediated reactions, acute respiratory complications, acute cardiorespiratory failure, severe infusion reactions, spinal or cervical cord compression); **AND**
- Disease response with treatment as defined by improvement or stability from pre-treatment baseline by the following:
  - Reduction in uGAG levels; **AND**
    - Improvement in or stability of 12-minute walk test compared (12-MWT); **OR**
    - Improvement in or stability of 3-minute stair climb test; **OR**
    - Improvement in or stability of pulmonary function testing (e.g., FEV1, etc.)

NALTREXONE/NALOXONE

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Naltrexone (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

VIVITROL

- Patient must be 18 years old or over; **AND**
- Patient does not have acute hepatitis or severe hepatic impairment (Child-Pugh C); **AND**
- Patient is not receiving concurrent treatment with opioid analgesics; **AND**
- Patient does not have current physiologic opioid dependence; **AND**
- Patient is not experiencing acute opioid withdrawal; **AND**
- Patient has not failed the naloxone challenge test or does not have positive urine screen for opioids; **AND**

Diagnosis of Opioid Dependence:

- Patient is in a comprehensive rehabilitation program; **AND**
- Patient has undergone opioid detoxification for at least 7 days; **AND**
- Patient has, or is anticipated to have, difficulty adhering to daily oral naltrexone

Diagnosis of alcohol dependence:

- Documented participation in a comprehensive management program including psychosocial support; **AND**
- Patient has failed to adhere to oral naltrexone, disulfiram, or acamprosate therapy; **AND**
- Patient has not had an alcoholic drink for 7 days prior to initiation of therapy

GENERIC NALOXONE AUTO INJECTOR

Patient had a trial and failure, or has a contraindication or intolerance to Narcan

CLINICAL CRITERIA FOR RENEWAL

- Documented continued clinical benefit to the patient as defined by complete abstinence from or reduction in the use of alcohol/opioids confirmed on urine drug screen; **AND**
- Documented participation in and adherence to a comprehensive management/rehabilitation program including psychosocial support; **AND**
- Continued administration is necessary to prevent relapse**; AND**
- Absence of unacceptable toxicity from the drug.
  Examples of unacceptable toxicity include the following: hepatotoxicity (e.g., acute hepatitis, clinically significant liver dysfunction, etc.), severe injection site reactions, eosinophilic (allergic) pneumonia, hypersensitivity reactions including anaphylaxis, development of depression or suicidal thinking, etc.

Excluded item	
Evzio (*naloxone*) INJ	**EX**

EX = Excluded Drug – Not covered on this formulary.

NATPARA® (PARATHYROID HORMONE)

Length of Authorization:	Initial approval 3 months, Renewal 6 months
Initiative:	SPC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Hypocalcemia due to hypoparathyroidism**

- Patient is 18 years of age or older; **AND**
- Both the patient and the prescriber are enrolled in and meet to conditions of the NATPARA REMS Program; **AND**
- Patient has not responded adequately to calcium supplements **and** active forms of vitamin D; **AND**
- Patient has sufficient baseline 25-hydroxyvitamin D; **AND**
- Baseline serum calcium (albumin-corrected) is ≥ 7.5 mg/dL; **AND**
- Baseline 24-hour urinary calcium excretion has been obtained; **AND**
- Patient is not at increased risk for osteosarcoma (i.e., Paget's disease of bone, unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, patients with hereditary disorders predisposing them to osteosarcoma, or patients with a prior history of external beam or implant radiation therapy involving the skeleton); **AND**
- Patient does not have hypoparathyroidism due to either of the following:
  - Calcium-sensing receptor mutations
  - Acute post-surgical hypoparathyroidism

CLINICAL CRITERIA FOR RENEWAL

- Disease response as indicated by serum calcium (albumin-corrected) ≤ 9 mg/dL; **AND**
- Reduction or elimination of supplemental vitamin D and/or calcium; **AND**
- Patient does not have hypocalcemia or hypercalciuria; **AND**
- Patient has not developed skeletal bony abnormality or bone pain; **AND**
- Absence of unacceptable toxicity from the drug (e.g., osteosarcoma, severe hypercalcemia, severe hypocalcemia, digoxin toxicity, serious hypersensitivity reactions).

NAVELBINE® (VINORELBINE)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- The patient is at least 18 years of age, unless otherwise specified; **AND**

Coverage is provided in the following conditions:

- Non-Small Cell Lung Cancer
- AIDS-Related Kaposi Sarcoma
- Breast Cancer
- Hodgkin's Lymphoma
- Ovarian Cancer (including Epithelial/Fallopian Tube/Primary Peritoneal Cancers)
- Small Cell Lung Cancer
- Soft Tissue Sarcoma
  - Extremity/Superficial Trunk, Head/Neck
  - Retroperitoneal/Intra-Abdominal
  - Angiosarcoma
  - Rhabdomyosarcoma
  - Desmoid Tumors (Aggressive Fibromatosis)
  - Solitary Fibrous Tumor
- Malignant Pleural Mesothelioma
- Non-Hodgkin Lymphoma
  - B-Cell Lymphomas
    - Follicular Lymphoma (Grade 1-2)
    - Post-Transplant Lymphoproliferative Disorders (monomorphic)
    - Mantle Cell Lymphoma
    - AIDS-Related B-Cell Lymphoma (includes AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, and HHV8-positive diffuse large B-cell lymphoma, not otherwise specified (NOS))
    - Histologic Transformation of Nodal Marginal Zone Lymphoma or Follicular Lymphoma to Diffuse Large B-Cell Lymphoma
    - High-Grade B-Cell Lymphomas
  - T-Cell Lymphomas
    - Adult T-Cell Leukemia/Lymphoma
    - Hepatosplenic Gamma-Delta T-Cell Lymphoma
    - Peripheral T-Cell Lymphoma
  - Primary Cutaneous Lymphomas
    - Mycosis Fungoides/Sézary Syndrome
    - Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

- Uterine Sarcoma
  - Used for stage II-IV disease for one of the following:
    - High-grade endometrial stromal sarcoma (ESS)
    - Undifferentiated uterine sarcoma (UUS)
    - Uterine leiomyosarcoma (uLMS)
- Vulvar Squamous Cell Carcinoma
- Salivary Gland Tumors

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include myelosuppression (neutropenia, anemia, and thrombocytopenia), hepatotoxicity, severe constipation/bowel obstruction, extravasation/tissue injury, neurologic toxicity, pulmonary toxicity/respiratory failure, etc.

NERLYNX® (NERATINIB)

Length of Authorization:	6 months, and may be renewed unless otherwise specified Extended adjuvant therapy for breast cancer may be renewed one time for a total length of therapy of 1 year
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**

- Patient is at least 18 years old; **AND**
- Patient's disease is human epidermal growth factor receptor 2 (HER2)-positive *; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with moderate or strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
  - Coadministration with moderate CYP3A4 and P-gp dual inhibitors (e.g., ketoconazole, itraconazole, verapamil, quinidine, etc.); **AND**
  - Coadministration with proton pump inhibitors (e.g., lansoprazole, esomeprazole, omeprazole, etc.), or if acid-reduction therapy is required, use of H2-receptor antagonists or antacids may be used at staggered administration times; **AND**
- Used as a single-agent therapy; **AND**
  - Patient has hormone receptor (HR)-positive disease; **AND**
  - Must be used for extended adjuvant treatment; **AND**
  - Patient completed adjuvant trastuzumab-based therapy within the preceding 1 year; **AND**
  - Patient has 4 or more positive nodes; **AND**
  - Patient has a perceived high risk of recurrence; **OR**
- Used in combination with capecitabine; **AND**
  - Used as third-line therapy and beyond; **AND**
    - Patient has inflammatory disease and experienced no response to pre-operative systemic therapy; **OR**
    - Patient has advanced, recurrent, unresectable, or metastatic disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Central Nervous System (CNS) Cancers**

- Patient is at least 18 years old; **AND**
- Patient's disease is human epidermal growth factor receptor 2 (HER2)-positive *; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with moderate or strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
  - Coadministration with moderate CYP3A4 and P-gp dual inhibitors (e.g., ketoconazole, itraconazole, verapamil, quinidine, etc.); **AND**
  - Coadministration with proton pump inhibitors (e.g., lansoprazole, esomeprazole, omeprazole, etc.), or if acid-reduction therapy is required, use of H2-receptor antagonists or antacids may be used at staggered administration times; **AND**
- Used in combination with capecitabine; **AND**
- Patient has brain metastases from HER2-positive breast cancer; **AND**
  - Used as initial treatment in patients with small, asymptomatic brain lesions; **OR**
  - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

***HER2 overexpression must be confirmed as follows:**
• Immunohistochemistry (IHC) assay 3+; **OR** • Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number ≥ 4.0 signals/cell; **OR** • Dual-probe in situ hybridization (ISH) assay **and** concurrent IHC indicating one of the following: – HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number < 4.0 signals/cell **and** concurrent IHC 3+; **OR** – HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 6.0 signals/cell **and** concurrent IHC 2+ or 3+; **OR** – HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 4.0 and < 6.0 signals/cell **and** concurrent IHC 3+

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe and/or persistent diarrhea, severe hepatotoxicity, etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- The total length of therapy has not exceeded 1 year when used as extended adjuvant therapy in breast cancer

NEUPRO® (ROTIGOTINE PATCH)

Length of Authorization:	1 Year
Initiative:	MNC: Parkinson's (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

- Patient is ≥ 18 years of age; **AND**
- Patient has a diagnosis of Parkinson's disease **OR** moderate-to-severe primary restless legs syndrome; **AND**
- History of failure, contraindication, or intolerance to **two** of the following:
  - Pramipexole IR
  - Pramipexole ER
  - Ropinirole IR
  - Ropinirole ER; **OR**
- Patient has difficulty swallowing solid dosage forms or cannot swallow tablets.

CLINICAL CRITERIA FOR RENEWAL

- Patient has demonstrated clinical improvement in response to treatment; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use.

NEUROPATHIC PAIN AGENTS

Length of Authorization:	1 year
Initiative:	MNC: Neuropathic Pain Agents (IE 2462 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

GRALISE®

Diagnosis of **Neuropathic Pain**

- Patient must have a trial and failure of gabapentin

BRAND LIDODERM® 5% PATCH

- Patient must have a trial and failure of generic lidocaine 5% patches

CLINICAL CRITERIA FOR INITIAL APPROVAL

HORIZANT®

Diagnosis of **chronic persistent restless leg syndrome or postherpetic neuralgia (PHN) (must have had PHN for at least 3 months)**

- Patient is 18 years of age or older; **AND**
- Provider attests to informing patients and caregivers to monitor for emergence of worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior, may cause significant driving impairment, somnolence/Sedation and dizziness and alcohol should be avoided; **AND**
- Patient must **not** have iron deficiency anemia **or** renal failure; **AND**
- Must have a history of failure, contraindication or intolerance to **or** is not successfully managed with gabapentin for PHN; **OR**
- For chronic persistent RLS, must have a history of failure, contraindications, or intolerance to **or** is not successfully managed with pramipexole (IR) or ropinirole (IR) **and** gabapentin (IR).

CLINICAL CRITERIA FOR RENEWAL

- Patient has had benefit from therapy; **AND**
- Patient's condition has not progressed or worsened while on therapy; **AND**
- Patient has not developed any contraindications or other exclusions to its continued use (i.e., emergence or worsening of depression, suicidal thoughts or behavior, and/or unusual changes in mood or behavior).

ZTLIDO® 1.8% PATCH

- Patient is 18 years of age or older; **AND**
- Has a diagnosis of post-herpetic neuralgia (PHN); **AND**
- If the patient is using 3 patches per day, a trial and failure or intolerance of generic lidocaine 5% patches is required.

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient has had a disease response; **AND**
- Patient is free of unacceptable toxicity from the drug.

NEW FDA-APPROVED INDICATIONS

Length of Authorization:	1 year, or length of therapy as appropriate
Initiative:	Use the defined initiative for the requested medication

DEFINITION

For new FDA-approved indications which are not addressed in the existing-drug specific PA guideline

CLINICAL CRITERIA

Technicians:

- Create PA and escalate to pharmacist

Pharmacists:

- Request will be reviewed on a case-by-case basis by a clinical pharmacist; **AND**
- Prescribed medication is being used for an FDA-approved indication; **AND**
- All components of the FDA-approved indication are met (e.g., concomitant use, previous therapy requirements, age limitations, testing requirements, etc.). Note: reference universal criteria for the medication with indications already in the criteria; **AND**
- Prescribed medication will be used at a dose which is within the FDA recommendation.

Notes:

- An "off-label" use of a drug is defined as a use for a non-FDA approved indication.
- For off-label indications, follow off-label use guideline.
- For any excluded medications follow medical exception guideline.

NEXAVAR® (SORAFENIB)

Length of Authorization:	6 Months, may be renewed For Ovarian Cancer, coverage will be provided for a total of six 21-day cycles and may not be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Renal Cell Cancer**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with **all** of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with neomycin; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
- Patient has advanced disease.

Diagnosis of **Hepatocellular Cancer (HCC)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with **all** of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with neomycin; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single-agent; **AND**
  - Patient has unresectable disease; **OR**
  - Patient has Child-Pugh Class A or B7 disease only; **AND**
    - Patient has metastatic disease or extensive liver tumor burden; **OR**
    - Patient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Angiosarcoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with **all** of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with neomycin; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent

Diagnosis of **Desmoid Tumors (Aggressive Fibromatosis)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with **all** of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with neomycin; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
- Timeframe for a treatment response is more critical; **AND**
- Used as primary treatment or for treatment of gross residual disease (R2 resection) in abdominal wall tumors; **AND**
  - Patient has ongoing progression with potential morbidity or significant symptoms in anatomic location where progression would not be morbid; **OR**
  - Patient has documented progression in anatomic location where progression would be morbid; **OR**
  - Patient has no documented progression in anatomic location where progression would be morbid but there are concerns for morbidity or significant symptoms

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with neomycin; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has unresectable, recurrent, or metastatic disease; **AND**
- Used as a single agent; **AND**
- Used after failure on approved therapies including each of the following: imatinib, sunitinib, regorafenib, and ripretinib

Diagnosis of **Solitary Fibrous Tumor**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with neomycin; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent

Diagnosis of **Thyroid Carcinoma – Medullary**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with neomycin; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
- Patient has recurrent or persistent metastatic disease; **AND**
- Patient has progressive or symptomatic disease; **AND**
  - Treatment with clinical trials, vandetanib, or cabozantinib are not available or appropriate; **OR**
  - Disease has progressed on vandetanib or cabozantinib

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Thyroid Carcinoma – Differentiated (Follicular Carcinoma/Hürthle Cell Carcinoma/Papillary Carcinoma)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with neomycin; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
- Patient has recurrent, persistent, or metastatic disease; **AND**
  - Patient is refractory to radioactive iodine; **OR**
  - Patient has progressive and/or symptomatic disease that is not susceptible to radioactive iodine (RAI) therapy

Diagnosis of **Chordoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with neomycin; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent for recurrent disease with conventional or chondroid histology

Diagnosis of **Osteosarcoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with neomycin; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has relapsed, refractory, or metastatic disease; **AND**
- Used as a single agent; **AND**
- Used as second line therapy

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Ovarian Cancer (Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with neomycin; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has recurrent or persistent disease; **AND**
- Used in combination with topotecan; **AND**
- Patient has platinum-resistant disease; **AND**
- Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease)

Diagnosis of **Acute Myeloid Leukemia (AML)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with neomycin; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has FLT3-ITD mutation-positive disease; **AND**
  - Used in combination with azacitidine or decitabine; **AND**
    - Patient has relapsed or refractory disease; **OR**
    - Used as induction therapy in patients ≥ 60 years of age who are not candidates for or decline intensive therapy; **OR**
    - Used as post-induction therapy following response to previous lower intensity therapy with the same regimen in patients ≥ 60 years of age; **OR**
  - Used as a component of repeating the initial successful induction regimen for relapsed or refractory disease in patients experiencing a late relapse (≥ 12 months after induction regimen); **AND**
    - Treatment has not been administered continuously; **AND**
    - Treatment was not previously stopped due to development of clinical resistance

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
  - Coadministration with neomycin; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has eosinophilia and FLT3 rearrangement; **AND**
  - Patient has chronic phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: cardiac ischemia and/or infarction, hemorrhage, severe hypertension, transaminase elevations leading to hepatitis, severe dermatologic toxicity (Stevens-Johnson syndrome (SJS), toxic epidermal necrosis (TEN)], gastrointestinal perforation, QT interval prolongation, risk of impaired wound healing, impairment of thyroid stimulating hormone suppression in differentiated thyroid carcinoma, etc.; **AND**

Acute Myeloid Leukemia (AML)

- Disease stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes

- Disease response as evidenced by at least one of the following:
  - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
  - Stabilization or improvement as evidenced by a complete response [CR] (i.e. morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

Ovarian Cancer

- May NOT be renewed

All Other Indications

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

NEXLETOL® (BEMPEDOIC ACID) AND NEXLIZET® (BEMPEDOIC ACID/EZETIMIBE)

Length of Authorization:	1 Year
Initiative:	MNC: Lipotropics (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient must be ≥ 18 years of age; **AND**
- Patient has a diagnosis of one of the following:
  - Atherosclerotic cardiovascular disease (ASCVD); **OR**
  - Heterozygous familial hypercholesterolemia (HeFH); **AND**
- Patient has failed to reach a target LDL-C despite prescriber attestation that the patient is adherent to diet and maximally-tolerated doses of statins prior to the lipid panel demonstrating suboptimal reduction; **AND**
- Therapy will be used in conjunction with diet and maximally-tolerated doses of a statin (Note: if patient is statin intolerant, they do not have to continue with a statin); **AND**
- Patient must **not** be concurrently using simvastatin greater than 20 mg or pravastatin greater than 40 mg; **AND**
- Patient must have a trial of generic ezetimibe.

CLINICAL CRITERIA FOR RENEWAL:

- Patient must continue to meet initial criteria; **AND**
- Patient is experiencing symptom improvement; **AND**
- The patient is not experiencing any treatment-limiting adverse reactions of the medication

NEXVIAZYME™ (AVALGLUCOSIDASE ALFA-NGPT)

Length of Authorization:	12 months, may be renewed
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Pompe disease (acid alpha-glucosidase (GAA) deficiency)**

- Patient is 1 year of age or older ; **AND**
- Will not be used in combination with other enzyme replacement therapies (i.e., alglucosidase-alfa); **AND**
- Patient has not experienced a severe hypersensitivity reaction, including anaphylaxis to alglucosidase alfa *(Note: exception to this criterion can be made when Nexviazyme is used as part of a desensitization procedure)*; **AND**
- Patient is not susceptible to fluid volume overload; **OR**
  - Patient has an acute underlying respiratory illness or compromised cardiac or respiratory function for which fluid restriction is indicated; **AND**
- Diagnosis has been confirmed by one of the following:
  - Deficiency of acid alpha-glucosidase (GAA) enzyme activity; **OR**
  - Detection of biallelic pathogenic variants in the GAA gene by molecular genetic testing; **AND**
- Patient has a diagnosis of late-onset (non-infantile) disease; **AND**
- Patient has documented baseline values for FVC and/or 6MWT

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include anaphylaxis and severe hypersensitivity reactions, severe infusion-associated reactions, acute cardiorespiratory failure, etc.; **AND**
- Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: disease stabilization or improvement in FVC and/or 6MWT; **AND**
- Patient is being monitored for antibody formation (including neutralizing antibodies)

NINLARO® (IXAZOMIB)

Length of Authorization:	• 6 months, may be renewed unless otherwise specified • Waldenström Macroglobulinemia: Initial coverage will be provided for 6 months consisting of six 4-week cycles and may be renewed up to a maximum of six 8-week cycles • Systemic Light Amyloidosis: Coverage may be renewed up to a maximum of twelve 4-week cycles
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, phenytoin, carbamazepine, St. John's Wort); **AND**
- Used as primary therapy for symptomatic disease or for disease relapse after 6 months, following primary induction therapy with the same regimen; **AND**
  - Used in combination with lenalidomide and dexamethasone in patients who are not transplant candidates; **OR**
  - Used in combination with cyclophosphamide and dexamethasone in patients who are transplant candidates; **OR**
- Used as maintenance therapy ; **AND**
  - Used as single agent therapy; **AND**
    - Patient has symptomatic disease after response to primary myeloma therapy; **OR**
    - Patient had disease response or stable disease following autologous hematopoietic stem cell transplant; **OR**
- Used for relapsed or progressive disease; **AND**
  - Used in combination with dexamethasone with or without lenalidomide or cyclophosphamide after failure of at least one prior therapy; **OR**
  - Used in combination with dexamethasone and pomalidomide; **AND**
    - Patient has received at least two prior therapies, including an immunomodulatory agent (e.g., lenalidomide or thalidomide) and proteasome inhibitor (e.g., bortezomib, carfilzomib); **AND**
    - Disease has progressed on or within 60 days of completion of the last therapy

Diagnosis of **Systemic Light Chain Amyloidosis**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, phenytoin, carbamazepine, St. John's Wort); **AND**
- Used for relapsed or refractory disease; **AND**
  - Used as a single agent; **OR**
  - Used in combination with dexamethasone with or without lenalidomide

Diagnosis of **Waldenström macroglobulinemia**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, phenytoin, carbamazepine, St. John's Wort); **AND**
- Used in combination with rituximab and dexamethasone; **AND**
  - Used as primary therapy; **OR**
  - Used for relapsed disease if previously used as primary therapy that was well tolerated and elicited a prolonged response

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include gastrointestinal toxicities (e.g., diarrhea, constipation, nausea, vomiting), thrombocytopenia, peripheral neuropathy, peripheral edema, hepatotoxicity, severe rash, thrombotic microangiopathy including thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
  - Waldenström Macroglobulinemia: Patient has not exceeded the maximum of six 8-week cycles of maintenance therapy
  - Systemic Light Chain Amyloidosis: Patient has not exceeded the maximum of twelve 4-week cycles

NITROGLYCERIN

Length of Authorization:	1 year
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

GONITRO

Diagnosis of **angina pectoris due to coronary artery disease**

- Patient is 18 years of age or older; **AND**
- Patient has failed a trial of a preferred short acting nitroglycerin; **AND**
- Patient is not currently taking:
  - PDE-5 inhibitors such as sildenafil, tadalafil, or vardenafil
  - soluble guanylate cyclase (sGC) stimulators, such as riociguat
- Patient does not have severe anemia

NO CRITERIA PA REQUIRED DRUGS

Length of Authorization:	May be up to 1 year
Initiative:	MNC: Category A PA drugs (IE 2462 / NCPDP 75)

For drugs with a prior authorization requirement for which a guideline is unavailable, the requested drug will be approved based on both of the following criteria:

- **One** of the following:
  - Diagnosis is an FDA-approved indication; **OR**
  - Meets the off-label criteria; **AND**
  - Meets the FDA approved dosing or evidence-based dosing guidelines; **AND**
  - History of failure, contraindication, or intolerance of TWO appropriate formulary alternatives (if available, and appropriate, for patient)

Do not use this for step or quantity limit review. Use drug specific step and QL criteria for the drug.

NOCTIVA® AND NOCDURNA® (DESMOPRESSIN ACETATE)

Length of Authorization:	1 Year (initial and renewal)
Initiative:	MNC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **nocturnal polyuria** (voiding ≥ 2 times per night) (confirmed by a 24-hour urine collection)

- For Noctiva: patient is 50 years of age or older **OR** for Nocdurna: patient is 18 years of age or older; **AND**
- Patient is not pregnant; **AND**
- Does not have hyponatremia or history of hyponatremia; **AND**
- Does not have polydipsia; **AND**
- Does not have primary nocturnal enuresis; **AND**
- Will not be used with loop diuretics or systemic or inhaled glucocorticoids; **AND**
- Estimated glomerular filtration rate must be above 50 mL/min/1.73 m^2; **AND**
- Must not have syndrome of inappropriate antidiuretic hormone secretion (SIADH); **AND**
- Does not have any illnesses that may cause fluid or electrolyte imbalance; **AND**
- Does not have congestive heart failure (NYHA Class II-IV); **AND**
- Does not have uncontrolled hypertension; **AND**
- Does not have central diabetes insipidus (DDAVP and its generics only); **AND**
- Does not have hemophilia A or von Willebrand's disease (type 1) (Stimate only).
- ***In addition to the above clinical criteria:***
  - ***For Noctiva, patient must have a trial of Nocdurna***

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient is free of unacceptable toxicity from the drug.

NORTHERA® (DROXIDOPA)

Length of Authorization:	1 month
Initiative:	SPC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **symptomatic neurogenic orthostatic hypotension (NOH)**

- NOH is caused by one of the following conditions:
  - Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, pure autonomic failure); **OR**
  - Dopamine beta-hydroxylase deficiency; **OR**
  - Non-diabetic autonomic neuropathy**; AND**
- Prescribed by or in consultation with one of the following specialists:
  - Cardiologist
  - Neurologist
  - Nephrologist**; AND**
- Attempt has been made to manage NOH through at least one non-pharmacologic intervention (e.g., use of compression stockings/abdominal binder, increasing salt/fluid intake, patient participates in regular exercise, discontinue, or reduce hypotensive or anti-hypertensive medications); **AND**
- History of failure, contraindication, or intolerance to one of the following agents:
  - Fludrocortisone acetate
  - Midodrine

CLINICAL CRITERIA FOR RENEWAL

- Documentation of positive clinical response to therapy
- Renewal time frame: 12 months

NUBEQA® (DAROLUTAMIDE)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Prostate Cancer**

- Patient is at least 18 years of age; **AND**
- Patient will receive concurrent treatment with a GnRH-analog or has had a bilateral orchiectomy; **AND**
- Will not be used in combination with other androgen receptor inhibitors (e.g., enzalutamide, apalutamide); **AND**
- Patient will avoid concomitant use with combined P-gp and strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient will avoid concomitant use with combined P-gp and strong CYP3A4 inhibitors (e.g., clarithromycin, fluvoxamine, ketoconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will implemented; **AND**
- Patient has **non-metastatic** castration-resistant disease (nmCRPC)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include any Grade 3 or higher toxicities, intolerable adverse reactions experienced by the patient, etc.

NUCALA® (MEPOLIZUMAB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Respiratory Agents: (IE 2462 / NCPDP 75)

CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Severe Asthma**

- Patient is at least 6 years of age; **AND**
- Must not be used in combination with another anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody (e.g., benralizumab, omalizumab, reslizumab, dupilumab); **AND**
- Patient must have severe* disease; **AND**
- Patient must have asthma with an eosinophilic phenotype defined as blood eosinophils ≥ 300 cells/µL within previous 12 months or ≥ 150 cells/µL within 6 weeks of dosing; **AND**
- Must be use for add-on maintenance treatment in patients regularly receiving **both** of the following:
  - Medium to high-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifier); **AND**
- Will not be used for treatment acute bronchospasm or status asthmaticus; **AND**
- Patient must have two or more exacerbations in the previous year requiring daily oral corticosteroids for at least 3 days (in addition to the regular maintenance therapy defined above); **AND**
- Baseline measurement of at least one of the following for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV_1)

***Components of severity for classifying asthma as SEVERE may include any of the following (not all inclusive):**
• Symptoms throughout the day • Nighttime awakenings, often 7 times per week • SABA use for symptom control occurs several times per day • Extremely limited normal activities • Lung function (percent predicted FEV_1) < 60% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

Diagnosis of **Eosinophilic Granulomatosis with Polyangiitis (EGPA)/Churg-Strauss Syndrome**

- Patient is least 18 years of age; **AND**
- Must not be used in combination with another anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody (e.g., benralizumab, omalizumab, reslizumab, dupilumab); **AND**
- Patient has a confirmed diagnosis of EGPA (AKA Churg-Strauss Syndrome); **AND**
- Patient must have blood eosinophils ≥ 150 cells/µL within 6 weeks of dosing; **AND**
- Patient has been on stable doses of concomitant oral corticosteroid therapy for at least 4 weeks (e.g., prednisone or prednisolone at a dose of 7.5 mg/day); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission, or rate of relapses).

CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

Eosinophilic Granulomatosis Polyangiitis (EGPA), defined as all of the following:
• History or presence of asthma • Blood eosinophil level > 10% or an absolute eosinophil count > 1000 cells/mm^3 • Two or more of the following criteria: – Histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration or eosinophil rich granulomatous inflammation – Neuropathy – Pulmonary infiltrates – Sinonasal abnormalities – Cardiomyopathy – Glomerulonephritis – Alveolar hemorrhage – Palpable purpura – Antineutrophil Cytoplasmic Antibody (ANCA) positivity

Diagnosis of **Hypereosinophilic Syndrome (HES)**

- Patient is at least 12 years of age; **AND**
- Must not be used in combination with another anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody (e.g., benralizumab, omalizumab, reslizumab, dupilumab); **AND**
- Patient has been diagnosed with HES for at least 6 months prior to starting treatment; **AND**
- Patient does NOT have non-hematologic secondary HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy) or FIP1L1-PDGFRα kinase-positive HES; **AND**
- Patient has a history of 2 or more HES flares within the previous 12 months (e.g., documented HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy); **AND**
- Patient must have blood eosinophils ≥ 1000 cells/µL within 4 weeks of dosing; **AND**
- Used in combination with stable doses of at least one other HES therapy (e.g., oral corticosteroids, immunosuppressive agents, cytotoxic therapy)

Diagnosis of **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)**

- Patient is at least 18 years of age; **AND**
- Must not be used in combination with another anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody (e.g., benralizumab, omalizumab, reslizumab, dupilumab); **AND**
- Patient has bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks; **AND**
- Patient has failed on at least 8 weeks of intranasal corticosteroid therapy; **AND**
- Other causes of nasal congestion/obstruction have been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Therapy will be used in combination with intranasal corticosteroids unless not able to tolerate or is contraindicated

CRITERIA FOR RENEWAL

- Must not be used in combination with another anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody (e.g., benralizumab, omalizumab, reslizumab, dupilumab, etc.); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: parasitic (helminth) infection, herpes zoster infection, severe hypersensitivity reactions, etc.; **AND**
- For **Severe Asthma**
  - Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
    - Use of systemic corticosteroids
    - Two- fold or greater decrease in inhaled corticosteroid use for at least 3 days
    - Hospitalizations
    - ER visits
    - Unscheduled visits to healthcare provider; **OR**
  - Improvement from baseline in forced expiratory volume in 1 second (FEV_1)
- For **Eosinophilic Granulomatosis with Polyangiitis/Churg-Strauss Syndrome**
  - Disease response as indicated by improvement in signs and symptoms compared to baseline as evidenced in one or more of the following:
    - Patient is in remission (defined as a Birmingham Vasculitis Activity Score [BVAS] score=0 and a prednisone/prednisolone daily dose of ≤ 7.5 mg)
    - Decrease in maintenance dose of systemic corticosteroids
    - Improvement in BVAS score compared to baseline
    - Improvement in asthma symptoms or asthma exacerbations
    - Improvement in duration of remission or decrease in the rate of relapses.
- For **Hypereosinophilic Syndrome** (HES)
  - Disease response as indicated by a decrease in HES flares from baseline (**Note:** An HES flare is defined as worsening of clinical signs and symptoms of HES or increasing eosinophils (on at least 2 occasions), resulting in the need to increase oral corticosteroids or increase/add cytotoxic or immunosuppressive HES therapy)
- For **Chronic Rhinosinusitis with Nasal Polyps** (CRSwNP)
  - Disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans, and/or an improvement on a disease activity scoring tool (e.g., nasal polyposis score [NPS], nasal congestion [NC] symptom severity score, sino-nasal outcome test-22 [SNOT-22], etc.); **OR**
  - Patient had an improvement in at least one (1) of the following response criteria:
    - Reduction in nasal polyp size
    - Reduction in need for systemic corticosteroids
    - Improvement in quality of life
    - Improvement in sense of smell
    - Reduction of impact of comorbidities

DOSAGE AND ADMINISTRATION

Indication	Dose
Severe Asthma with an eosinophilic phenotype	Pediatric patients 6 to 11 years of age (single dose vial only): • 40 mg self-administered subcutaneously once every 4 weeks Adults and adolescents 12 years of age and older: • 100 mg self-administered subcutaneously once every 4 weeks.
Eosinophilic Granulomatosis with Polyangiitis/Churg-Strauss Syndrome	300 mg self-administered subcutaneously once every 4 weeks as 3 separate 100 mg injections. Administer each injection at least 2 inches apart.
Hypereosinophilic Syndrome (HES)	300 mg administered subcutaneously once every 4 weeks as 3 separate 100 mg injections. Administer each injection at least 2 inches apart.
Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)	100 mg administered subcutaneously once every 4 weeks.

**** Single dose vial must be prepared and administered by a healthcare professional**

Max ML (per dose and over time):

Indication	# mL to build in FirstTrax℠	Per # days
Severe Asthma with an eosinophilic phenotype	1 mL (100 mg/mL)	28
Eosinophilic Granulomatosis with Polyangiitis	3 mL (300 mg/mL)	28
Hypereosinophilic Syndrome (HES)	3 mL (300 mg/mL)	28
Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)	1 mL (100 mg/mL)	28

NUEDEXTA® (DEXTROMETHORPHAN / QUININE SULFATE)

Length of Authorization:	3 months
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Pseudobulbar affect (PBA)**

- Prescriber is a specialist in the field of Neurology, Psychiatry, or Geriatrician.

NULIBRY™ (FOSDENOPTERIN)

Length of Authorization:	6 months for initial, 1 year for renewals
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Molybdenum Cofactor Deficiency Type A (MoCD Type A)**

- Will not be used in combination with other substrate replacement therapy (e.g., recombinant cyclic pyranopterin monophosphate, etc.); **AND**
- Must be prescribed by or in consultation with a specialist in medical genetics or pediatric neurology; **AND**
- Patient has a diagnosis of MoCD Type A, confirmed by a mutation in the *MOCS1* gene suggestive of disease, identified by molecular genetic testing; **OR**
- Patient has biochemical features suggestive of MoCD Type A (i.e., elevated sulfites in urine, low serum uric acid, elevated urinary xanthine and hypoxanthine) and will be treated presumptively while awaiting genetic confirmation; **AND**
- Patient has baseline values for the following:
  - Elevated urinary s-sulfocysteine (SSC) normalized to creatinine; **AND**
  - Clinical notes regarding signs and symptoms of disease, including seizure frequency/duration, growth, and developmental milestones

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe phototoxicity, clinically significant infection, etc.; **AND**
- Disease response compared to pre-treatment baseline as evidenced by the following:
  - Reduction in urinary SSC normalized to creatinine; **AND**
  - Stabilization or improvement in one or more signs and symptoms of disease, including seizure frequency/duration, growth, achievement of developmental milestones; **OR**
- Patient initiated therapy as an inpatient based upon a presumptive diagnosis of MoCD Type A that was subsequently confirmed by genetic testing; **AND**
  - Patient is responding to therapy compared to one or more pre-treatment baseline parameters that prompted the workup for MoCD.

NULOJIX® (BELATACEPT)

Length of Authorization:	1 Year
Initiative:	SPC: Immunomodulators: Systemic (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **kidney transplant rejection prophylaxis**

- Patient is EBV seropositive; **AND**
- Must be used in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids; **AND**
- Prescribed by a kidney transplant specialist

NUTRITIONAL DIET SUPPLEMENTS

Length of Authorization:	6 months
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Nutritional diet supplements are a benefit builder category, Check CRM. For the client which chooses to prior auth these agents, see below

- Must be prescribed by a physician; **AND**
- Must be intended to assist in dietary nutrition for a medical condition **or** to prevent a medical condition

ODOMZO® (SONIDEGIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Basal Cell Carcinoma**

- Patient is at least 18 years of age; **AND**
- Women of child-bearing age must have a negative pregnancy test prior to initiation of therapy (**Note**: females of reproductive potential should use effective contraception during and for at least 20 months after the last dose and males of reproductive potential should also do so during and for at least 8 months after the last dose); **AND**
- Patient's serum creatine kinase (CK) will be obtained at baseline and periodically monitored during therapy; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong CYP3A4 inhibitors (e.g., nefazadone, itraconazole); **OR**
  - Long-term (≥ 14 days) coadministration with moderate CYP3A4 inhibitors (e.g., aprepitant, ciprofloxacin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **OR**
  - Coadministration with moderate or strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort); **AND**
- Used as a single agent; **AND**
- Patient has locally advanced disease; **AND**
  - Disease has recurred following surgery or radiation therapy; **OR**
  - Patient is not a candidate for surgery or radiation therapy

CLINICAL CRITERIA FOR RENEWAL

- Disease response as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe musculoskeletal reactions including creatine kinase elevations, premature fusion of the epiphyses); **AND**
- Patient does not have any of the following:
  - Serum CK elevation greater than 2.5 times ULN with worsening renal function
  - Serum CK elevation greater than 10 times ULN
  - Recurrent serum CK elevation greater than 5 times ULN
  - Recurrent severe or intolerable musculoskeletal adverse reactions

OFF-LABEL USE

Length of Authorization:	1 year, or length of therapy as appropriate
Initiative:	Use the defined initiative for the requested medication

DEFINITIONS

- An "off-label" use of a drug is defined as a use for a non-FDA approved indication. That is, one that is not listed on the drug's official label/prescribing information.
- In order to meet the requirement that the use of the drug is reasonable and necessary for the treatment of disease, the drug must be safe and effective for its intended use. Drugs approved for marketing by the Food and Drug Administration (FDA) are generally considered safe and effective when used for indications specified on the labeling.
- Off-label use criteria can be used when diagnosis is not part of criteria or step requirements
- Drug level criteria—including drug specific off-label criteria, should take precedence.

CLINICAL CRITERIA

Technicians:

- Create PA and escalate to pharmacist

Pharmacists:

- Request will be reviewed on a case-by-case basis by a clinical pharmacist; **AND**
- The drug is approved by the FDA; **AND**
- The drug is medically necessary to treat the condition; **AND**
- Documented history of failure, contraindication, or intolerance to standard, conventional therapies to treat or manage the disease or condition where available; **AND**
- The drug has been **recognized for treatment of that condition by**:
  - **ONE** of the following acceptable compendia:
    - Micromedex: Class I, Class IIa, Class IIb (if evidence is compelling)
    - AFHS-DI narrative text is supportive
    - Clinical Pharmacology narrative text is supportive
    - Lexi-Drug Off label and Evidence Level A

      NCCN Category of evidence and consensus of 1 or 2A (follow criteria for off-label chemotherapy);

OR

- Clinical Practice guidelines produced to standardize patient care utilizing best practices based upon a transparent review of the available clinical evidence. The most recently published guidelines must be used; **OR**
- Two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

CHEMOTHERAPY OFF-LABEL INDICATION PROCEDURES

RPhs: For off-label chemotherapy drug use, the provider should attempt to submit the clinical studies to support the rationale for off-label use. Lack of supporting documentation does not automatically trigger a denial. You are still responsible for researching the off-label diagnosis to gather category of evidence to support approval or denial decision.

Off-label chemotherapy use:

The National Comprehensive Cancer Network (NCCN) drugs and biologics compendium with a category of evidence and consensus of 1 or 2A is approvable if the study matches the diagnosis. In addition, other criteria must be fulfilled if the logic for step or a trial or failure of an alternate drug makes clinical sense

NCCN Category of Evidence: 2B. In the event of a 2B study supporting the drug request, research to ensure the request and the study matches. Most 2B studies have limited caliber and weight to support approval but use your clinical judgment

In the event the studies regarding the oncology 2B study or the validity of such a study continues to not correspond with the patient profile, you have the option to consult with internal pharmacists specializing in cancer; Nick Manno email: nmanno@magellanhealth.com or Bob Greer email: rwgreer@magellanhealth.com or an alternative consult with our medical director, Dr Chodroff or PCR specializing in oncology by contacting Robin Corbett.

ONCASPAR® (PEGASPARGASE)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 1 month of age; **AND**
- Patient must not have a history of serious thrombosis or hemorrhagic events with prior L-asparaginase therapy; **AND**
- Patient must not have a history of pancreatitis, including pancreatitis related to prior L- asparaginase therapy; **AND**
- Patient must not have severe hepatic impairment (i.e., Child-Pugh class C); **AND**
- Used as a component of a multi-agent chemotherapy; **AND**
- Patient meets one of the following**:**
  - Patient has a hypersensitivity to native forms of L-asparaginase; **OR**
  - Used as first line/induction therapy; **OR**
  - Used as consolidation therapy; **AND**
    - Patient has Philadelphia chromosome (Ph)-positive B-ALL; **AND**
      - Treatment regimen includes a tyrosine kinase inhibitor (e.g., bosutinib, dasatinib, imatinib, nilotinib, or ponatinib); **OR**
    - Patient has Ph chromosome-negative B-ALL; **OR**
    - Patient has Ph chromosome-like B-ALL *(pediatric patients only)*; **OR**
    - Patient has T-ALL; **OR**
    - Used as part of an interfant regimen for infant ALL; **OR**
  - Used for relapsed/refractory disease; **AND**
    - Patient has Ph chromosome-negative B-ALL or T-ALL; **OR**
    - Patient has Ph chromosome-positive B-ALL; **AND**
      - Patient is refractory to tyrosine kinase inhibitor therapy; **OR**
      - Used in combination with a tyrosine kinase inhibitor (e.g., bosutinib, dasatinib, imatinib, nilotinib, ponatinib, etc.) as part of a regimen not previously given; **OR**
    - Used as systemic CNS-directed therapy

Diagnosis of **T-Cell Lymphomas**

- Patient is at least 1 month old; **AND**
- Patient must not have a history of serious thrombosis or hemorrhagic events with prior L-asparaginase therapy; **AND**
- Patient must not have a history of pancreatitis, including pancreatitis related to prior L- asparaginase therapy; **AND**
- Patient must not have severe hepatic impairment (i.e., Child-Pugh class C); **AND**
- Used as a component of a multi-agent chemotherapy; **AND**
- Patient has Extranodal NK/T-Cell Lymphoma nasal type disease; **OR**
- Patient has aggressive NK-cell leukemia (ANKL); **OR**
- Used for Hepatosplenic T-Cell Lymphoma as additional therapy if no response or progressive disease after first-line therapy

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include anaphylaxis and serious hypersensitivity reactions, serious thrombotic events, pancreatitis, glucose intolerance, hemorrhage, hepatotoxicity, etc.; **AND**

Acute Lymphoblastic Leukemia (ALL)

- Disease stabilization or improvement as evidenced by a complete response (CR) (i.e., morphologic, cytogenetic, or molecular complete response [CR]), complete hematologic response ,or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH)

T-Cell Lymphoma

- Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread

ONIVYDE® (IRONOTECAN LIPOSOME)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Pancreatic Adenocarcinoma**

- Patient does not have bowel obstruction; **AND**
- Patient is 18 years of age or older; **AND**
- Must be used in combination with fluorouracil and leucovorin; **AND**
  - Patient has locally advanced or metastatic disease; **AND**
  - Used after disease progression with one of the following:
    - Fluoropyrimidine (5-FU or capecitabine) based therapy without irinotecan; **OR**
    - Gemcitabine-based therapy; **OR**
  - Patient has local or metastatic disease recurrent post-resection; **AND**
    - Patient completed primary therapy < 6 months ago; **AND**
      - Patient previously received one of the following:
      - Fluoropyrimidine (5-FU or capecitabine) based therapy without irinotecan; **OR**
      - Gemcitabine-based therapy; **OR**
    - Patient completed primary therapy ≥ 6 months ago

CLINICAL CRITERIA FOR RENEWAL:

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe diarrhea, severe neutropenia, pulmonary toxicity (interstitial lung disease), severe hypersensitivity reactions, etc

ONPATTRO™ (PATISIRAN LIPID COMPLEX) IV

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Polyneuropathy due to Hereditary Transthyretin-Mediated (hATTR) Amyloidosis /Familial Amyloidotic Polyneuropathy (FAP)**

- Patient must be at least 18 years old; **AND**
- Patient is receiving supplementation with vitamin A at the recommended daily allowance; **AND**
- Must not be used in combination with other transthyretin (TTR) reducing agents (e.g., inotersen, tafamidis); **AND**
- Patient has a definitive diagnosis of hATTR amyloidosis/FAP as documented by amyloid deposition on tissue biopsy and identification of a pathogenic *TTR* variant using molecular genetic testing; **AND**
- Used for the treatment of polyneuropathy as demonstrated by at least **two** of the following criteria:
  - Subjective patient symptoms are suggestive of neuropathy
  - Abnormal nerve conduction studies are consistent with polyneuropathy
  - Abnormal neurological examination is suggestive of neuropathy; **AND**
- Patient's peripheral neuropathy is attributed to hATTR/FAP and other causes of neuropathy have been excluded; **AND**
- Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., Medical Research Council (MRC) muscle strength); **AND**
- Patient has not been the recipient of an orthotopic liver transplant (OLT).

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, ocular symptoms related to hypovitaminosis A, etc.; **AND**
- Disease response compared to pre-treatment baseline as evidenced by stabilization or improvement in one or more of the following:
  - Signs and symptoms of neuropathy
  - MRC muscle strength

ONUREG® (AZACITIDINE)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Acute Myeloid Leukemia (AML)**

- Patient is 18 years of age or older; **AND**
- Therapy will not be substituted for intravenous or subcutaneous azacitidine; **AND**
- Patient does not have a diagnosis of myelodysplastic syndrome (MDS); **AND**
- Patient does not have a hypersensitivity to another product containing azacitidine (e.g., Vidaza, etc.); **AND**
- Patient does not have severe hepatic impairment (i.e., total bilirubin > 3 times the upper limit of normal); **AND**
- Used as a single agent; **AND**
- Used as post-remission maintenance treatment; **AND**
  - Patient achieved a complete remission/response (CR) or a complete remission with incomplete blood count recovery (CRi) following intensive induction therapy; **OR**
    - Patient is unable to complete intensive curative therapy; **OR**
    - Patient is ≥ 60 years of age and has declined or is not fit/eligible for allogeneic hematopoietic stem cell transplant; **OR**
  - Patient has treatment-related disease other than core binding factor and/or unfavorable cytogenetics and/or molecular abnormalities; **AND**
    - Patient is < 60 years of age and has declined or is not fit/eligible for allogeneic hematopoietic stem cell transplant

CLINICAL CRITERIA FOR RENEWAL:

- Disease response with treatment as defined by stabilization or improvement, as evidenced by a complete response (CR) (i.e., morphologic, cytogenetic or molecular complete response), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe myelosuppression, etc.

OPDIVO® (NIVOLUMAB) IV

Length of Authorization:	6 months; may be renewed • Adjuvant use in the treatment of cutaneous melanoma can be authorized up to a maximum of 12 months of therapy. • Use in the treatment of classical Hodgkin lymphoma in combination with brentuximab vedotin can be authorized up to a maximum of 12 weeks of therapy and may not be renewed. • Adjuvant treatment of esophageal and esophagogastric/gastroesophageal junction cancer can be authorized up to a maximum of 12 months of therapy. • Adjuvant treatment of urothelial carcinoma can be authorized up to a maximum of one (1) year of therapy. • The following indications may be renewed up to a maximum of 2 years of therapy: – NSCLC (in combination with ipilimumab with or without platinum-doublet chemotherapy) – MPM – Vulvar cancer – Renal cell carcinoma in combination with cabozantinib – Gastric cancer – Esophagogastric/gastroesophageal junction cancer or esophageal adenocarcinoma (in combination with fluoropyrimidine- and platinum-containing chemotherapy)
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cutaneous Melanoma**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy, unless otherwise specified; **AND**
- Used as first-line therapy for unresectable or metastatic disease; **AND**
  - Used as a single agent or in combination with ipilimumab; **OR**
- Used as subsequent therapy for unresectable or metastatic* disease; **AND**
  - Used for retreatment of disease as re-induction as a single agent or in combination with ipilimumab in patients who experienced disease control (i.e., complete or partial response or stable disease) from prior checkpoint inhibitor therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**
  - Used after disease progression or maximum clinical benefit from BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib); **AND**
    - Used as a single agent or in combination with ipilimumab if checkpoint inhibitor immunotherapy was not previously used; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

        - Used in combination with ipilimumab for patients who progressed on single agent checkpoint inhibitor immunotherapy; **OR**
- Used as adjuvant treatment as a single agent; **AND**
    - Patient has lymph node involvement and has undergone complete resection, complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; **OR**
    - Patient has satellite/in-transit metastases or recurrence and has no evidence of disease after complete excision; **OR**
    - Patient has undergone TLND and/or complete resection of nodal recurrence; **OR**
    - Patient has undergone complete resection of distant metastatic disease

**Metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease*

Diagnosis of **Uveal Melanoma**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Patient has distant metastatic disease; **AND**
- Used as a single agent or in combination with ipilimumab

Diagnosis of **Hepatocellular Carcinoma (HCC)**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Patient has unresectable or metastatic disease, inoperable (*i.e., by performance status, comorbidity, or with minimal or uncertain extrahepatic-disease*) liver-confined disease, or disease with extensive liver tumor burden; **AND**
- Used as subsequent therapy; **AND**
    - Patient has Child-Pugh Class A or B disease; **AND**
        - Used as a single agent**; AND**
    - Patient has Child-Pugh Class A disease; **AND**
        - Used in combination with ipilimumab

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy unless otherwise specified; **AND**
- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **AND**
    - Used for one of the following:
      - Patients with performance status (PS) 0-1 who have tumors that are negative for actionable molecular markers** and PD-L1 expression < 1%
      - Patients with PS 0-1 who are positive for one of the following molecular markers: BRAF V600E mutations, NTRK1/2/3 gene fusions, or MET exon 14 skipping mutations
      - PD-L1 expression-positive (PD-L1 ≥ 1%) tumors, as detected by an FDA or CLIA compliant test, that are negative for actionable molecular markers**; **AND**
    - Used in combination with ipilimumab; **OR**
    - Used in combination with ipilimumab and platinum-doublet chemotherapy (e.g., pemetrexed and either carboplatin or cisplatin for non-squamous cell histology, paclitaxel and carboplatin for squamous cell histology); **OR**
  - Used as subsequent therapy; **AND**
    - Used as a single agent; **OR**
    - Used for one of the following:
      - Patients with PS 0-1 who have ROS1 rearrangement-positive tumors and have received prior targeted therapy
      - Patients with PS 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E mutations, NTRK1/2/3 gene fusions, or MET exon 14 skipping mutations; **AND**
    - Used in combination with ipilimumab; **OR**
    - Used in combination with ipilimumab, pemetrexed, and either carboplatin or cisplatin for non-squamous cell histology; **OR**
    - Used in combination with ipilimumab, paclitaxel, and carboplatin for squamous cell histology; OR
  - Used as continuation maintenance therapy in combination with ipilimumab; **AND**
    - Patient has achieved a response or stable disease following first-line therapy with nivolumab and ipilimumab with or without chemotherapy

*** Note: Actionable molecular genomic biomarkers include EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, and RET rearrangement. If there is insufficient tissue to allow testing for all the EGFR, ALK, ROS1, BRAF, MET, and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Renal Cell Carcinoma**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Used in combination with ipilimumab for clear cell histology; **AND**
  - Used as first-line therapy in patients with advanced, relapsed, or stage IV disease with intermediate or poor risk; **OR**
  - Used as first-line therapy in patients with relapsed or stage IV disease with favorable risk; **OR**
  - Used as subsequent therapy in patients with relapsed or stage IV disease; **OR**
- Used as a single agent; **AND**
  - Used as subsequent therapy in patients with advanced, relapsed, or stage IV disease and clear cell histology ; **OR**
  - Patient has relapsed or stage IV disease and non-clear cell histology; **OR**
- Used in combination with cabozantinib (Cabometyx® only) for clear cell histology; **AND**
  - Used as first-line therapy for advanced disease, relapsed or stage IV disease; **OR**
  - Used as subsequent therapy in patients with relapsed or stage IV disease

Diagnosis of **Adult Classical Hodgkin Lymphoma (cHL)**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Used as a single agent; **AND**
  - Patient has relapsed or progressive disease after autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin; **OR**
  - Used as third-line or subsequent therapy OR as palliative therapy in patients > 60 years of age; **AND**
    - Patient has relapsed or progressive disease after autologous HSCT; **OR**
    - Patient has relapsed or refractory disease and is transplant-ineligible based on comorbidities or failure of second-line chemotherapy; **OR**
    - Patient is post-allogeneic stem-cell transplant; **OR**
  - Used in combination with brentuximab vedotin; **AND**
    - Used as subsequent therapy (if not previously used) for relapsed or refractory disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Pediatric Classical Hodgkin Lymphoma (cHL)**

- Patient age is 18 years and under*; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Patient has relapsed or refractory disease; **AND**
- Used in patients heavily pretreated (with platinum or anthracycline-based chemotherapy) or if a decrease in cardiac function was observed; **AND**
  - Used as subsequent therapy (if not previously used); **AND**
    - Used as a single agent or in combination with brentuximab; **OR**
  - Used as re-induction therapy; **AND**
    - Used in combination with brentuximab; **OR**
    - Used in combination with brentuximab and radiation therapy (ISRT) in highly favorable patients who may avoid autologous stem cell rescue (ASCR) *(i.e., initial stage other than IIIB or IVB, no prior exposure to RT, duration of CR1 > 1 year, absence of extranodal disease or B symptoms at relapse)*

***** *Pediatric Hodgkin lymphoma may be applicable to adolescent and young adult (AYA) patients up to the age of 39 years.*

Diagnosis of **Squamous Cell Carcinoma of the Head and Neck (SCCHN)**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Used as single agent therapy; **AND**
- Patient has unresectable, recurrent, persistent, or metastatic disease; **AND**
- Disease has progressed on or after platinum-based therapy; **AND**
- Patient does not have nasopharyngeal disease.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Urothelial Carcinoma (Bladder Cancer)**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Used as a single agent; **AND**
  - Used for disease that progressed during or following platinum-containing chemotherapy*** or** as second-line treatment after therapy other than a platinum or an immune checkpoint inhibitor; **AND**
    - Patient has one of the following diagnoses:
      - Locally advanced or metastatic urothelial carcinoma; **OR**
      - Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder; **OR**
      - Metastatic or local bladder cancer recurrence post-cystectomy; **OR**
      - Recurrent or metastatic primary carcinoma of the urethra; **AND**
        - Patient does not have recurrence of stage T3-4 disease or palpable inguinal lymph nodes; **OR**
      - Metastatic upper genitourinary (GU) tract tumors; **OR**
      - Metastatic urothelial carcinoma of the prostate; **OR**
  - Used as adjuvant therapy; **AND**
    - Patient has urothelial carcinoma of the bladder, ureter, or renal pelvis; **AND**
    - Patient underwent radical surgical resection; **AND**
    - Patient is at high risk of disease recurrence******

**** Note:***
If patient was progression free for >12 months after platinum therapy, consider re-treatment with platinum-based therapy if the patient is still platinum eligible (see below for cisplatin- or carboplatin-ineligible comorbidities).

- *Cisplatin-ineligible comorbidities may include the following: CrCl < 60 mL/min, PS ≥ 2, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, grade ≥ 2 peripheral neuropathy, or NYHA class ≥ 3. Carboplatin may be substituted for cisplatin particularly in those patients with a CrCl < 60 mL/min or a PS of 2.*
- *Carboplatin-ineligible comorbidities may include the following: CrCl < 30 mL/min, PS > 3, grade > 3 peripheral neuropathy, or NYHA class > 3, etc.*

***** Note:***
High risk of disease recurrence is defined as:

- *ypT2-ypT4a or ypN+ for patients who received neoadjuvant cisplatin;* ***OR***
- *pT3-pT4a or pN+ for patients who did not receive neoadjuvant cisplatin and are also ineligible for adjuvant cisplatin therapy*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Colorectal Cancer (CRC)**

- Patient is at least 12 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Patient's disease must be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); **AND**
  - Used as a single agent or in combination with ipilimumab; **AND**
    - Used for advanced or metastatic disease that progressed following treatment with one of the following:
      - Fluoropyrimidine-, oxaliplatin-, and/or irinotecan-based chemotherapy; OR
      - Non-intensive therapy ; **OR**
    - Used as primary treatment for unresectable or medically inoperable, locally advanced, or metastatic disease *(excluding use as neoadjuvant therapy in rectal cancer)* ; **OR**
    - Used for unresectable (or medically inoperable) metastases that remain unresectable after primary systemic therapy

***** *Single agent nivolumab should be used in patients who are not candidates for intensive therapy*

Diagnosis of **Merkel Cell Carcinoma**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Used as a single agent; **AND**
- Patient has metastatic or recurrent disseminated disease

Diagnosis of **Central Nervous System (CNS) Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) unless otherwise specified; **AND**
- Used in one of the following treatment settings:
  - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
  - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options; **AND**
- Used as a single-agent or in combination with ipilimumab for the treatment of brain metastases in patients with melanoma; **OR**
- Used as a single-agent for the treatment of brain metastases in patients with PD-L1 positive non-small cell lung cancer (NSCLC)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Anal Carcinoma**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Patient has metastatic squamous cell disease; **AND**
- Used as a single agent for subsequent therapy

Diagnosis of **Gestational Trophoblastic Neoplasia**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Used as single-agent therapy for multiagent chemotherapy resistant disease; **AND**
  - Patient has intermediate placental site trophoblastic tumor (PSTT) or epithelioid trophoblastic tumor (ETT); **AND**
    - Patient has recurrent or progressive disease; **AND**
    - Patient was previously treated with a platinum/etoposide containing regimen; **OR**
  - Patient has high risk disease (i.e., ≥ 7 Prognostic score or stage IV disease)

Diagnosis of **Malignant Pleural Mesothelioma**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Used as a single agent or in combination with ipilimumab as subsequent therapy; **OR**
- Used in combination with ipilimumab as first-line therapy in patients with stage IIIB or IV disease, sarcomatoid histology, medically inoperable tumors, or unresectable disease

Diagnosis of **Small Bowel Adenocarcinoma/Advanced Ampullary Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Patient has advanced or metastatic disease that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR): **AND**
- Used as single agent or in combination with ipilimumab; **AND**
  - Used as initial therapy; **OR**
  - Used as subsequent therapy for patients with no prior oxaliplatin exposure in the adjuvant treatment setting and no contraindication to oxaliplatin therapy

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Extranodal NK/ T-Cell Lymphoma**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Used as a single agent for relapsed or refractory nasal type disease; **AND**
- Disease progressed following additional treatment with an alternative asparaginase-based chemotherapy regimen not previously used; **AND**
- Participation in a clinical trial is unavailable

Diagnosis of **Esophageal Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Patient is not a surgical candidate or has unresectable, advanced, recurrent, or metastatic disease; **AND**
  - Patient has squamous cell carcinoma (SCC); **AND**
    - Used as a single agent for subsequent therapy; **OR**
  - Patient has adenocarcinoma; **AND**
    - Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; **OR**
- Used as adjuvant treatment of completely resected disease; **AND**
  - Used as a single agent in patients with residual disease following neoadjuvant chemoradiotherapy (CRT)

Diagnosis of **Esophagogastric/Gastroesophageal Junction Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Patient is not a surgical candidate or has unresectable, advanced, recurrent, or metastatic disease; **AND**
  - Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; **OR**
- Used as adjuvant treatment of completely resected disease; **AND**
  - Used as a single agent in patients with residual disease following neoadjuvant chemoradiotherapy (CRT)

Diagnosis of **Gastric Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Patient is not a surgical candidate or has unresectable, advanced, recurrent, or metastatic disease; **AND**
  - Used in combination with fluoropyrimidine- and platinum-containing chemotherapy

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Endometrial Carcinoma (Uterine Neoplasms)**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Used as a single agent; **AND**
- Used as second-line therapy for mismatch repair deficient (dMMR) recurrent, metastatic, or high-risk disease

Diagnosis of **Vulvar Cancer (Squamous Cell Carcinoma)**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Used as a single agent; **AND**
- Used as second-line therapy for HPV-related advanced, recurrent, or metastatic disease

Diagnosis of **Small Cell Lung Cancer (SCLC)**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab) prior to initiation of therapy; **AND**
- Used as subsequent systemic therapy; **AND**
- Used as a single agent; **AND**
  - Used for relapse following complete response, partial response, or stable disease with primary treatment; **AND**
    - Patient did not relapse while on maintenance atezolizumab or durvalumab; **OR**
  - Used for primary progressive disease

Genomic Aberration/Mutational Driver Targeted Therapies (Note: *not all inclusive, refer to guidelines for appropriate use*) §				
Sensitizing *EGFR* mutation-positive tumors	*ALK* rearrangement-positive tumors	*ROS1* rearrangement-positive tumors	*BRAF* V600E-mutation positive tumors	*NTRK* Gene Fusion positive tumors
• Afatinib • Erlotinib • Dacomitinib • Gefitinib • Osimertinib • Amivantamab *(exon-20 insertion)*	• Alectinib • Brigatinib • Ceritinib • Crizotinib • Lorlatinib	• Ceritinib • Crizotinib • Entrectinib	• Dabrafenib • ± Trametinib • Vemurafenib	• Larotrectinib • Entrectinib
PD-1/PD-L1 expression-positive tumors (≥1%)	*MET* Exon-14 skipping mutations	*RET* rearrangement-positive tumors	KRAS G12C mutations	
• Pembrolizumab • Atezolizumab • Nivolumab ± ipilimumab	• Capmatinib • Crizotinib • Tepotinib	• Selpercatinib • Cabozantinib • Vandetanib • Pralsetinib	• Sotorasib	

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe infusion reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), severe immune-mediated adverse reactions (e.g., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis/renal dysfunction, adverse skin reactions/rash, encephalitis), hepatotoxicity when taken with cabozantinib, etc.; **AND**
- **Cutaneous Melanoma (adjuvant therapy)**
  - Patient has not exceeded a maximum of one (1) year of therapy
- **Cutaneous Melanoma (re-induction therapy)**
  - Refer to initial criteria *(see Cutaneous Melanoma – Used for retreatment of disease as re-induction)*
- **Non-Small Cell Lung Cancer (in combination with ipilimumab with or without platinum-doublet chemotherapy)**
  - Patient has not exceeded a maximum of two (2) years of therapy
- **Non-Small Cell Lung Cancer (maintenance therapy)**
  - Refer to initial criteria
- **MPM**
  - Patient has not exceeded a maximum of two (2) years of therapy
- **Vulvar Cancer**
  - Patient has not exceeded a maximum of two (2) years of therapy
- **Renal Cell Carcinoma (in combination with cabozantinib)**
  - Patient has not exceeded a maximum of two (2) years of therapy
- **Urothelial Carcinoma (adjuvant therapy)**
  - Patient has not exceeded a maximum of one (1) year of therapy
- **Esophageal and Esophagogastric/Gastroesophageal Junction Cancer (adjuvant therapy)**
  - Patient has not exceeded a maximum of one (1) year of therapy
- **Gastric Cancer, Esophagogastric/Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma (in combination with fluoropyrimidine- and platinum-containing chemotherapy)**
  - Patient has not exceeded a maximum of two (2) years of therapy
- **cHL (in combination with brentuximab vedotin)**
  - Coverage may not be renewed

OPHTHALMICS: ALLERGIC CONJUNCTIVITIS

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Ophthalmics (IE 2462 / NCPDP 75)

STEP THERAPY (NO GRANDFATHERING)

BEPREVE, LASTACAFT

The patient has had a trial and failure of generic olopatadine AND azelastine

ZERVIATE

The patient has had a trial and failure of generic olopatadine AND azelastine

PRECISION FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Ophthalmics (IE 2462 / NCPDP 75)

STEP THERAPY (NO GRANDFATHERING)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

ELESTAT

The patient has had a trial and failure of generic olopatadine or azelastine

BEPREVE, LASTACAFT

The patient has had a trial and failure of generic olopatadine AND azelastine

OPHTHALMICS: ANTI-INFLAMMATORY

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Ophthalmics (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

BROMSITE, ILEVRO, NEVANAC

- For Ilevro and Nevanac: if patient is 10 years through 17 years of age, approve.
- For BromSite: patient is 18 years of age or older, **or** for Ilevro and Nevanac: patient is 18 years of age of older; **AND**
- Patient has tried the following medications:
  - Generic diclofenac **or** flurbiprofen **or** ketorolac; **AND**
  - Prolensa

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient is free of unacceptable toxicity from the drug.

PRECISION FORMULARY CRITERIA

Length of Authorization:	1 Year
Initiative:	MNC: Ophthalmics (IE 2462 / NCPDP 75 – HICL)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient is free of unacceptable toxicity from the drug.

OPHTHALMICS: DRY EYE AGENTS

Length of Authorization:	Initial approval: 3 months, Renewal: 6 months
Initiative:	MNC: Ophthalmics (IE 2462 / NCPDP 75)

STANDARD FORMULARY CLINICAL CRITERIA

RESTASIS® AND CEQUA® (NO GRANDFATHERING FOR CEQUA)

- For Restasis®: patient is 16 years of age or older (for all indications) **or** for Cequa®: patient is 18 years of age or older (for all indications); **AND**
- Diagnosis of Sjogren's disease (approve, no additional criteria below need to be met); **OR**
- Diagnosis of moderate to severe keratoconjunctivitis sicca (KCS) or chronic dry eye disease (DED)- due to KCS; **AND**
  - Prescribed by an ophthalmologist, optometrist, or rheumatologist; **AND**
  - Patient has one of the following:
    - Corneal fluorescein staining score of > 2 points in any field on a 0 to 4-point scale; **OR**
    - Schirmer test (STT) of 1 to 10 mm in 5 minutes; **OR**
    - Tear break up time (TBUT) positive for dry eye; **AND**
  - Patient has tried and failed any one of the following therapies
    - Lubricating artificial tear drops or ointments (e.g., Refresh Tears®, any polyvinyl alcohol based drops or ointments, any carboxymethylcellulose based drops or ointments) administered at least 4 times per day (recommended lipid based eye drops Systane® Balance, Refresh® Optive Advanced, Soothe® XP, Retaine® MGD); **OR**
    - Punctal plugs
  - **Note:** For Cequa®: In addition to the above criteria, patient must have tried and failed or have a contraindication or intolerance to both Restasis® and Xiidra®
- Diagnosis of severe atopic keratoconjunctivitis; **AND**
  - Patient has tried and failed at least two ophthalmic steroids; or patient has a contraindication or intolerance to ophthalmic steroids; **AND**
  - Prescribed by an ophthalmologist, optometrist or rheumatologist
  - For Cequa®: In addition to the above criteria, patient must have tried and failed or have a contraindication or intolerance to both Restasis® and Xiidra®

STANDARD FORMULARY CLINICAL CRITERIA *(CONTINUED)*

XIIDRA®

- Patient is 17 years of age or older (for all indications); **AND**
- Patient has chronic dry eye secondary to Sjogren's syndrome (approve, no additional criteria below needs to be met); **OR**
- Patient has a diagnosis of chronic dry eye disease (DED) not associated with seasonal allergies; **AND**
- Prescribed by an ophthalmologist, optometrist or rheumatologist**; AND**
- Patient has presence of conjunctival redness; **AND**
- Patient has one of the following:
  - Corneal fluorescein staining score of > 2 points in any field on a 0 to 4 point scale; **OR**
  - Schirmer test (STT) of 1 to 10 mm in 5 minutes; **OR**
  - Tear break up time (TBUT) positive for dry eye; **AND**
- Patient has tried and failed any one of the following therapies:
  - Lubricating artificial tear drops or ointments (e.g., Refresh Tears®, any polyvinyl alcohol-based drops or ointments, any carboxymethylcellulose based drops or ointments) administered at least 4 times per day (recommended lipid based eye drops, Systane® Balance, Refresh® Optive Advance, Soothe® XP, Retaine® MGD)

CLINICAL CRITERIA FOR RENEWAL

- Diagnosis of Sjogren's disease (approve, no additional criteria needs to be met); **OR**
- For other diagnoses: Patient has attested to using medicine without break in therapy. If there was a break in therapy, refer to initial approval criteria; **AND**
- Have improvement in signs of DED as measured by one of the following:
  - Decrease in corneal fluorescein staining score; **OR**
  - Increase in number of mm per 5 minutes using Schirmer tear test; **OR**
  - Improvement in Tear break up time (TBUT); **AND**
- Decrease in conjunctival redness; **AND**
- Improvement in ocular discomfort.

PRECISION FORMULARY CLINICAL CRITERIA

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

RESTASIS®

- Patient is 16 years of age or older (for all indications); **AND**
- Diagnosis of Sjogren's disease (approve, no additional criteria below need to be met); **OR**
- Diagnosis of moderate to severe keratoconjunctivitis sicca (KCS) or chronic dry eye disease (DED) due to KCS; **AND**
  - Prescribed by an ophthalmologist, optometrist, or rheumatologist; **AND**
  - Patient has one of the following:
    - Corneal fluorescein staining score of > 2 points in any field on a 0 to 4-point scale; **OR**
    - Schirmer test (STT) of 1 to 10 mm in 5 minutes; **OR**
    - Tear break up time (TBUT) positive for dry eye; AND
  - Patient has tried and failed any one of the following therapies
    - Lubricating artificial tear drops or ointments (e.g., Refresh Tears®, any polyvinyl alcohol-based drops or ointments, any carboxymethylcellulose based drops or ointments) administered at least 4 times per day (recommended lipid-based eye drops, Systane® Balance, Refresh® Optive Advance, Soothe® XP, Retaine® MGD); **OR**
    - Punctal plugs; **OR**
- Diagnosis of severe atopic keratoconjunctivitis; **AND**
  - Patient has tried and failed at least two ophthalmic steroids; or patient has a contraindication or intolerance to ophthalmic steroids; **AND**
  - Prescribed by an ophthalmologist, optometrist, or rheumatologist

XIIDRA®

- Patient is 17 years of age or older (for all indications); **AND**
- Patient has chronic dry eye secondary to Sjogren's syndrome (approve, no additional criteria below needs to be met); **OR**
- Patient has a diagnosis of chronic dry eye disease (DED) not associated with seasonal allergies; **AND**
- Prescribed by an ophthalmologist, optometrist, or rheumatologist**; AND**
- Patient has presence of conjunctival redness; **AND**
- Patient has one of the following:
  - Corneal fluorescein staining score of > 2 points in any field on a 0 to 4-point scale; **OR**
  - Schirmer test (STT) of 1 to 10 mm in 5 minutes; **OR**
  - Tear break up time (TBUT) positive for dry eye; **AND**
- Patient has tried and failed any one of the following therapies:
  - Lubricating artificial tear drops or ointments (e.g., Refresh Tears®, any polyvinyl alcohol-based drops or ointments, any carboxymethylcellulose based drops or ointments) administered at least 4 times per day (recommended lipid-based eye drops, Systane® Balance, Refresh® Optive Advance, Soothe® XP, Retaine® MGD).

CLINICAL CRITERIA FOR RENEWAL

- Diagnosis of Sjogren's disease (approve, no additional criteria need to be met); **OR**
- For other diagnoses: patient has attested to using medicine without break in therapy. If there was a break in therapy, refer to initial approval criteria; **AND**
- Have improvement in signs of DED as measured by one of the following:
  - Decrease in corneal fluorescein staining score; **OR**
  - Increase in number of mm per 5 minutes using Schirmer tear test; **OR**
  - Improvement in Tear break up time (TBUT); **AND**
- Decrease in conjunctival redness; **AND**
- Improvement in ocular discomfort.

OPHTHALMICS: OTHERS

Length of Authorization:	1 single injection into each affected eye, may not be renewed: for Jetrea 8 weeks of total treatment per eye for Oxervate, may not be renewed
Initiative:	SPC: Ophthalmics (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

JETREA® (OCRIPLASMIN)

Diagnosis of **Vitreomacular Adhesion (VMA)**

- Patient is 18 years or older; **AND**
- Patient has a diagnosis confirmed by optical coherence tomography (OCT) or dynamic B-scan ultrasound; **AND**
- Patient has symptomatic disease (e.g., decreased sharpness of vision, photopsia [seeing flashes of light], micropsia [objects appear smaller than actual size], metamorphopsia [distorted vision], decreased visual acuity)
- May not be renewed

OXERVATE

- Patient is 2 years of age or older; **AND**
- Patient must have a diagnosis of moderate-to-severe (stage 2 or stage 3) neurotrophic keratitis (NK); **AND**
- Prescribed by or in consultation with an ophthalmologist; **AND**
- Prescriber attestation that patient or caregiver has been counseled on proper administration technique.

Note: 8 weeks of total treatment per eye per lifetime

OPHTHALMICS: SPECIALTY

Length of Authorization:	1 year, eligible for renewal Lucentis- Coverage for (mCNV) will be provided for 3 months and may be renewed, all other diagnosis coverage is 1 year, eligible for renewal Retisert- 1 implant every 30 months, may be renewed Ozurdex: 1 implant per affected eye every 4 to 6 months and may be renewed
Initiative:	SPC: Ophthalmics (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

BEOVU® (BROLUCIZUMAB-DBLL)

Definitive Diagnosis of **Neovascular (Wet) Age-Related Macular Degeneration (AMD)**

- Patient is 18 years or older; **AND**
- Patient is free of ocular and/or peri-ocular infections; **AND**
- Patient does not have active intraocular inflammation; **AND**
- Therapy will not be used with other ophthalmic VEGF inhibitors (e.g., aflibercept, ranibizumab, pegaptanib, bevacizumab); **AND**
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**

BEVACIZUMAB OPHTHALMIC (AVASTIN, MVASI, ZIRABEV, BEVACIZUMAB COMPOUND)

Definitive Diagnosis of **Neovascular (Wet) Age-Related Macular Degeneration (AMD), Macular Edema Following Retinal Vein Occlusion (RVO), Myopic Choroidal Neovascularization (mCNV), Diabetic Macular Edema (DME), or Diabetic Retinopathy (DR)**

- Patient is at least 18 years of age; **AND**
- Patient is free of ocular and/or peri-ocular infections; **AND**
- Therapy will not be used concomitantly with other ophthalmic VEGF inhibitors (e.g., aflibercept, ranibizumab, pegaptanib, brolucizumab); **AND**
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment

EYLEA®

Definitive Diagnosis of **Neovascular (Wet) Age-Related Macular Degeneration (AMD), Macular Edema Following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), or Diabetic Retinopathy (DR)**

- Patient is at least 18 years of age; **AND**
- Patient is free of ocular and/or peri-ocular infections; **AND**
- Patient does not have active intraocular inflammation; **AND**
- Therapy will not be used with other ophthalmic VEGF inhibitors (e.g., brolucizumab-dbll, ranibizumab, pegaptanib, bevacizumab); **AND**
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

LUCENTIS® AND BYOOVIZ™

Definitive Diagnosis of **Neovascular (Wet) Age-Related Macular Degeneration (AMD), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), Macular Edema Following Retinal Vein Occlusion (RVO), or Myopic Choroidal Neovascularization (mCNV)**

- Patient is at least 18 years of age; **AND**
- Patient is free of ocular and/or peri-ocular infections; **AND**
- Therapy will not be used with other ophthalmic VEGF inhibitors (e.g., aflibercept, pegaptanib, brolucizumab-dbll, bevacizumab)

MACUGEN®

Definitive Diagnosis of **Neovascular Age-Related Macular Degeneration (AMD), Diabetic Macular Edema (DME), or Diabetic Retinopathy (DR)**

- Patient is at least 18 years of age; **AND**
- Patient is free of ocular and/or peri-ocular infections; **AND**
- Therapy will not be used with other ophthalmic VEGF inhibitors (e.g., aflibercept, ranibizumab, brolucizumab, bevacizumab); **AND**
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment**; AND**

RETISERT®

Diagnosis of **Chronic Non-Infectious Uveitis Affecting the Posterior Segment of the Eye**

- Patient is at least 12 years of age; **AND**
- Patient is free of ocular or periocular infections; **AND**
- Patient has had chronic disease for at least one year; **AND**
- Must not be used in combination with other sustained-release intravitreal corticosteroids (e.g., dexamethasone implant); **AND**
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Patient's intraocular pressure is measured at baseline and periodically throughout therapy; **AND**
- Other causes of uveitis have been ruled out (e.g., infection, malignancy)

OZURDEX®

Diagnosis of **Diabetic Macular Edema (DME), Macular Edema Following Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion (CRVO) or Non-Infectious Uveitis Affecting the Posterior Segment of the Eye**

- Patient is at least 18 years of age; **AND**
- Patient is free of ocular and periocular infections; **AND**
- Patient does not have glaucoma with a cup to disk ratio of greater than 0.8; **AND**
- Patient does not have a torn or ruptured posterior lens capsule; **AND**
- Must not be used in combination with other sustained-release intravitreal corticosteroids (e.g., fluocinonide acetonide implant); **AND**
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically throughout treatment; **AND**
- Patient's intraocular pressure is measured at baseline and periodically throughout therapy

CLINICAL CRITERIA FOR RENEWAL

EYLEA® AND MACUGEN®

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: endophthalmitis, increase in intraocular pressure, anaphylaxis/anaphylactoid reactions, etc.; **AND**
- Patient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity [BCVA]) and continued administration is necessary for the maintenance treatment of the condition

LUCENTIS®

- Absence of unacceptable toxicity from the drug (e.g., endophthalmitis and retinal detachments, increase in intraocular pressure, arterial thromboembolic events) **AND**
- Patient has had a beneficial response to therapy; **AND**
  - Patient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity [BCVA]) and continued administration is necessary for the maintenance treatment of the condition; **OR**
  - Myopic choroidal neovascularization **only**
    - Continued administration is necessary due to disease activity (i.e., drop in vision, visual symptoms [e.g., metamorphopsia] or the presence of intra-/sub- retinal fluid or active leakage).

RETISERT®

- Absence of unacceptable toxicity from the drug (e.g., cataract formation, endophthalmitis, increased intra-ocular pressure); **AND**
- Disease response as indicated by:
  - Stabilization of visual acuity or improvement in BCVA score when compared to baseline; **OR**
  - Improvement in vitreous haze score (decrease in inflammation)

OZURDEX®

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include posterior subcapsular cataracts, increased intraocular pressure, endophthalmitis, eye inflammation, retinal detachments, etc.; **AND**

Retinal Vein Occlusion Macular Edema/Diabetic Macular Edema

- Disease response as indicated by stabilization of visual acuity or improvement in best-corrected visual acuity (BCVA) score when compared to baseline

Posterior Segment Uveitis

- Disease response as indicated by:
  - Stabilization of visual acuity or improvement in BCVA score when compared to baseline; **OR**
  - Improvement in vitreous haze score (decrease in inflammation)

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

BEVACIZUMAB OPHTHALMIC

- Absence of unacceptable toxicity from the drug (e.g., severe injection site reactions, bleeding, or serious eye infections and vision loss due to endophthalmitis); **AND**
- Patient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity [BCVA]) and continued administration is necessary for the maintenance treatment of the condition; **OR**
- **Myopic choroidal neovascularization ONLY:** Continued administration is necessary due to disease activity (i.e., drop in vision, visual symptoms [e.g., metamorphopsia], or the presence of intra-/sub- retinal fluid or active leakage)

BEOVU® (BROLUCIZUMAB-DBLL)

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: endophthalmitis and retinal detachment, increase in intraocular pressure, arterial thromboembolic events, retinal vasculitis and/or retinal vascular occlusion; **AND**
- Patient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity [BCVA]) and continued administration is necessary for the maintenance treatment of the condition

OPIOID ANALGESICS: TIRF (TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL)

STANDARD FORMULARY CRITERIA

Length of Authorization:	3-6 months
Initiative:	MNC: Fentanyl: Buccal (IE 2462 / NCPDP 75)

Diagnosis of **Cancer Pain**

- Prescribed by an oncologist or board-certified pain specialist; **AND**
- Patient does not have a history of respiratory depression or any medical conditions that increase the risk of respiratory depression; **AND**
- Patient is not on a benzodiazepine or sedative hypnotic; **AND**
- Patients requesting Actiq® or its generic (fentanyl citrate oral lozenge) are 16 years of age or older; **OR**
- Patients requesting Abstral®, Fentora®, Lazanda®, and Subsys® are 18 years of age or older; **AND**
- Patient has breakthrough pain (BTP) due to cancer; **AND**
- Patient is on a concomitant, around-the-clock, long-acting opioid product, for underlying persistent cancer pain; **AND**
- Patient is considered opioid tolerant as defined by taking one of the following opioid equivalent dosages for one week or longer: (Refs: TIRF REMS, PIs for all TIRF products); **AND**
  - at least 60 mg oral morphine/day,
  - at least 25 mcg transdermal fentanyl/hour,
  - at least 30 mg of oral oxycodone daily,
  - at least 8 mg oral hydromorphone daily,
  - at least 25 mg oral oxymorphone daily, or
  - an equianalgesic dose of another opioid
- Patient has tried and failed at least two different short-acting opioid analgesics to control pain before requesting a TIRF product as add-on therapy; **AND**
- For brand name TIRF products: Patient has tried and failed generic fentanyl citrate lozenge; **AND**
- Dose requested is below QL for the drug (listed for reference)
  - If conditions above are met, approve for 6 months
- For requests that exceed the QL (1 to 2x the QL):
  - Patient is enrolled in hospice; **OR**
  - Prescriber attests that the patient's dose of a concomitant LA opioid is being increased or provides rationale on why it cannot be; **AND**
  - Patient is being monitored by a board-certified pain specialist with oncology experience; **AND**
  - Provide rationale on why the patient's dose is being titrated over the max; **AND**
  - If conditions above are met, approve for 3 months.
- For requests that exceed the QL (above 2x the QL):
  - Submit to medical director for review.
- Reference quantity limits:
  - Recommended maximum dosage limits once effective breakthrough dose is found:
  - Abstral: 800 mcg/dose, 2 doses/breakthrough pain episode, 4 treated episodes/day
  - Actiq (and its generic, fentanyl citrate oral lozenge): 1600 mcg/dose, 4 treated episodes/day
  - Fentora: 800 mcg/dose, 4 treated episodes/day
  - Lazanda: 800 mcg/dose, 4 doses/day
  - Subsys: 1600 mcg/dose, 2 doses/breakthrough pain episode, 4 treated episodes/day

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient is free of unacceptable toxicity from the drug.
- If conditions above are met, approve for **3-6 months** (depending on initial criteria parameters the member meets)

PRECISION FORMULARY CRITERIA

Length of Authorization:	3-6 months
Initiative:	MNC: Fentanyl: Buccal (IE 2462 / NCPDP 75 – HICL)

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

Diagnosis of **Cancer Pain**

- Prescribed by an oncologist or board-certified pain specialist; **AND**
- Patient does not have a history of respiratory depression or any medical conditions that increase the risk of respiratory depression; **AND**
- Patient is not on a benzodiazepine or sedative hypnotic; **AND**
- Patients requesting Actiq® or its generic (fentanyl citrate oral lozenge) are 16 years of age or older; **OR**
- Patients requesting Abstral®, Fentora®, Lazanda®, and Subsys® are 18 years of age or older; **AND**
- Patient has breakthrough pain (BTP) due to cancer; **AND**
- Patient is on a concomitant, around-the-clock, long-acting opioid product, for underlying persistent cancer pain; **AND**
- Patient is considered opioid tolerant as defined by taking one of the following opioid equivalent dosages for one week or longer: (Refs: TIRF REMS, PIs for all TIRF products); **AND**
  - at least 60 mg oral morphine/day,
  - at least 25 mcg transdermal fentanyl/hour,
  - at least 30 mg of oral oxycodone daily,
  - at least 8 mg oral hydromorphone daily,
  - at least 25 mg oral oxymorphone daily, or
  - an equianalgesic dose of another opioid
- Patient has tried and failed at least two different short-acting opioid analgesics to control pain before requesting a TIRF product as add-on therapy; **AND**
- For brand name TIRF products: Patient has tried and failed generic fentanyl citrate lozenge; **AND**
- Dose requested is below QL for the drug (listed for reference)
  - If conditions above are met, approve for 6 months
- For requests that exceed the QL (1 to 2x the QL):
  - Patient is enrolled in hospice; **OR**
  - Prescriber attests that the patient's dose of a concomitant LA opioid is being increased or provides rationale on why it cannot be; **AND**
  - Patient is being monitored by a board-certified pain specialist with oncology experience; **AND**
  - Provide rationale on why the patient's dose is being titrated over the max; **AND**
  - If conditions above are met, approve for 3 months.
- For requests that exceed the QL (above 2x the QL):
  - Submit to medical director for review.

PRECISION FORMULARY CRITERIA *(CONTINUED)*

- Reference quantity limits:
  - Recommended maximum dosage limits once effective breakthrough dose is found:
  - Abstral: 800 mcg/dose, 2 doses/breakthrough pain episode, 4 treated episodes/day
  - Actiq (and its generic, fentanyl citrate oral lozenge): 1600 mcg/dose, 4 treated episodes/day
  - Fentora: 800 mcg/dose, 4 treated episodes/day
  - Lazanda: 800 mcg/dose, 4 doses/day
  - Subsys: 1600 mcg/dose, 2 doses/breakthrough pain episode, 4 treated episodes/day

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient is free of unacceptable toxicity from the drug.
- If conditions above are met, approve for 3-6 months (depending on initial criteria parameters the member meets)

ORAL CONTRACEPTIVES

Length of Authorization:	1 year
Reason Code:	MNC: Category A: PA required

The following client(s) have oral contraceptives excluded from their drug plan as per Builder:

- Agnesian Healthcare

The medication may be approved if it is deemed medically necessary. Oral contraceptives will **not** be covered for contraception.

Examples of Medical Necessity:

- Menorrhagia: Excessive vaginal bleeding
- Endometriosis
- Dysfunctional Uterine Bleeding (DUB)
- Excessive polyps
- Anemia secondary to vaginal bleeding
- Polycystic ovarian syndrome
- Severe Acne

Evaluate to see if the patient has failed first line therapy for the patient's condition (if available).

Examples above are not all inclusive.

ORGOVYX® (RELUGOLIX)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Advanced Prostate Cancer:**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with P-gp inhibitors (e.g., amiodarone, azithromycin, tucatinib, etc.), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with combined P-gp and strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has androgen sensitive disease

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet indication-specific relevant criteria, such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in initial criteria; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include QT/QTc interval prolongations, etc.

ORILISSA® (ELAGOLIX SODIUM)

Length of Authorization:	Initial: 150 mg: 1 year, 200 mg: 6 months. Renewal: 150 mg: 1 year (maximum duration for this dose is 24 months), 200 mg: no renewal
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Endometriosis** (confirmed vs. presumptive)

- Patient is at least 18 years of age; **AND**
- Must be prescribed by, or in consultation with, a specialist in gynecology, reproductive health, or endocrinology; **AND**
- Patient has failed an adequate trial of the following therapies:
  - Non-steroidal anti-inflammatory drugs (NSAIDs); **AND**
  - Hormonal contraceptives **or** progestins (including oral or transdermal formulations, vaginal ring, intrauterine device, or injections); **AND**
- Pregnancy is excluded prior to initiating treatment; **AND**
- Patient will use effective non-hormonal contraception during treatment with Orilissa and for 28 days after stopping therapy; **AND**
- Patient does not have osteoporosis (which is defined as a Z score less than -1.5 at spine and femur [total hip]); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh C); **AND**
- Patient is not on concomitant strong organic anion transport polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine, gemfibrozil).

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet the initial criteria; **AND**
- Provide verbal attestation that the patient does not have osteoporosis and provide the Z score (patient should not have a Z score less than -1.5 at spine and femur [total hip]); **AND**
- Patient is considered to have clinically meaningful response to treatment.

ORKAMBI® (LUMACAFTOR/IVACAFTOR)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cystic Fibrosis**

- Patient is at least 2 years of age; **AND**
- Patient has a baseline percent predicted forced expiratory volume in 1 second (FEV_1)- *reported measurements may be used on renewal*; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with any other cystic fibrosis transmembrane conductance regulator (CFTR)-targeted therapy containing one or more of the following: ivacaftor, lumacaftor, tezacaftor, elexacaftor; **AND**
  - Coadministration with strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, posaconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, St. John's Wort, etc.); **AND**
- Patient has a baseline ophthalmological test obtained prior to initiation of therapy and will continue to have follow-up ophthalmological examinations periodically thereafter (pediatric patients only); **AND**
- Patient is homozygous (mutation is present on both alleles) for the *F508del* mutation in the CFTR gene, as confirmed by an FDA-cleared or CLIA-compliant CF mutation test

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

- Disease response as indicated by one or more of the following:
  - Decreased pulmonary exacerbations compared to pre-treatment baseline
  - Improvement or stabilization of lung function as measured by percent predicted FEV_1 within the previous 30 days compared to pre-treatment baseline
  - Decrease in decline of lung function as measured by percent predicted FEV_1 within the previous 30 days compared to pre-treatment baseline
  - Improvement in quality of life (e.g., Cystic Fibrosis Questionnaire-Revised [CFQ-R] score), weight gain, or growth; **AND**
- Patient has not received a lung transplant; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include liver-related events (e.g., elevated ALT, AST, or bilirubin), respiratory events (e.g., chest discomfort, dyspnea, and abnormal respiration), increased blood pressure, development of non-congenital cataracts or lens opacities, etc.

ORTIKOS™ (BUDESONIDE ER)

Length of Authorization:	1 year, may be renewed
Initiative:	MNC: Miscellaneous: PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Treatment of mild to moderate Crohn's disease involving the ileum and/or ascending colon**

- Patient is 8 years of age or older; **AND**
- Patient has had a trial and failure, intolerance, or contraindication to generic budesonide delayed-release 3 mg capsules

Diagnosis of **Maintenance of clinical remission of mild to moderate Crohn's disease involving the ileum and/or ascending colon**

- Patient is 18 years of age or older; **AND**
- Patient has had a trial and failure, intolerance, or contraindication to generic budesonide delayed-release 3 mg capsules

CLINICAL CRITERIA FOR RENEWAL

- The patient has benefited from therapy; **AND**
- The patient's condition has not progressed or worsened while on therapy; **AND**
- The patient has not developed any contraindications or other exclusions to its continued use

OSTEOARTHRITIS AGENTS

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

Length of Authorization:	6 months and may be renewed
Initiative:	SPC: Hyaluronic Acid Derivatives (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Osteoarthritis** of the knee:

- Documented symptomatic osteoarthritis of the knee; **AND**
- The patient has had a trial and failure to BOTH of the following conservative methods which has not resulted in functional improvement after at least 3 months:
  - Non-Pharmacologic Approach (e.g., physical, psychosocial, or mind-body [e.g., land based or aquatic exercise, physical therapy, tai chi, yoga, weight management, cognitive behavioral therapy, knee brace or cane, etc.]); **AND**
  - Pharmacologic Approach (e.g., topical NSAIDs, oral NSAIDs with or with oral proton pump inhibitors, COX-2 inhibitors, topical capsaicin, acetaminophen, tramadol, duloxetine, etc.); **AND**
- The patient has failed to adequately respond to aspiration and injection of intra-articular steroids; **AND**
- Patient has not received therapy with intra-articular long-acting corticosteroid type drugs (e.g., Zilretta, etc.) within the previous 6 months of therapy; **AND**
- The patient reports pain which interferes with functional activities (e.g., ambulation, prolonged standing); **AND**
- Patient does not have any conditions which would preclude intra-articular injections (e.g., active joint infection, unstable joint, bleeding disorders, etc.); **AND**
- **Standard, Precision/Plus:** For non-preferred products: patient must have a documented failure, contraindication, intolerance, or ineffective response with a minimum 3-month trial of BOTH Euflexxa and Synvisc (or Synvisc-One); **OR**
- Patient is continuing treatment with requested product.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by improvement in signs and symptoms of pain and a stabilization or improvement in functional capacity during the 6-month period following the previous series of injections as evidenced by objective measures; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe joint swelling and pain, severe infections, anaphylactic or anaphylactoid reactions, etc.

ENHANCED FORMULARY CRITERIA

Length of Authorization:	6 months and may be renewed
Initiative:	SPC: Hyaluronic Acid Derivatives (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Osteoarthritis** of the knee:

- Documented symptomatic osteoarthritis of the knee; **AND**
- The patient has had a trial and failure to BOTH of the following conservative methods which has not resulted in functional improvement after at least 3 months:
  - Non-Pharmacologic Approach (e.g., physical, psychosocial, or mind-body [e.g., land based or aquatic exercise, physical therapy, tai chi, yoga, weight management, cognitive behavioral therapy, knee brace or cane, etc.]); **AND**
  - Pharmacologic Approach (e.g., topical NSAIDs, oral NSAIDs with or with oral proton pump inhibitors, COX-2 inhibitors, topical capsaicin, acetaminophen, tramadol, duloxetine, etc.); **AND**
- The patient has failed to adequately respond to aspiration and injection of intra-articular steroids; **AND**
- Patient has not received therapy with intra-articular long-acting corticosteroid type drugs (i.e., Zilretta, etc.) within the previous 6 months of therapy; **AND**
- The patient reports pain which interferes with functional activities (e.g., ambulation, prolonged standing); **AND**
- Patient does not have any conditions which would preclude intra-articular injections (e.g., active joint infection, unstable joint, bleeding disorders, etc.); **AND**
- **Enhanced:** For non-preferred products: Patient must have a documented failure, contraindication, intolerance, or ineffective response with a minimum 3-month trial of ALL preferred products: Durolane, Euflexxa, Gelsyn-3, and Supartz; **OR**
- Patient is continuing treatment with requested product.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by improvement in signs and symptoms of pain and a stabilization or improvement in functional capacity during the 6-month period following the previous series of injections as evidenced by objective measures; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe joint swelling and pain, severe infections, anaphylactic or anaphylactoid reactions, etc.

CORE FORMULARY CRITERIA

Core: All hyaluronic acid derivatives are non-formulary.

OTIC ANTIBIOTICS

Length of Authorization:	1 year
Initiative:	MNC: Miscellaneous: PA required (IE 2462 / NCPDP 75, 50081 and 2193)

STEP CRITERIA (NO GRANDFATHERING)

CETRAXAL, CIPRO HC, OTOVEL

- The patient has failed a trial of a generic otic ciprofloxacin/dexamethasone

OXBRYTA® (VOXELOTOR)

Length of Authorization:	Initial: 6 months, Renewal: 12 months
Initiative:	SPC: miscellaneous pa required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR APPROVAL

Diagnosis of **Sickle Cell Disease**

- Patient must be 12 years or older; **AND**
- Hemoglobin (Hb) lab values are obtained within 30 days of the date of administration (unless otherwise indicated); **AND**
- Will not to be used in combination with crizanlizumab (Adakveo) or L-glutamine (Endari); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with fluconazole or strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, phenobarbital, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has a confirmed diagnosis of sickle-cell disease, of any genotype (e.g., HbSS, HbSC, HbS/beta0-thalassemia, HbS/beta+-thalassemia, and others) as determined by one of the following:
  - Identification of significant quantities of HbS with or without an additional abnormal β-globin chain variant by hemoglobin assay; **OR**
  - Identification of biallelic *HBB* pathogenic variants where at least one allele is the p.Glu6Val pathogenic variant on molecular genetic testing; **AND**
- Patient had an insufficient response to a minimum 3-month trial of hydroxyurea (unless contraindicated or intolerant); **AND**
- Patient has symptomatic anemia with a baseline hemoglobin (Hb) between ≥ 5.5 g/dL to ≤ 10.5 g/dL prior to start of therapy; **AND**
- Other causes of anemia (e.g., hemolysis not attributed to SCD, bleeding, vitamin deficiency, etc.) have been ruled out.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions); **AND**
- Disease response as evidenced by an increase in hemoglobin of > 1 g/dL from baseline

OXLUMO™ (LUMASIRAN)

Length of Authorization:	Initial: 6 months, Renewal: 12 months
Initiative:	SPC: miscellaneous pa required

CLINICAL CRITERIA FOR APPROVAL

Diagnosis of **Primary Hyperoxaluria type 1 (PH1)**

- Patient has not had a liver transplant; **AND**
- Must be prescribed by or in consultation with a specialist in genetics, nephrology, or urology; **AND**
- Patient has a definitive diagnosis of primary hyperoxaluria type 1, as evidenced by one of the following:
  - Patient has a biallelic pathogenic mutation in the alanine:glyoxylate aminotransferase (*AGXT)* gene as identified on molecular genetic testing; **OR**
  - Identification of alanine:glyoxylate aminotransferase (AGT) enzyme deficiency on liver biopsy; **AND**
- Patient has a baseline for one or more of the following:
  - Urinary oxalate excretion level (corrected for BSA)
  - Spot urinary oxalate: creatinine ratio
  - Estimated glomerular filtration rate (eGFR)

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet indication-specific relevant criteria (not including prerequisite therapy, etc.) identified in initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe injection site reactions, etc**.; AND**
- Disease response as evidenced by a decrease in urinary oxalate excretion from baseline, a reduction in spot urinary oxalate: creatinine ratio from baseline, and/or stabilization of glomerular filtration rate

OZOBAX® (BACLOFEN SOLUTION)

Length of Authorization:	12 months and renewable
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient must be ≥ 12 years of age; **AND**
- Patient has had a trial of baclofen tablets UNLESS the patient has difficulty swallowing solid dosage forms, or the dosage needed is not available in another formulation

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet initial criteria; **AND**
- Patient is experiencing symptom improvement; **AND**
- The patient is not experiencing any treatment-limiting adverse reactions of the medication

PADCEV™ (ENFORTUMAB VEDOTIN-EJFV)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Bladder Cancer/Urothelial Carcinoma:**

- Patient is at least 18 years of age; **AND**
- Used as a single agent therapy; **AND**
- Patient has one of the following diagnoses:
  - Locally advanced or metastatic urothelial carcinoma; **OR**
  - Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder; **OR**
  - Local or metastatic bladder cancer recurrence post-cystectomy; **OR**
  - Recurrent or metastatic primary carcinoma of the urethra; **AND**
    - Patient does not have recurrence of stage T3-4 disease or palpable inguinal lymph nodes; **OR**
  - Metastatic upper genitourinary (GU) tract tumors; **OR**
  - Metastatic urothelial carcinoma of the prostate; **AND**
- Used as subsequent therapy; **AND**
  - Patient previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor (i.e., nivolumab, pembrolizumab, atezolizumab, avelumab, etc.); **AND**
    - Patient previously received platinum-containing chemotherapy (e.g., carboplatin, cisplatin, etc.); **OR**
    - Patient is ineligible for cisplatin-containing chemotherapy (i.e., baseline creatinine clearance < 60 mL/min, ECOG PS ≥ 2, hearing impairment ≥ grade 2, etc.)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hyperglycemia or diabetic ketoacidosis, severe peripheral neuropathy, ocular disorders including vision changes, severe skin reactions (e.g. Steven Johnson syndrome, toxic epidermal necrolysis, etc.), infusion site extravasation, etc.

PALYNZIQ™ (PEGVALIASE-PQPZ)

Length of Authorization:	1 Year
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient must be 18 years of age or greater; **AND**
- Patient must have confirmed diagnosis of **phenylketonuria (PKU)**; **AND**
- Physician must be a metabolic specialist; **AND**
- Patient must have uncontrolled blood phenylalanine concentrations > 600 micromol/L with current therapy; **AND**
- Patient must adhere to dietary restriction of protein and phenylalanine; **AND**
- In patients responsive to tetrahydrobiopterin (BH4), a failure to an adequate trial of sapropterin (Kuvan) has been demonstrated; **AND**
- The patient is **not** concurrently receiving sapropterin (Kuvan) therapy.

CLINICAL CRITERIA FOR RENEWAL

- Maintain blood phenylalanine concentration reductions of 20% below baseline measurements; **AND**
- Remain free from anaphylactic episodes with therapy.

PARAPLATIN® (CARBOPLATIN)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081, and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of:

- Anal carcinoma (squamous cell)
- Ovarian cancer
- Bladder cancers (includes urothelial, non-urothelial, urothelial of variant histology, upper GU, prostate, and urethra cancers)
- Bone cancer (includes Ewing's sarcoma and osteosarcoma)
- Breast cancer
- Cervical cancer
- Central nervous system cancers (includes adult low-grade [WHO grade I or II] glioma, adult intracranial and spinal ependymoma, adult medulloblastoma)
- Esophageal and esophagogastric junction cancers (squamous cell carcinoma; adenocarcinoma)
- Gastric adenocarcinoma
- Gestational trophoblastic neoplasia
- Head and neck cancers (squamous cell carcinoma or occult primary)
- Hodgkin lymphoma
- Kidney cancer (non-clear cell)
- Malignant pleural mesothelioma
- Melanoma (cutaneous and uveal)
- Neuroendocrine tumors (includes poorly differentiated/large or small cell, adrenal, carcinoid tumors of the GI tract, lung, or thymus, well-differentiated grade 3)
- B-cell lymphoma
  - Follicular lymphoma
  - Diffuse large B-cell lymphoma
  - Mantle cell lymphoma
  - AIDS-related lymphoma
  - Burkitt lymphoma
  - Post-transplant lymphoproliferative disorder (monomorphic)
  - Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
  - High grade B-cell lymphomas
  - Pediatric aggressive mature B-cell lymphoma
- Merkel cell carcinoma
- Non-small cell lung cancer
- Occult primary
- Primary cutaneous lymphomas
  - Mycosis fungoides/Sézary syndrome
  - Primary cutaneous CD30+ T-cell lymphoproliferative syndrome
- Prostate cancer
- Small cell lung cancer
- Soft tissue sarcoma (rhabdomyosarcoma)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- T-cell lymphoma
  - Peripheral T-cell lymphomas
  - Adult T-cell leukemia/lymphoma
  - Extranodal NK/T-cell lymphoma, nasal type
  - Hepatosplenic gamma-delta T-cell lymphoma
  - Breast implant-associated anaplastic large cell lymphoma (ALCL)
- Testicular cancer
- Thymomas and thymic carcinomas
- Anaplastic thyroid carcinomas
- Uterine neoplasms/endometrial carcinomas
- Vulvar cancer (squamous cell carcinoma)
- Small bowel adenocarcinoma/advanced ampullary cancer
- Skin cancer (squamous cell)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug

PARKINSON'S

Length of Authorization:	1 year 6 months for Duopa
Initiative:	MNC: Parkinson's (IE 2462 / NCPDP 75) – Xadago SPC: Miscellaneous pa required (IE 2462 / NCPDP 75, 50081 and 2193) for Gocovi, Osmolex, Duopa, Nourianz

CLINICAL CRITERIA FOR INITIAL APPROVAL

DUOPA

INITIAL CRITERIA

Diagnosis of **Advanced Parkinson's disease**

- Patient is 18 years of age or older; **AND**
- Patient has not received a nonselective monoamine oxidase inhibitor (e.g., phenelzine, tranylcypromine, etc.) within the previous 2 weeks; **AND**
- Patient has persistent motor fluctuations ("Off" time) while on treatment with oral immediate-release carbidopa-levodopa and other Parkinson's disease medications; **AND**
- Patient is levodopa-responsive; **AND**
- Patient experiences 3 or more hours of "Off" time with their current Parkinson's disease drug therapy

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria identified above; **AND**
- Patient continues to receive benefit from therapy; **AND**
- Absence of unacceptable toxicity from the drug (e.g., nausea, depression, peripheral edema, hypertension, upper respiratory tract infection, oropharyngeal pain)

GOCOVRI, OSMOLEX ER

INITIAL CRITERIA

- Diagnosis of dyskinesia associated with Parkinson's disease; **AND**
- Patient must be on concomitant levodopa-based therapy; **AND**
- Patient has had an adequate trial of or is intolerant to amantadine immediate-release; **AND**
- Patient should **not** receive live vaccines during treatment due to possible interference of antiviral properties, however inactivated vaccines may be utilized

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria identified above; **AND**
- Patient continues to receive benefit from therapy; **AND**
- Absence of unacceptable toxicity from the drug

CLINICAL CRITERIA FOR INITIAL APPROVAL

NOURIANZ

INITIAL CRITERIA

Diagnosis of **Parkinson's disease**

- Patient is 18 years of age or older; **AND**
- Documented diagnosis of Parkinson's disease (PD); **AND**
- Patient is experiencing "off" episodes of PD at least 2 hours/day on average; **AND**
- Patient must be on a concomitant stable levodopa-based therapy regimen; **AND**
- Patient is unable to control "off" symptoms with adequate adjunctive therapies (e.g., dopamine agonists, monoamine oxidase-B [MOA-B] inhibitors, catechol-O-methyltransferase [COMT] inhibitors); **AND**
- Patient is monitored for tobacco smoking and the dose adjusted accordingly; **AND**
- Patient does not have a major psychotic disorder; **AND**
- Patient is not pregnant or is using proper contraception; **AND**
- Patient does not have severe hepatic impairment (Child-Pugh C); **AND**
- Patient will avoid concomitant use with strong CYP3A4 inducers (e.g., rifampin, etc.)

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria identified above; **AND**
- Absence of unacceptable toxicity or treatment related adverse event from the drug (e.g., dyskinesias exacerbation, hallucinations/psychotic behavior, impulse control/compulsive behaviors); **AND**
- Patient has clinically meaningful response to treatment)

XADAGO

INITIAL CRITERIA

- Patient is 18 years of age or older; **AND**
- Patient has Parkinson's disease; **AND**
- Patient is receiving concomitant therapy with carbidopa/levodopa and experiencing "off episodes"; **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Score > 9); **AND**
- Patient is not taking dextromethorphan; **AND**
- Patient is not taking other MAO-I inhibitors or other drugs that are potent inhibitors of monoamine oxidase (e.g., linezolid); **AND**
- Patient is not taking other serotonergic drugs (e.g., SNRIs, SSRIs, TCAs, St. John's wort, cyclobenzaprine); **AND**
- Patient is not taking opioid drugs (e.g., meperidine, methadone, propoxyphene, tramadol); **AND**
- Patient is not taking sympathomimetic medications (e.g., methylphenidate, amphetamine); **AND**
- Must try and fail rasagiline or selegiline
- **Quantity Limit**: 1 tablet/day

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria identified above; **AND**
- Patient continues to receive benefit from therapy; **AND**
- Absence of unacceptable toxicity from the drug (e.g., nausea, depression, peripheral edema, hypertension, upper respiratory tract infection, oropharyngeal pain)

PEMAZYRE® (PEMIGATINIB)

Length of Authorization:	6 months and may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cholangiocarcinoma**

- Patient is 18 years of age or older; **AND**
- Patient has received ophthalmological examinations (i.e., assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography) at baseline and periodically throughout therapy; **AND**
- Patient serum phosphate level is measured at baseline and periodically throughout therapy; **AND**
- Therapy will not be used concomitantly with other selective FGFR-inhibitors (e.g., erdafitinib); **AND**
- Patient will not be on concomitant therapy with any of the following:
  - Strong or moderate CYP3A-Inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Strong or moderate CYP3A4 inhibitors (e.g., fluconazole, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Must be used as a single agent; **AND**
- Patient has unresectable locally advanced or metastatic disease; **AND**
- Patient has a susceptible gene mutation rearrangement or fusion in the fibroblast growth factor receptor 2 (FGFR2) gene, as determined by an FDA-approved or CLIA-compliant test; **AND**
- Used subsequent to at least 1 systemic therapy

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia**

- Patient is 18 years of age or older; **AND**
- Patient has received ophthalmological examinations (i.e., assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography) at baseline and periodically throughout therapy; **AND**
- Patient serum phosphate level is measured at baseline and periodically throughout therapy; **AND**
- Therapy will not be used concomitantly with other selective FGFR-inhibitors (e.g., erdafitinib); **AND**
- Patient will not be on concomitant therapy with any of the following:
  - Strong or moderate CYP3A-Inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Strong or moderate CYP3A4 inhibitors (e.g., fluconazole, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has FGFR1 rearrangement; **AND**
  - Patient has chronic or blast phase disease; **AND**
    - Treatment with a clinical trial is unavailable; **OR**
  - Patient has lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., central serous retinopathy/retinal pigment epithelial detachment [CSR/RPED], severe hyperphosphatemia); **AND**
- Patient serum phosphate level is < 7.0 mg/dL

PENICILLAMINE AGENTS

Length of Authorization:	Initial: 4 Months, Renewal: 6 months
Initiative:	MNC: Miscellaneous: PA Required

CLINICAL CRITERIA FOR INITIAL APPROVAL

CUPRIMINE, DEPEN, D-PENAMINE, PENICILLAMINE

- Patient does not have any history of penicillamine-related aplastic anemia or agranulocytosis; **AND**
- Prescriber attests ongoing compliance to monitor appropriate laboratory parameters and discussion of potential serious adverse effects discussed with the patient/when to seek medical attention (e.g., routine urinalysis, white and differential blood cell count, hemoglobin determination, direct platelet count twice weekly, and symptom monitoring during the first month of therapy, every 2 weeks for the next 5 months, and monthly thereafter); **AND**
- Patient is not using concurrent gold therapy or antimalarials; **AND**
- Patient has a diagnosis of **Wilson's disease**; **AND**
  - Diagnosis is confirmed by ≥ 1 of the following: ceruloplasmin is < 20 mg/dL, urinary copper ≥ 40 mcg/24 hours, liver biopsy results consistent with Wilson's disease, genetic testing consistent with Wilson's disease, Kayser-Fleischer rings, or Leipzig score ≥ 4; **AND**
  - Prescriber has documented patient's ongoing attempt to minimize dietary intake of copper (≤ 2 mg/day; avoidance of chocolate, nuts, shellfish, mushrooms, liver, molasses, broccoli, and cereals and dietary supplements enriched with copper); **AND**
  - Prescriber affirms discussion with patient regarding compliance, including the risk of sensitivity reactions following treatment interruptions; **AND**
  - Patient is also prescribed 25 mg/day pyridoxine; **AND**
  - Patient is also taking a copper-free multivitamin; **AND**
  - Patient is also taking oral zinc (or has a contraindication to taking oral zinc); **AND**
  - Patient has had an adequate trial and failure of a preferred agent for Wilson's disease (e.g., trientine); **AND**
  - For Cuprimine and generic penicillamine capsules only: Have had an adequate trial and failure or intolerance to Depen®; OR
  - Patient is continuing therapy, documented by prescriber as effective based on laboratory analysis (e.g., serum copper); **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient has a diagnosis of **cystinuria; AND**
  - Diagnosis is confirmed by nephrolithiasis and 1 of the following: family history of cystinuria, stone analysis confirming cystine stones, elevated urine cystine output (e.g., 300 mg/day); **AND**
  - If patient is of childbearing potential, patient is not pregnant, or nursing or prescriber affirms that a full discussion of the risk versus benefits in child-bearing women have been discussed with patient; **AND**
  - Prescriber affirms discussion with patient regarding compliance, including the risk of sensitivity reactions following treatment interruptions; **AND**
  - Patient has had a trial and failure (documented signs and/or symptoms of cystine stones) of conservative and/or nonpharmacologic treatments (e.g., patient's ongoing attempt to minimize dietary intake of methionine [unless not clinically appropriate, such as growing child or pregnant], protein and sodium restriction, increased fluid intake; urinary alkalization); **AND**
  - Patient is also prescribed 25 mg/day pyridoxine; **AND**
  - Patient is also using a multivitamin; **AND**
  - Patient has had an adequate trial and failure of ≥ 1 preferred agent (e.g., generic tiopronin); **AND**
  - For Cuprimine and generic penicillamine capsules only: have had an adequate trial and failure or intolerance to Depen®; OR
  - Patient is continuing therapy, documented by prescriber as effective based on laboratory analysis (e.g., urine cystine) or lack of stone formation; **OR**
- Patient has a diagnosis of **rheumatoid arthritis (RA); AND**
  - RA is considered severe and active, as documented by disease severity scale (e.g., Patient Activity Scale [PAS], Routine Assessment of Patient Index Data 3 [RAPID3], Clinical Disease Activity Index [CDAI], Disease Activity Score [DAS] 28; Simplified Disease Activity Index [SDAI], other reliable measures); **AND**
  - Patient ≥ 18 years old; **AND**
  - If patient is of childbearing potential, patient is not pregnant or nursing; **AND**
  - Patient does not have a history of renal insufficiency or current renal insufficiency; **AND**
  - Patient is also prescribed 25 mg/day pyridoxine; **AND**
  - Patient is not taking mineral supplements; **AND**
  - Prescriber documents adequate discussion with the patient concluding that the benefits outweigh adverse effect risk of penicillamine; **AND**
  - Patient has had an adequate trial and failure of ≥ 2 traditional disease-modifying antirheumatic drugs (DMARDs; e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) as monotherapy, 1 of which should be methotrexate, unless contraindicated; **AND**
  - Patient has failed an adequate trial of combination conventional therapy; **AND**
  - Patient has had an adequate trial and failure of ≥ 3 biologic DMARDs with differing cellular targets, 2 of which should be a tumor necrosis factor alpha (TNFα) inhibitor, unless contraindicated; **AND**
  - Patient has failed an adequate trial of nontraditional, small-molecule DMARD therapy (e.g., tofacitinib); **AND**
  - For Cuprimine and generic penicillamine capsules only: have had an adequate trial and failure or intolerance to Depen®; OR
  - Patient is continuing penicillamine therapy

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet above criteria, based on indication; **AND**
- Patients symptoms are clinically improving, as documented by provider; **AND**
- Prescriber affirms ongoing patient compliance; **AND**
- Patient has no treatment-limiting adverse effects (e.g., reduction in white blood cell count < 3,500 mm^3, platelets < 100,000 mm^3, or persistent decrease in WBC or platelets [3 successive determinations]; proteinuria or hematuria, particularly in RA patients [risk versus benefit consideration in Wilson's disease or cystinuria]; signs or symptoms of Goodpasture's syndrome [e.g., hemoptysis, pulmonary infiltrates]; pulmonary symptoms consistent with obliterative bronchiolitis [e.g., exertional dyspnea, unexplained cough or wheezing]; new neurological symptoms [e.g., Myasthenic syndrome]; pemphigus [e.g., pemphigus vulgaris, pemphigus foliaceus]; persistent drug fever or rash; hypersensitivity reaction or drug eruption; or persistent stomatitis); **AND**
- Documentation of liver function testing every 6 months (every 3 months in patients with Wilson's disease for the first 12 months of treatment); **AND**
- If used for cystinuria for ≥ 12 months, patient has had an x-ray for renal stones in the past 12 months; **AND**
- Patient is receiving proper concurrent therapy, as described above, and iron supplementation if appropriate in Wilson's disease and cystinuria; **AND**
- If used for RA, a stepwise reduction in dosage has resulted in worsened disease severity/disease control.

PEPAXTO® (MELPHALAN FLUFENAMIDE)

Length of Authorization:	6 months and may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma**

- Patient is at least 18 years of age; **AND**
- Patient does not have a history of serious allergic reactions to melphalan; **AND**
- Therapy will NOT be used as a conditioning regimen for transplant; **AND**
- Patient has relapsed, refractory, or progressive disease; **AND**
- Used in combination with dexamethasone; **AND**
- Patient received at least four prior lines of therapy and is refractory to a proteasome inhibitor (e.g., bortezomib, carfilzomib, etc.), an immunomodulatory agent (e.g., lenalidomide, pomalidomide, etc.), and a CD38-directed antibody (e.g., daratumumab, isatuximab, etc.); **AND**
- Provider attests to discussing with patient the possible risks and benefits of therapy with Pepaxto in the context of other treatments and will monitor therapy accordingly

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe thrombocytopenia, severe neutropenia, severe anemia, clinically significant infections, secondary malignancies, etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Provider attests to discussing with the patient the risks and benefits of continued therapy with Pepaxto in the context of other treatments

PERJETA® (PERTUZUMAB)

Length of Authorization:	6 months and may be renewed Use for neo-adjuvant and adjuvant breast cancer is limited to a total of 1 year of treatment [18 cycles] **(*Note: When used for recurrent or metastatic breast cancer, therapy may be continued until disease progression or unmanageable toxicity.)**
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2-positive* (HER2) disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Therapy will not be used in combination with pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); **AND**
- Used as neoadjuvant (or preoperative) or adjuvant treatment; **AND**
  - Patient has locally advanced, node positive, or inflammatory disease; **AND**
  - Used in combination with a trastuzumab-based regimen; **OR**
- Used for recurrent unresectable or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
  - Used as first line therapy in combination with trastuzumab and either paclitaxel **or** docetaxel; **OR**
  - Used as subsequent therapy in combination with a trastuzumab-based regimen; **AND**
    - Patient was previously treated with trastuzumab and chemotherapy; **AND**
    - Patient has not previously received pertuzumab

Diagnosis of **Colorectal Cancer**

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2-positive* (HER2) disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Therapy will not be used in combination with pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); **AND**
- Used for RAS and BRAF wild-type (WT) disease in combination with trastuzumab; **AND**
- Patient has not previously received HER2-targeted therapy; **AND**
  - Used as subsequent therapy for progression of advanced or metastatic disease after at least one prior line of treatment in the advanced or metastatic disease setting; **OR**
  - Patient is not appropriate for intensive therapy; **AND**
    - Used as primary treatment for unresectable or medically inoperable, locally advanced, or metastatic disease *(excluding use as neoadjuvant therapy)*; **OR**
    - Used for unresectable (or medically inoperable) metastatic disease that remains unresectable after primary systemic therapy

❖ *If confirmed using an immunotherapy assay – http://www.fda.gov/companiondiagnostics*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Head and Neck Cancer**

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2-positive* (HER2) disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Therapy will not be used in combination with pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); **AND**
- Patient has salivary gland tumors; **AND**
- Used in combination with trastuzumab; **AND**
- Used for one of the following:
  - Recurrent disease with distant metastases; **OR**
  - Unresectable locoregional recurrence with prior radiation therapy (RT); **OR**
  - Unresectable second primary with prior RT

***HER2-positive overexpression criteria:**
• Immunohistochemistry (IHC) assay 3+; **OR** • Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number ≥ 4.0 signals/cell; **OR** • Dual-probe in situ hybridization (ISH) assay **and** concurrent IHC indicating one of the following: – HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number < 4.0 signals/cell **and** concurrent IHC 3+; **OR** – HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 6.0 signals/cell **and** concurrent IHC 2+ or 3+; **OR** – HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 4.0 and < 6.0 signals/cell **and** concurrent IHC 3+

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include left ventricular dysfunction, severe infusion-related reactions, hypersensitivity reactions/anaphylaxis, etc.; **AND**
- Left ventricular ejection fraction (LVEF) within the previous 3 months as follows:
  - Neoadjuvant and adjuvant breast cancer: LVEF is ≥ 50% OR LVEF has had an **absolute** decrease of < 10% from baseline
  - All other indications: LVEF is > 45% OR LVEF is 40% to 45% and **absolute** decrease is < 10% from baseline; **AND**
- Use for adjuvant **or** neo-adjuvant breast cancer treatment is limited to up to a year of treatment (total of 18 cycles).

PHESGO® (PERTUZUMAB, TRASTUZUMAB, AND HYALURONIDASE-ZZXF)

Length of Authorization:	6 months, may be renewed Use in the neoadjuvant/adjuvant setting is limited to a total of 1 year (up to 18 cycles)
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**:

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-positive* disease as determined by an FDA-approved or CLIA-compliant test; **AND**
- Therapy will not be used in combination with pertuzumab, trastuzumab (or trastuzumab biosimilar product [e.g., Ogivri, Kanjinti, Trazimera, Herzuma, Ontruzant]), or trastuzumab and hyaluronidase-oysk (Herceptin Hylecta); **AND**
- Therapy will not be substituted for or with pertuzumab or any trastuzumab-based formulation (i.e., trastuzumab [or trastuzumab biosimilar product], ado-trastuzumab emtansine, fam-trastuzumab deruxtecan-nxki, trastuzumab-hyaluronidase, etc.) **AND**
- Patient does not have a known hypersensitivity to an alternative formulation of trastuzumab or pertuzumab; **AND**
- Used as neoadjuvant therapy; **AND**
  - Patient has locally advanced, inflammatory, or early stage disease; **OR**
- Used as adjuvant therapy; **AND**
  - Patient has locally advanced or node positive disease OR early stage disease at high risk of recurrence; **OR**
- Used for recurrent or metastatic disease; **AND**
  - Used as first-line therapy in combination with either paclitaxel or docetaxel; **OR**
  - Used as second-line therapy ; **AND**
    - Patient was previously treated with trastuzumab and chemotherapy; **AND**
    - Patient has not previously received pertuzumab

*HER2-positive overexpression criteria:
• Immunohistochemistry (IHC) assay 3+; **OR** • Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number ≥ 4.0 signals/cell; **OR** • Dual-probe in situ hybridization (ISH) assay AND concurrent IHC indicating one of the following: – HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number < 4.0 signals/cell AND concurrent IHC 3+; **OR** – HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 6.0 signals/cell AND concurrent IHC 2+ or 3+; **OR** – HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 4.0 and < 6.0 signals/cell AND concurrent IHC 3+

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: cardiotoxicity (e.g., left ventricular dysfunction, cardiomyopathy, etc.), pulmonary toxicity (i.e., pneumonitis), neutropenia, infusion-related reactions, etc.; **AND**
- **Breast Cancer (neoadjuvant or adjuvant treatment)**:
  - Left ventricular ejection fraction (LVEF) is ≥ 50% OR LVEF **absolute** decrease is < 10% from pre-treatment baseline (LVEF results must be within the previous 3 months); **AND**
  - Patient has not exceeded a maximum of 1 year of therapy (18 cycles)
- **Breast Cancer (metastatic)**:
  - Left ventricular ejection fraction (LVEF) is > 45% OR is between 40-45% and **absolute** decrease is < 10% from pre-treatment baseline (LVEF results must be within the previous 3 months)

PHOTOFRIN® (PORFIMER SODIUM)

Length of Authorization:	1 month, may be renewed Coverage may be renewed for up to a maximum of 3 courses of therapy, each separated by at least 1 month, for esophageal cancer, endobronchial cancer, basal cell skin cancer, and squamous cell skin cancer. Coverage may be renewed for up to a maximum of 3 courses of therapy, each separated by at least 3 months, for high-grade dysplasia in Barrett's esophagus
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Esophageal Cancer**:

- Patient is at least 18 years of age; **AND**
- Patient does not have porphyria; **AND**
- Will not be used concomitantly with other photosensitizing agents (e.g., tetracyclines, sulfonamides, phenothiazines, sulfonylurea hypoglycemic agents, thiazide diuretics, griseofulvin, fluoroquinolones, etc.); **AND**
- Patient does not have any of the following contraindications to photodynamic therapy (PDT) which is to occur post-porfimer administration:
  - Tracheoesophageal or bronchoesophageal fistula
  - Tumors eroding into a major blood vessel
  - Esophageal or gastric varices or esophageal ulcers > 1 cm in diameter
  - Emergent use for severe acute respiratory distress due to an obstructing endobronchial lesion; **AND**
- Patient has completely obstructing disease; **OR**
- Patient has partially obstructing disease and cannot be satisfactorily treated with Nd:YAG laser therapy

Diagnosis of **Endobronchial Cancer**:

- Patient is at least 18 years of age; **AND**
- Patient does not have porphyria; **AND**
- Will not be used concomitantly with other photosensitizing agents (e.g., tetracyclines, sulfonamides, phenothiazines, sulfonylurea hypoglycemic agents, thiazide diuretics, griseofulvin, fluoroquinolones, etc.); **AND**
- Patient does not have any of the following contraindications to photodynamic therapy (PDT) which is to occur post-porfimer administration:
  - Tracheoesophageal or bronchoesophageal fistula
  - Tumors eroding into a major blood vessel
  - Esophageal or gastric varices or esophageal ulcers > 1 cm in diameter
  - Emergent use for severe acute respiratory distress due to an obstructing endobronchial lesion; **AND**
- Used to treat microinvasive endobronchial non-small-cell lung cancer (NSCLC) in patients for whom surgery and radiotherapy are not indicated; **OR**
- Used for reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial NSCLC

Diagnosis of **High-Grade Dysplasia in Barrett's Esophagus**:

- Patient is at least 18 years of age; **AND**
- Patient does not have porphyria; **AND**
- Will not be used concomitantly with other photosensitizing agents (e.g., tetracyclines, sulfonamides, phenothiazines, sulfonylurea hypoglycemic agents, thiazide diuretics, griseofulvin, fluoroquinolones, etc.); **AND**
- Patient does not have any of the following contraindications to photodynamic therapy (PDT) which is to occur post-porfimer administration:
  - Tracheoesophageal or bronchoesophageal fistula
  - Tumors eroding into a major blood vessel
  - Esophageal or gastric varices or esophageal ulcers > 1 cm in diameter
  - Emergent use for severe acute respiratory distress due to an obstructing endobronchial lesion; **AND**
- Used for ablation in patients who do not undergo esophagectomy

Diagnosis of **Basal Cell Skin Cancer**:

- Patient is at least 18 years of age; **AND**
- Patient does not have porphyria; **AND**
- Will not be used concomitantly with other photosensitizing agents (e.g., tetracyclines, sulfonamides, phenothiazines, sulfonylurea hypoglycemic agents, thiazide diuretics, griseofulvin, fluoroquinolones, etc.); **AND**
- Patient does not have any of the following contraindications to photodynamic therapy (PDT) which is to occur post-porfimer administration:
  - Tracheoesophageal or bronchoesophageal fistula
  - Tumors eroding into a major blood vessel
  - Esophageal or gastric varices or esophageal ulcers > 1 cm in diameter
  - Emergent use for severe acute respiratory distress due to an obstructing endobronchial lesion; **AND**
- Patient has superficial disease

Diagnosis of **Squamous Cell Skin Cancer**:

- Patient is at least 18 years of age; **AND**
- Patient does not have porphyria; **AND**
- Will not be used concomitantly with other photosensitizing agents (e.g., tetracyclines, sulfonamides, phenothiazines, sulfonylurea hypoglycemic agents, thiazide diuretics, griseofulvin, fluoroquinolones, etc.); **AND**
- Patient does not have any of the following contraindications to photodynamic therapy (PDT) which is to occur post-porfimer administration:
  - Tracheoesophageal or bronchoesophageal fistula
  - Tumors eroding into a major blood vessel
  - Esophageal or gastric varices or esophageal ulcers > 1 cm in diameter
  - Emergent use for severe acute respiratory distress due to an obstructing endobronchial lesion; **AND**
- Patient has actinic keratoses OR cutaneous squamous cell carcinoma in situ (Bowen's disease)

CLINICAL CRITERIA FOR RENEWAL

- Patient derived benefit from previous administration; **AND**
- Absence of unacceptable toxicity from the drug. Examples include gastroesophageal fistula and perforation, pulmonary or gastroesophageal hemorrhage, airway obstruction and respiratory distress, esophageal stricture, thromboembolism, etc.; **AND**
- The patient has not exceeded a maximum of 3 courses of therapy at the interval specified in initial section

PIQRAY® (ALPELISIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**:

- Patient is at least 18 years of age; **AND**
- Patient has a baseline fasting plasma glucose, HbA1c, and does not have diabetes mellitus Type 1 or uncontrolled Type 2; **AND**
- Patient does not have a history of acute pancreatitis within 1 year of therapy or a past medical history of chronic pancreatitis; **AND**
- Patient has not received prior treatment with other PI3K inhibitors (e.g., idelalisib, duvelisib, copanlisib); **AND**
- Patient has not received prior treatment with a mammalian target of rapamycin (mTOR) inhibitor (e.g., everolimus); **AND**
- Patient has not received prior chemotherapy for advanced breast cancer; **AND**
- Patient has not previously been treated with fulvestrant; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with BCRP inhibitors (e.g., ritonavir, imatinib, cyclosporin A, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
- Patient has hormone receptor (HR)-positive disease; **AND**
- Used as subsequent therapy in combination with fulvestrant; **AND**
- Used for recurrent, unresectable, advanced, or metastatic disease; **OR**
  - Patient has inflammatory disease with no response to pre-operative systemic therapy; **AND**
- Patient has no visceral crisis; **AND**
- Patient is postmenopausal, premenopausal with ovarian ablation/suppression**,** or is male with suppression of testicular steroidogenesis; **AND**
- Patient has the presence of one or more PIK3CA-mutations in tumor tissue or plasma specimens, as detected by any FDA-approved or CLIA-compliant test

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity, severe cutaneous reactions [≥ Grade 3 rash], severe hyperglycemia [> 250 mg/dL], severe pneumonitis/interstitial-lung-disease, severe diarrhea [≥ Grade 2], severe pancreatitis [≥ Grade 2])

POLIVY™ (POLATUZUMAB VEDOTIN-PIIG)

Length of Authorization:	6 months, may **not** be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **B-Cell Lymphomas**

- Patient is at least 18 years of age; **AND**
- Patient will receive prophylaxis for *Pneumocystis jirovecii* pneumonia and herpesvirus; **AND**
- Patient does not currently have Grade ≥ 2 peripheral neuropathy; **AND**
- Patient does not have CNS lymphoma; **AND**
- Patient has diffuse large B-cell lymphoma (DLBCL)**Φ** or high-grade B-cell lymphoma (high-grade includes with translocations of MYC and BCL2 and/or BCL6 and not otherwise specified); **AND**
  - Patient has partial response, no response, relapsed, progressive or refractory disease; **AND**
  - Patient is not a candidate for stem cell transplant; **AND**
  - Used as a single agent or in combination with bendamustine and/or rituximab; **AN**
  - Used as subsequent treatment; **OR**
- Patient has low-grade (grade 1, 2) follicular lymphoma (FL); **AND**
  - Patient has progressive or refractory disease; **AND**
  - Used as a single-agent or in combination with bendamustine and/or rituximab; **AND**
  - Used as subsequent treatment; **OR**
- Patient has monomorphic post-transplant lymphoproliferative disorder (B-cell type); **AND**
  - Patient has partial response, persistent disease, or progressive disease; **AND**
  - Used as a single-agent or in combination with bendamustine and/or rituximab; **AND**
  - Used as subsequent treatment after at least two prior lines of chemoimmunotherapy**; **OR**
- Patient has AIDS-related B-cell lymphoma; **AND**
  - Used as subsequent treatment; **AND**
  - Used as a single-agent or in combination with bendamustine (with or without rituximab)**; AND**
    - Patient has relapsed AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, or HHV8-positive diffuse large B-cell lymphoma, not otherwise specified (NOS); **OR**
  - Used as a single-agent or in combination with bendamustine**; AND**
    - Patient has relapsed AIDS-related plasmablastic lymphoma and is not a candidate for transplant; **OR**
- Patient has histologic transformation disease; **AND**
  - Used as a single-agent or in combination with bendamustine and/or rituximab; **AND**
  - Patient has transformation of FL to DLBCL without translocations of MYC and BCL2 and/or BCL6; **AND**
    - Patient had minimal or no chemoimmunotherapy prior to histologic transformation to DLBCL and have no response or progressive disease after chemoimmunotherapy; **OR**
    - Patient had multiple prior therapies including ≥2 lines of chemoimmunotherapy for indolent or transformed disease; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient has transformation nodal marginal zone lymphoma to DLBCL; **AND**
  - Patient had multiple prior therapies including ≥ 2 lines of chemoimmunotherapy for indolent or transformed disease

(****Note**: For patients with relapsed disease who received prior bendamustine, response duration must have been > 1 year)

CLINICAL CRITERIA FOR RENEWAL

- May not be renewed

POMALYST® (POMALIDOMIDE)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma**

- Patient is at least 18 years of age; **AND**
- Females of reproductive potential must have two (2) negative pregnancy tests before initiation of therapy and use two (2) contraception methods starting four (4) weeks prior to initiation, during, and at least 4-weeks after discontinuing therapy; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the POMALYST Risk Evaluation and Mitigation Strategy (REMS); **AND**
- Patient will receive thromboprophylaxis, unless contraindicated; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with programmed death (PD-1/PD-L1)-targeted therapy (e.g., avelumab, durvalumab, atezolizumab, pembrolizumab, nivolumab, cemiplimab); **AND**
  - Coadministration with strong CYP1A2 inhibitors (e.g., ciprofloxacin, fluvoxamine, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has relapsed or progressive disease and received at least two (2) prior therapies, including an immunomodulatory agent (e.g., lenalidomide or thalidomide) and a proteasome inhibitor (e.g., bortezomib); **AND**
  - Patient has demonstrated disease progression on or within 60 days of completion of last therapy; **AND**
    - Used in combination with dexamethasone with or without one of the following: bortezomib, carfilzomib, ixazomib, selinexor, or cyclophosphamide; **OR**
    - Used as a single agent if patient is steroid-intolerant; **OR**
  - Used in combination with dexamethasone and either daratumumab, elotuzumab, or isatuximab; **OR**
- Patient has POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome; **AND**
  - Used in combination with dexamethasone; **AND**
    - Used as induction therapy for transplant eligible patients; **OR**
    - Used for transplant ineligible patients

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Primary CNS Lymphoma**

- Patient is at least 18 years of age; **AND**
- Females of reproductive potential must have two (2) negative pregnancy tests before initiation of therapy and use two (2) contraception methods starting four (4) weeks prior to initiation, during, and at least 4-weeks after discontinuing therapy; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the POMALYST® Risk Evaluation and Mitigation Strategy (REMS); **AND**
- Patient will receive thromboprophylaxis, unless contraindicated; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with programmed death (PD-1/PD-L1)-targeted therapy (e.g., avelumab, durvalumab, atezolizumab, pembrolizumab, nivolumab, cemiplimab); **AND**
  - Coadministration with strong CYP1A2 inhibitors (e.g., ciprofloxacin, fluvoxamine, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Used as single-agent therapy; **AND**
  - Used for relapsed or refractory disease; **AND**
    - Patient has failed prior methotrexate-based regimen without prior radiation therapy; **OR**
    - Patient has received prior whole brain radiation therapy; **OR**
    - Patient has received prior high-dose chemotherapy with stem cell rescue; **OR**
  - Used as induction therapy; **AND**
    - Patient is unsuitable for or intolerant to high-dose methotrexate

Diagnosis of **Systemic Light Chain Amyloidosis**

- Patient is at least 18 years of age; **AND**
- Females of reproductive potential must have two (2) negative pregnancy tests before initiation of therapy and use two (2) contraception methods starting four (4) weeks prior to initiation, during, and at least 4-weeks after discontinuing therapy; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the POMALYST® Risk Evaluation and Mitigation Strategy (REMS); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with programmed death (PD-1/PD-L1)-targeted therapy (e.g., avelumab, durvalumab, atezolizumab, pembrolizumab, nivolumab, cemiplimab); **AND**
  - Coadministration with strong CYP1A2 inhibitors (e.g., ciprofloxacin, fluvoxamine, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will receive thromboprophylaxis, unless contraindicated; **AND**
- Patient has relapsed or refractory disease; **AND**
- Used in combination with dexamethasone

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Kaposi Sarcoma**

- Patient is at least 18 years of age; **AND**
- Females of reproductive potential must have two (2) negative pregnancy tests before initiation of therapy and use two (2) contraception methods starting four (4) weeks prior to initiation, during, and at least 4-weeks after discontinuing therapy; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the POMALYST® Risk Evaluation and Mitigation Strategy (REMS); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with programmed death (PD-1/PD-L1)-targeted therapy (e.g., avelumab, durvalumab, atezolizumab, pembrolizumab, nivolumab, cemiplimab); **AND**
  - Coadministration with strong CYP1A2 inhibitors (e.g., ciprofloxacin, fluvoxamine, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will receive thromboprophylaxis, unless contraindicated; **AND**
- Patient has AIDS-related Kaposi sarcoma; **AND**
  - Used in combination with highly active antiretroviral therapy (HAART); **AND**
    - Patient has failed on at least one month of HAART; **AND**
      - Patient does not have symptomatic pulmonary Kaposi sarcoma or symptomatic visceral Kaposi sarcoma (except for non-ulcerating disease restricted to the oral cavity); **OR**
    - Patient has relapsed or refractory advanced cutaneous, oral, visceral, or nodal disease ; **AND**
      - Used as subsequent therapy after failure on first-line systemic therapy and alternative first-line systemic therapy**; OR**
- Patient is HIV-negative; **AND**
  - Used as subsequent therapy as a single agent

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hematologic toxicity [anemia, neutropenia, or thrombocytopenia], hepatotoxicity, venous or arterial thromboembolism, severe cutaneous reactions, dizziness/confusional state, neuropathy, development of second primary malignancy, tumor lysis syndrome, severe hypersensitivity [including angioedema, anaphylaxis, and anaphylactic reactions])

PORTRAZZA® (NECITUMUMAB)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is 18 years or older; **AND**
- Patient must have metastatic disease; **AND**
- Disease must have squamous cell histology; **AND**
- Must be used in combination with **BOTH** gemcitabine and cisplatin; **AND**
- Patient must have a performance status of 0-2; **AND**
- Must be used as first-line therapy

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., cardiopulmonary arrest, hypomagnesemia, severe dermatologic toxicity, severe infusion reactions and venous/arterial thromboembolic events)

POTELIGEO® (MOGAMULIZUMAB-KPKC)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Mycosis Fungoides (MF)/Sézary Syndrome (SS)**

- Patient is at least 18 years of age ; **AND**
- Used as single agent therapy; **AND**
- Patient has relapsed or refractory disease; **AND**
  - Patient has received at least one previous systemic therapy (**Note:** topical and/or photochemotherapy cannot be considered systemic therapies); **OR**
- Used as primary treatment as systemic therapy *(excluding use for stage IA-IIA mycosis fungoides with B1 blood involvement)*

Diagnosis of **Adult T-Cell Leukemia/Lymphoma**

- Patient is at least 18 years of age; **AND**
- Used as single agent therapy; **AND**
- Used as subsequent therapy in patients with acute or lymphoma subtypes which did not respond to first-line therapy.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include dermatologic toxicity (e.g., Stevens-Johnson syndrome [SJS] and toxic epidermal necrolysis [TEN], etc.), severe infusion reactions, fatal and life-threatening infections, autoimmune complications, etc.

PRETOMANID

Length of Authorization:	6 months
Initiative:	MNC: Antibiotics (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is ≥ 18 years of age; **AND**
- Patient has pulmonary extensively drug resistant (XDR) or treatment-intolerant or nonresponsive multidrug –resistant (MDR) tuberculosis (TB); **AND**
- Prescribed by or in consultation with an infectious disease specialist or pulmonologist, provided patient has reasonable access; **AND**
- Patient is concomitantly taking bedaquiline and linezolid

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet the above criteria; **AND**
- Patient has demonstrated clinical improvement in response to treatment**; AND**
- Patient has not developed any contraindications or other exclusions to its continued us.

PREVYMIS® (LETERMOVIR)

Length of Authorization:	100 days, may not be renewed
Initiative:	SPC: miscellaneous pa required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR APPROVAL

- Patient is ≥ 18 years; **AND**
- Allogeneic hematopoietic stem cell transplant (HSCT) recipient; **AND**
- Seropositive for CMV within 1 year before or < 100 days after HSCT; **AND**
- Patient is **not** receiving concurrent therapy with any of the following:
  - Pimozide
  - Ergot alkaloids
  - Cyclosporine in conjunction with either pitavastatin or simvastatin

CLINICAL CRITERIA FOR RENEWAL

- Coverage cannot be renewed

PRIALT® (ZICONOTIDE)

Length of Authorization:	1 Month
Initiative:	SPC: Neuropathic agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **severe chronic pain**

- Patient has had a failure or intolerance to intrathecal morphine; **AND**
- Patient does not have a pre-existing condition that would rent IT administration hazardous; **AND**
- Patient does not have a pre-existing history of psychosis (schizophrenia, schizoaffective, bipolar, manic, etc.); **AND**
- Patient does not have a presence of infection at the microinfusion injection site, uncontrolled bleeding diathesis, or spinal canal obstruction that impairs circulation of CSF.

CLINICAL CRITERIA FOR RENEWAL

Demonstrated pain relief based on physician assessment.

PROLEUKIN® (ALDESLEUKIN, IL-2)

Length of Authorization:	Coverage for RCC and melanoma is provided for 2 months and may be renewed Coverage for HSCT is provided for 4 months and may be renewed.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Renal Cell carcinoma:**

- Patient must be at least 18 years of age; **AND**
- Patient must have normal cardiac function (i.e., normal ejection fraction and unimpaired wall motion) as determined by thallium stress testing prior to initiating therapy; **AND**
- Patient must have normal pulmonary function determined by formal pulmonary function testing (i.e., FEV 1 > 2 liters or ≥ 75% of predicted for height and age) prior to initiating therapy; **AND**
- Patient must have a baseline serum creatinine of ≤ 1.5 mg/dL prior to initiating therapy; **AND**
- Pre-existing bacterial infections should be adequately treated prior to initiation of therapy; **AND**
- Patient has an ECOG performance status of 0-1; **AND**
- Proleukin will be administered in a hospital setting under close supervision of a qualified physician; **AND**
- Patient must not have an organ allograft; **AND**
- Patient must not have untreated or active CNS metastases; **AND**
- Patient has relapsed or metastatic disease; **AND**
- Used as a single agent; **AND**
- Used as first-line therapy; **AND**
- Patient has predominant clear cell histology

Diagnosis of **Melanoma:**

- Patient must be at least 18 years old; **AND**
- Patient must have normal cardiac function (i.e., normal ejection fraction and unimpaired wall motion) as determined by thallium stress testing prior to initiating therapy; **AND**
- Patient must have normal pulmonary function determined by formal pulmonary function testing (i.e., FEV 1 > 2 liters or ≥ 75% of predicted for height and age) prior to initiating therapy; **AND**
- Patient must have a baseline serum creatinine of ≤ 1.5 mg/dL prior to initiating therapy; **AND**
- Pre-existing bacterial infections should be adequately treated prior to initiation of therapy; **AND**
- Patient has an ECOG performance status of 0-1; **AND**
- Proleukin will be administered in a hospital setting under close supervision of a qualified physician; **AND**
- Patient must not have an organ allograft; **AND**
- Patient must not have untreated or active CNS metastases; **AND**
- Patient must have unresectable or metastatic disease; **AND**
- Used as a single agent: **AND**
  - Used as first line therapy ; **OR**
  - Used as subsequent therapy; **AND**
    - Patient has disease progression or used after maximum clinical benefit from BRAF targeted therapy; **AND**
    - Patient does not have inadequate organ reserves

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Hematopoietic Cell Transplantation:**

- Patient must be at least 18 years old; **AND**
- Patient must have normal cardiac function (i.e., normal ejection fraction and unimpaired wall motion) as determined by thallium stress testing prior to initiating therapy; **AND**
- Patient must have normal pulmonary function determined by formal pulmonary function testing (i.e., FEV 1 > 2 liters or ≥ 75% of predicted for height and age) prior to initiating therapy; **AND**
- Patient must have a baseline serum creatinine of ≤ 1.5 mg/dL prior to initiating therapy; **AND**
- Pre-existing bacterial infections should be adequately treated prior to initiation of therapy; **AND**
- Patient has an ECOG performance status of 0-1; **AND**
- Proleukin will be administered in a hospital setting under close supervision of a qualified physician; **AND**
- Patient must not have an organ allograft; **AND**
- Patient must not have untreated or active CNS metastases; **AND**
- Used for chronic graft-versus-host disease (GVHD) as additional therapy in conjunction with systemic corticosteroids following no response (steroid-refractory disease) to first-line therapy options

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include capillary leak syndrome (CLS), sustained ventricular tachycardia (≥ 5 beats), cardiac arrhythmias not controlled or unresponsive to management; chest pain with ECG changes, consistent with angina or myocardial infarction; cardiac tamponade, intubation for > 72 hours, renal failure requiring dialysis > 72 hours, coma or toxic psychosis lasting > 48 hours, repetitive or difficult to control seizures; bowel ischemia/perforation, GI bleeding requiring surgery, serious manifestations of eosinophilia, etc.; **AND**
- Patient must not have developed moderate to severe lethargy or somnolence

PROLIA® (DENOSUMAB)

Length of Authorization:	1 year- May be renewed
Initiative:	SPC: Osteoporosis Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Osteoporosis in Men and Women:**

- Patient must be supplementing with 1,000 mg of calcium and at least 400 IU of Vitamin D daily; **AND**
- Patient must be 18 years of age or older; **AND**
- Patient must not have hypocalcemia; **AND**
- Patient must be at a high risk of fracture; **AND**
- Pregnancy ruled out prior to starting therapy in women of child-bearing potential; **AND**
- Women only: Patient must be post-menopausal; **AND**
- Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
  - Hip/femur DXA (femoral neck or total hip) or lumbar spine T-score ≤-2.5 and/or forearm DXA 33% (one-third) radius; **OR**
  - T-score ≤-1 or low bone mass **and** a history of fragility fracture to the hip or spine; **OR**
  - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%; **AND**
- Documented treatment failure or ineffective response to a minimum 12-month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate; risedronate, ibandronate, or zoledronic acid; **OR**
- Patient has a documented contraindication* or intolerance to BOTH oral bisphosphonates **and** intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid

Diagnosis of **Glucocorticoid-Induced Osteoporosis**

- Patient must be supplementing with 1,000 mg of calcium and at least 400 IU of vitamin D daily; **AND**
- Patient is at least 18 years of age; **AND**
- Pregnancy ruled out prior to starting therapy in women of child-bearing potential; **AND**
- Patient must not have hypocalcemia; **AND**
- Patient must be at a high risk of fracture; **AND**
- Patient will be initiating or is continuing systemic glucocorticoid therapy at a daily dosage equivalent to ≥ 7.5 mg of prednisone and is expected to remain on glucocorticoid therapy for at least 6 months; **AND**
  - Documented treatment failure or ineffective response to a minimum 12-month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; **OR**
  - Patient has a documented contraindication or intolerance to BOTH oral bisphosphonates AND intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid

Diagnosis of **Osteoporosis treatment and prevention in prostate cancer patients:**

- Patient must be supplementing with 1,000 mg of calcium and at least 400 IU of Vitamin D daily; **AND**
- Patient must be 18 years of age or older; **AND**
- Patient must not have hypocalcemia; **AND**
- Patient must be at a high risk of fracture; **AND**
- Documented hip DXA (femoral neck or total hip) or lumbar spine T-score ≤-1 (or patient meets the diagnostic criteria for osteoporosis above); **AND**
- Patient must be receiving androgen deprivation therapy for non-metastatic prostate cancer

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Osteoporosis treatment and prevention in breast cancer patients:**

- Patient must be supplementing with 1,000mg of calcium and at least 400 IU of Vitamin D daily; **AND**
- Patient must be 18 years of age or older; **AND**
- Pregnancy ruled out prior to starting therapy in women of child-bearing potential; **AND**
- Patient must not have hypocalcemia; **AND**
- Patient must be at a high risk of fracture; **AND**
- Patient must be receiving adjuvant aromatase inhibitor therapy for breast cancer

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

- Ineffective response is defined as one or more of the following:
  - Decrease in T-score in comparison with baseline T-score from DXA scam
  - Patient has a new fracture while on bisphosphonate therapy
- High risk for fractures include, but are not limited to, one or more of the following:
  - History of an osteoporotic fracture as an adult
  - Parental history of hip fracture
  - Low BMI
  - Rheumatoid arthritis
  - Alcohol intake (3 or more drinks per day)
  - Current smoking
  - History of oral glucocorticoids ≥ 5 mg per day of prednisone for > 3 months (ever)
- Examples of contraindications to oral bisphosphonate therapy include the following:
  - Documented inability to sit or stand upright for at least 30 minutes
  - Documented pre-existing gastrointestinal disorder such as inability to swallow, Barrett's esophagus, esophageal stricture, dysmotility, or achalasia

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe symptomatic hypocalcemia, osteonecrosis of the jaw, atypical femoral fractures, dermatological adverse reactions, severe infection, severe hypersensitivity/anaphylaxis, musculoskeletal pain); **AND**
- Disease response as indicated by one or more of the following:
  - Absence of fractures
  - Increase in bone mineral density compared to pretreatment base
- **Osteoporosis in Men and Women ONLY**:
  - After 5 years of treatment, patient will have a repeat DXA performed; **AND**
    - Patients with low-to moderate risk disease will have therapy changed to an oral or IV bisphosphonate unless there is a contraindication or intolerance to both dosage forms

PROMACTA® (ELTROMBOPAG)

Length of Authorization:	3 Months, may be renewed Aplastic anemia: Use in first-line therapy is limited to a maximum of 6 months of treatment (i.e., may be renewed one time only) Chronic hepatitis C: use is limited to a maximum of 48 weeks of treatment (in combination with interferon)
Initiative:	SPC: Blood Modifiers (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic immune (idiopathic) thrombocytopenia (ITP)**

- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., romiplostim, avatrombopag, lusutrombopag, etc.) or fostamatinib; **AND**
- Laboratory values are current (i.e., drawn within the previous 28 days); **AND**
- Eltrombopag is not being used to attempt to normalize platelet count; **AND**
- Patient is age 1 or older; **AND**
- Patient has had chronic ITP for at least 6 months (or meets the corticosteroid requirement below); **AND**
- Patient has previously failed any of the following treatments for ITP:
  - Patient has failed previous therapy with corticosteroids (i.e., patient had no response to at least a 3-month trial or is corticosteroid-dependent); **OR**
  - Patient has failed previous therapy with immunoglobulins; **OR**
  - Patient has had splenectomy; **AND**
- The patient is at increased risk for bleeding as indicated by platelet count is less than 30 x 10^9/L (30,000/mm^3)

Diagnosis of **Chronic Hepatitis C-associated thrombocytopenia**

- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., romiplostim, avatrombopag, lusutrombopag, etc.) or fostamatinib; **AND**
- Laboratory values are current (i.e., drawn within the previous 28 days); **AND**
- Eltrombopag is not being used to attempt to normalize platelet count; **AND**
- Patient is 18 years of age or older; **AND**
- Patient will be initiating and/or continuing interferon-based therapy to treat chronic hepatitis C; **AND**
- Patient is diagnosed with thrombocytopenia as indicated by platelet count of less than 75 × 10^9/L (75,000/mm^3); **AND**
- The patient's degree of thrombocytopenia precludes administration of interferon-based therapy in the absence of eltrombopag

Note: safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Severe Aplastic Anemia**

- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., romiplostim, avatrombopag, lusutrombopag) or fostamatinib; **AND**
- Laboratory values are current (i.e., drawn within the previous 28 days); **AND**
- Eltrombopag is not being used to attempt to normalize platelet count; **AND**
- Patient is diagnosed with severe aplastic anemia; **AND**
- Patient has one of the following:
  - Patient has bone marrow (BM) cellularity < 25%; **OR**
  - Patient has bone marrow (BM) cellularity < 50% if < 30% of BM is hematopoietic cells; **AND**
- Patient has at least 2 of the following:
  - Peripheral blood neutrophil count < 0.5 x 10^9/L
  - Peripheral blood platelet count < 20 x 10^9/L
  - Peripheral blood reticulocyte count < 20 x 10^9/L; **AND**
- Used in one of the following treatment settings
  - Used in first-line therapy; **AND**
    - Patient aged 2 years or older: **AND**
    - Patient has not received prior immunosuppressive therapy with antithymocyte globulin (ATG), alemtuzumab, or high-dose cyclophosphamide; **AND**
    - Used in combination with standard immunosuppressive therapy (i.e., antithymocyte globulin (ATG) and cyclosporine); **OR**
  - Used in refractory disease; **AND**
    - Patient has had at least a 3-month trial and failed previous therapy with ONE immunosuppressive therapy such as antithymocyte globulin, cyclosporine, or cyclophosphamide

Diagnosis of **Myelodysplastic Syndromes (MDS)**

- Patient is 18 years of age or older; **AND**
- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., romiplostim, avatrombopag, lusutrombopag) or fostamatinib; **AND**
- Laboratory values are current (i.e., drawn within the previous 28 days); **AND**
- Eltrombopag is not being used to attempt to normalize platelet count; **AND**
- Patient has lower risk disease [i.e., IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very Low, Low, Intermediate)]; **AND**
- Patient has severe or refractory thrombocytopenia (i.e., platelet count < 30 x 10^9/L or higher with a history of bleeding); **AND**
- Patient progressed or had no response to hypomethylating agents (e.g., azacitidine, decitabine), immunosuppressive therapy, or clinical trial

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hepatic decompensation in patients with chronic hepatitis C, hepatotoxicity (abnormal liver enzymes), risk of progression of myelodysplastic syndromes to acute myelogenous leukemia, thrombotic/thromboembolic complications (blood clots), cataracts, etc; **AND**
- Platelet count (within the preceding 28 days) does not exceed 400 x 10^9/L; **AND**

ITP

- Disease response indicated by the achievement and maintenance of a platelet count of at least 50 × 10^9/L as necessary to reduce the risk for bleeding; **OR**

Chronic Hepatitis C-associated thrombocytopenia

- Patient has not exceeded 48 weeks of therapy in combination with interferon; **AND**
- Continued administration is necessary in order to continue to receive interferon

Aplastic Anemia:

- First-line therapy:
  - Patient has not received more than 6 months of treatment; **AND**
  - Disease response indicated by 2 or more of the following criteria on 2 consecutive serial blood count measurements at least one week apart:
    - Platelet count increases to 20 x 10^9/L
    - Hemoglobin greater than 10 g/dL
    - ANC increase greater than 0.5 x 10^9/L.
    - Reticulocyte count greater than 60,000/mcL
- Refractory disease: response indicated by one or more of the following criteria on 2 consecutive serial blood count measurements at least one week apart:
  - Platelet count increases to 20 x 10^9/L above baseline, or stable platelet counts with transfusion independence for a minimum of 8 weeks
  - Hemoglobin increase by greater than 1.5 g/dL, or a reduction in greater than or equal to 4 units of RBC transfusions for 8 consecutive weeks
  - ANC increase of 100% or an ANC increase greater than 0.5 x 10^9/L.
  - Reticulocyte count greater than 60,000/mcL

MDS

- Patient has not developed acute myeloid leukemia (AML); **AND**
- Disease response indicated by an increase in platelet count compared to pretreatment baseline, reduction in bleeding events, or reduction in platelet transfusion requirements

PROPROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE 9 INHIBITOR (PCSK9)

Length of Authorization:	Initial approval 3 months, Renewal-12months
Initiative:	SPC: PCSK9 (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

PRALUENT

Diagnosis of **Primary Hyperlipidemia/Heterozygous Familial Hypercholesterolemia (HeFH) and Prevention of Cardiovascular Events**

- Patient is 18 years or older; **AND**
- Patient is not on other concomitant PCSK9-inhibitors (e.g., evolocumab); **AND**
- Must be prescribed by, or in consultation with, a specialist in cardiology, lipidology, or endocrinology; **AND**
- Therapy will be used in conjunction with diet alone or in conjunction with other lipid-lowering therapies unless the patient is unable to tolerate (e.g., statins, ezetimibe); **AND**
- Patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) (i.e., myocardial infarction, non-hemorrhagic stroke, or peripheral arterial disease) or ASCVD risk; **AND**
  - Patient can be classified into **one** of the following risk factor groups:
    - Extremely high risk ASCVD (defined as extensive burden of or active ASCVD, or ASCVD with extremely high burden of adverse poorly controlled risk cardiometabolic risk factors including HeFH or severe hypercholesterolemia (SH) with untreated LDL-C ≥ 220 mg/dL) with LDL-C ≥ 70 mg/dL
    - Very high risk ASCVD (defined as less extensive ASCVD and poorly controlled cardiometabolic risk factors) with LDL-C ≥ 100 mg/dL
    - High risk ASCVD with LDL-C ≥ 130 mg/dL; **AND**
      - Less extensive ASCVD and well-controlled risk factors; **OR**
      - SH with untreated LDL-C ≥ 220 mg/dL with poorly controlled risk factors; **AND**
  - Prior treatment history with highest available dose or maximally-tolerated dose of high intensity HMG-CoA reductase inhibitors (i.e., 'statin' therapy: atorvastatin 40 mg or 80 mg daily, rosuvastatin 20 mg or 40 mg daily, or simvastatin 80 mg daily unless contraindicated; **AND**
  - Patient has failed to reach a target LDL-C despite physician attestation that the patient is adherent to maximally-tolerated doses of statins prior to the lipid panel demonstrating suboptimal reduction; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

PRALUENT *(CONTINUED)*

Diagnosis of **Primary Hyperlipidemia/Heterozygous Familial Hypercholesterolemia (HeFH) and Prevention of Cardiovascular Events *(Continued)***

- Patient has a diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) as confirmed by genotyping OR by patient having a first-degree relative similarly affected or with premature coronary vascular disease (CVD) or with positive genetic testing for an LDL-C raising gene defect (LDL receptor, apoB, or PCSK9); **AND**
  - Used as one of the following:
    - Patient is currently undergoing LDL apheresis therapy; **OR**
    - Patient has prior treatment history with highest available dose or maximally-tolerated dose* of high intensity HMG-CoA reductase inhibitors (i.e., 'statin' therapy: atorvastatin 40 mg or 80 mg daily, rosuvastatin 20 mg or 40 mg daily, or simvastatin 80 mg daily unless contraindicated; **AND**
  - Patient has failed to reach a target LDL-C despite physician attestation that the patient is adherent to maximally-tolerated doses of statins prior to the lipid panel demonstrating suboptimal reduction; **AND**
  - Used as one of the following:
    - For primary prevention (i.e., patients without ASCVD) and LDL-C ≥ 100 mg/dL; **OR**
    - For secondary prevention (i.e., patients with ASCVD) and LDL-C ≥ 70 mg/dL

Diagnosis of **Homozygous Familial Hypercholesterolemia (HoFH)**

- Patient is at least 18 years of age; **AND**
- Patient is not on other concomitant PCSK9-inhibitors (e.g., evolocumab); **AND**
- Must be prescribed by, or in consultation with, a specialist in cardiology, lipidology, or endocrinology; **AND**
- Patient has a confirmed diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) by any of the following:
  - Documented DNA test for functional mutation(s) in LDL receptor alleles or alleles known to affect LDL receptor functionality; **OR**
  - Untreated LDL-C > 500 mg/dL or treated LDL-C ≥ 300 mg/dL; **AND**
    - Cutaneous or tendon xanthoma before age 10 years; **OR**
    - Untreated LDL-C levels consistent with HeFH in both parents; **AND**
- Patient has been receiving a stable dose of statin therapy (e.g., atorvastatin, rosuvastatin, or simvastatin) for at least 4 weeks, unless there is a documented lack of efficacy, contraindication, or intolerance; **AND**
- Therapy will be used in conjunction with other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

REPATHA

Diagnosis of **Hyperlipidemia (including Heterozygous Familial Hypercholesterolemia [HeFH]) and Prevention of Cardiovascular Events**

- Patient is not on other concomitant PCSK9-inhibitors (i.e., alirocumab); **AND**
- Must be prescribed by, or in consultation with, a specialist in cardiology, lipidology, or endocrinology; **AND**
- Therapy will be used in conjunction with diet alone or in conjunction with other lipid-lowering therapies unless the patient is unable to tolerate (e.g., statins, ezetimibe); **AND**
- Patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) (i.e., myocardial infarction, non-hemorrhagic stroke, or peripheral arterial disease) or ASCVD risk; **AND**
  - Patient is 10 years of age or older; **AND**
  - Patient can be classified into **one** of the following risk factor groups:
    - Extremely high risk ASCVD (defined as extensive burden of or active ASCVD, or ASCVD with extremely high burden of adverse poorly controlled risk cardiometabolic risk factors including HeFH or severe hypercholesterolemia (SH) with untreated LDL-C ≥ 220 mg/dL) with LDL-C ≥ 70 mg/dL
    - Very high risk ASCVD (defined as less extensive ASCVD and poorly controlled cardiometabolic risk factors) with LDL-C ≥ 100 mg/dL
    - High risk ASCVD with LDL-C ≥ 130 mg/dL; **AND**
      - Less extensive ASCVD and well-controlled risk factors; **OR**
      - SH with untreated LDL-C ≥ 220 mg/dL with poorly controlled risk factors; **AND**
    - Patient has a prior treatment history with the highest available dose or maximally-tolerated dose* of high intensity HMG-CoA reductase inhibitors (i.e., "statin" therapy: atorvastatin 40 mg or 80 mg daily, rosuvastatin 20 mg or 40 mg daily, or simvastatin 80 mg daily), unless contraindicated; **AND**
    - Patient has failed to reach a target LDL-C despite physician attestation that the patient is adherent to maximally-tolerated doses of statins prior to the lipid panel demonstrating suboptimal reduction; **OR**
- Patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following:
  - Genotyping; **OR**
    - Patient has a first-degree relative similarly affected; **OR**
    - Patient has premature coronary vascular disease (CVD); **OR**
    - Patient has positive genetic testing for an LDL-C raising gene defect (LDL receptor, apoB, or PCSK9); **AND**
  - Patient is 10 years of age or older; **AND**
  - Patient has prior treatment history with highest available dose or maximally-tolerated dose of high intensity HMG-CoA reductase inhibitors (i.e., "statin" therapy: atorvastatin 40 mg or 80 mg daily, rosuvastatin 20 mg or 40 mg daily, or simvastatin 80 mg daily unless contraindicated; **AND**
  - Patient has failed to reach a target LDL-C despite physician attestation that the patient is adherent to maximally-tolerated doses of statins prior to the lipid panel demonstrating suboptimal reduction; **AND**
  - Used as one of the following:
    - For primary prevention (i.e., patients without ASCVD) and LDL-C ≥ 100 mg/dL; **OR**
    - For secondary prevention (i.e., patients with ASCVD) and LDL-C ≥ 70 mg/dL

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

REPATHA *(CONTINUED)*

Diagnosis of **Homozygous Familial Hypercholesterolemia (HoFH)**.

- Patient is 10 years old or older; **AND**
- Patient is not on other concomitant PCSK9-inhibitor (i.e., alirocumab) therapy; **AND**
- Patient is not on combination therapy with a microsomal triglyceride transfer protein (MTP) inhibitor (i.e., lomitapide); **AND**
- Must be prescribed by, or in consultation with, a specialist in cardiology, lipidology, or endocrinology; **AND**
- Patient has a confirmed diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) by any of the following:
  - Documented DNA test for functional mutation(s) in LDL receptor alleles or alleles known to affect LDL receptor functionality; **OR**
  - Untreated LDL-C > 500 mg/dL or treated LDL-C ≥ 300 mg/dL; **AND**
    - Cutaneous or tendon xanthoma before age 10 years; **OR**
    - Untreated LDL-C levels consistent with HeFH in both parents; **AND**
- Patient has been receiving stable lipid lowering therapy for at least 4 weeks; **AND**
- Therapy will be used in conjunction with diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis)

CLINICAL CRITERIA FOR RENEWAL (MAY BE REQUESTED BY PRIMARY CARE PROVIDER)

- Absence of unacceptable toxicity from therapy (e.g., severe hypersensitivity); **AND**
- Physician attests that patient has had a reduction in LDL-C when compared to the baseline labs (prior to initiating alirocumab or evolocumab); **AND**
- Patient continues to adhere to diet and/or lipid lowering therapy established prior to the original approval of the requested medication; **AND**
- For Praluent® (**Primary Hyperlipidemia/Heterozygous Familial Hypercholesterolemia (HeFH) and Prevention of Cardiovascular Events)**: Dose escalation (up to the maximum dose and frequency specified below)- requests based on clinical and laboratory parameters being interpreted as an unsatisfactory response are defined as at least **one** of the following:
  - Patient has failed to achieve an LDL-C goal of < 100 mg/dL (or non-HDL-C < 130 mg/dL) if HeFH without ASCVD
  - Patient has failed to achieve an LDL-C goal of < 70 mg/dL (or non-HDL-C < 100 mg/dL) if ASCVD or HeFH with ASCVD
- For **Repatha Homozygous Familial Hypercholesterolemia (HoFH)**
  - Dose escalation (up to the maximum dose and frequency specified below):
    - Requests based on clinical and laboratory parameters being interpreted as an unsatisfactory response are defined as at least **one** of the following:
      - Patient has a serum-free PCSK9 level of ≥ 100 ng/mL
      - Patient has < 5% reduction in LDL-C from baseline

PROVENGE® (SIPULEUCEL-T/ LACTATED RINGERS)

Length of Authorization:	3 Doses only
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Prostate Cancer:**

- Patient has castration-recurrent metastatic disease; **AND**
- Patient has an ECOG Performance status of 0–1; **AND**
- Patient has no hepatic metastases; **AND**
- Must not be used in combination with chemotherapy; **AND**
- Patient is asymptomatic or minimally symptomatic; **AND**
- Patient's life expectancy is estimated to be greater than 6 months; **AND**
- Patient has not previously received therapy with sipuleucel-T

CLINICAL CRITERIA FOR RENEWAL

- Coverage cannot be renewed

PULMONARY ARTERIAL HYPERTENSION AGENTS

Length of Authorization:	Initial: 1 year, Renewal 2 years
Initiative:	SPC: Pulmonary Hypertension (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Pulmonary Arterial Hypertension (PAH)**

- Patient is at least 18 years old (≥ 17 for Remodulin® or ≥ 3 for Tracleer®); **AND**
  Note: Clinical review for use in pediatric patients, unless specified above, will occur on a case-by-case basis
- Patients of reproductive potential have had a negative pregnancy test prior to start of therapy (Opsumit®, Letairis®, Tracleer®, and Adempas® **only**); **AND**
- Both patient and prescriber are enrolled in the manufacturer's Risk Evaluation and Mitigation Strategy (REMS) program (Opsumit®, Letairis®, Tracleer®, and Adempas® **only**); **AND**
- Diagnosis confirmed by documented right heart catheterization with **all** the following:
  - Mean pulmonary artery pressure (mPAP) > 20 mm Hg; **AND**
  - Pulmonary arterial wedge pressure (PAWP) ≤ 15 mm Hg; **AND**
  - Pulmonary vascular resistance (PVR) ≥ 3 Wood units (240 dynes/sec/cm^5); **AND**
- Baseline assessment of 6-minute walk distance (6MWD) and/or B-type natriuretic peptide plasma levels (NT-proBNP); **AND**
- Patient does not have any of the following:
  - Patient will **not** receive concomitant treatment with organic nitrates (i.e., isosorbide mononitrate, isosorbide dinitrate, nitroglycerin) or riociguat (for Revatio®, Adcirca®, and Adempas® **only**); **AND**
  - Patient is **not** receiving concurrent treatment with riociguat (Revatio® intravenous [IV] **only**); **AND**
  - Patient does not have pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP) (**Adempas® only**); **AND**
  - Patient does not have heart failure with reduced left ventricular ejection fraction (**Flolan® only)**
  - Patient does not have congestive heart failure due to severe left ventricular systolic dysfunction **or** pulmonary edema (**Veletri® only**); **AND**
  - Patient will **not** receive concomitant treatment with strong CYP2C8 inhibitors (e.g., gemfibrozil) **(Uptravi® ONLY)**; **AND**
- Diagnosed with pulmonary arterial hypertension and classified as World Health Organization (WHO) Group 1 (See below for description of WHO classification for pulmonary hypertension); **AND**
- Pediatric patients are diagnosed with idiopathic or congenital pulmonary arterial hypertension (**Tracleer® only**); **AND**
- Designated as New York Heart Association (NYHA) or WHO functional class II-IV (See below for description of functional classes):
- Patient is treatment-naïve to PAH-specific pharmacotherapy §; **AND**
  - Patient is Functional Class II or Functional Class III without evidence of rapid disease progression or poor prognosis; **AND**
    - Patient had an inadequate response to calcium channel blocker therapy or is not a candidate for treatment with a calcium channel blocker (i.e., negative results for acute vasoreactivity, right ventricular failure, or contraindication to calcium channel blocker); **AND**
      - Patient will be treated with a combination of Letairis® and Adcirca®; **OR**
      - Patient is unwilling or unable to tolerate combination therapy; **AND**
        - Patient will be treated with Revatio® monotherapy; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Pulmonary Arterial Hypertension (PAH)** ***(Continued)***

- Patient is unwilling or unable to tolerate combination therapy and will receive monotherapy with an endothelial-receptor antagonist (ERA) **§**, phosphodiesterase-5 inhibitor (PDE5i) **§**, or Adempas®; **OR**
- Patient is Functional Class III with evidence of rapid progression of their disease, or other markers of a poor clinical prognosis; **AND**
  - Patient will be treated with continuous intravenous (IV) Flolan® or Veletri®; **OR**
  - Patient will be treated with IV or subcutaneous (SC) Remodulin®; **OR**
- Patient is Functional Class IV; **AND**
  - Patient will be treated with continuous IV Flolan®, or Veletri®; **OR**
  - Patient will be treated with IV or SC Remodulin®; **OR**
  - Patient is unwilling or unable to manage intravenous or subcutaneous prostacyclin analog therapy **§**; **AND**
  - Patient will be treated with an inhaled prostacyclin analog in combination with an oral PDE5i and an ERA **§**; **OR**

- Patient is Functional Class III or IV and had an inadequate clinical response (see criteria below) to monotherapy and will be adding a second class of PAH therapy as one of the following (see PAH pharmacotherapy table below)
  - Adding Revatio® to an intravenous epoprostenol; **OR**
  - Initiating an up-titration of the patient's current dose of IV Flolan® or Veletri®; **OR**
  - Adding an inhaled prostacyclin analog to an ERA or a PDE5i; **OR**
  - Adding Revatio® to an intravenous epoprostenol; **OR**
  - Adding Adempas to Tracleer®, Letairis®, or an inhaled prostacyclin analog; **OR**
  - Adding Opsumit® to a PDE5i or an inhaled prostacyclin analog; **OR**
- Patient is Functional Class III or IV with an inadequate clinical response (see criteria below) to two classes of PAH pharmacotherapy and will be adding a third class of PAH therapy (see PAH pharmacotherapy table below **§**;); **OR**
- Patient is currently on Letairis® with stable or symptomatic disease and will add Adcirca®; **OR**
- Patient is transitioning from Remodulin® to Orenitram® and using Remodulin® (treprostinil) and Orenitram® (treprostinil) concurrently; **OR**
- Patient is transitioning from epoprostenol to Remodulin® (treprostinil); **OR**
- Patient is temporarily unable to take oral Uptravi® therapy (for IV Uptravi®)

Pulmonary Hypertension Pharmacotherapy §		
Class	**Drug**	**Route of Administration**
Phosphodiesterase-5 inhibitors (PDE5i)	Revatio® (sildenafil) Adcirca® (tadalafil)	IV, Oral Oral
Prostacyclin analogs	Flolan®, Veletri® (epoprostenol) Orenitram®, Remodulin®, Tyvaso® (treprostinil) Ventavis® (iloprost)	IV Oral, IV/SC, Inhaled Inhaled
Endothelial-receptor antagonists (ERA)	Tracleer® (bosentan) Letairis® (ambrisentan) Opsumit® (macitentan)	Oral Oral Oral

Pulmonary Hypertension Pharmacotherapy §		
Class	**Drug**	**Route of Administration**
Soluble guanylate cyclase stimulators	Adempas® (riociguat) Must **not** be used in combination with PDE5i (e.g., Revatio®, Adcirca®) or intravenous prostacyclin analogs (e.g., Flolan®, Veletri®, Remodulin®) **Subcutaneous administration of Remodulin® is allowable with Adempas®**	Oral
Prostacyclin receptor agonists	Uptravi® (selexipag)	Oral

ADEMPAS®

Diagnosis of **Pulmonary Arterial Hypertension (PAH)**

- Follow criteria above

Diagnosis of **Chronic-Thromboembolic Pulmonary Hypertension (Adempas® only)**

- Patient is at least 18 years old; **AND**
- Patients of reproductive potential have had a negative pregnancy test prior to start of therapy; **AND**
- Both patient and prescriber are enrolled in the manufacturer's REMS program; **AND**
- Baseline 6-minute walk test (6MWD) performed; **AND**
- Patient is **not** concurrently on organic nitrates (e.g., isosorbide mononitrate, isosorbide dinitrate, nitroglycerin); **AND**
- Must not be used in combination with phosphodiesterase-5 inhibitors (PDE5i), prostacyclin analogs, or endothelial-receptor antagonists (ERAs); **AND**
- Patient does not have pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP); **AND**
- Patient does not have left heart disease or lung disease (e.g., COPD, interstitial lung disease, combined pulmonary fibrosis and emphysema [CPFE]); **AND**
- Diagnosis of chronic pulmonary thromboembolic hypertension (CTEPH) confirmed after at least 3 months of effective anticoagulation with **all** the following:
  - Mean pulmonary arterial pressure (mPAP) ≥ 25 mm Hg
  - Pulmonary arterial wedge pressure (PAWP) ≤ 15 mm Hg
  - Mismatch perfusion defects and/or specific diagnostic signs for CTEPH as seen on at least two of the following imaging methods: ventilation–perfusion (V/Q) scanning, pulmonary angiography, spiral computed tomography, or magnetic resonance angiography; **AND**
- Diagnosed with CTEPH and classified as WHO Group 4 (See below for description of WHO classification for pulmonary hypertension); **AND**
  - Patient is inoperable for surgery (i.e., pulmonary thromboendarterectomy); **AND**
    - Patient's pulmonary vascular resistance (PVR) > 300 dynes/sec/cm^5 measured at least 90 days after the start of full anticoagulation; **OR**
  - Patient has recurrent or persisting pulmonary hypertension with pulmonary vascular resistance (PVR) > 300 dynes/sec/cm^5 measured at least 180 days following pulmonary thromboendarterectomy.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

TYVASO®

Diagnosis of **Pulmonary Arterial Hypertension (PAH)**

- Follow criteria above

Diagnosis of **Pulmonary Hypertension Associated with Interstitial Lung Disease (PH-ILD) (Tyvaso only)**

- Patient is at least 18 years old; **AND**
- Patient diagnosed with pulmonary hypertension and classified as WHO Group 3 (See below for description of WHO classification for pulmonary hypertension); **AND**
- Diagnosis confirmed by documented right heart catheterization with **all** the following:
  - Mean pulmonary arterial pressure (mPAP) > 20 mmHg; **AND**
  - Pulmonary arterial wedge pressure (PAWP) ≤ 15 mmHg; **AND**
  - Pulmonary vascular resistance (PVR) ≥ 3 wood units (240 dynes-sec/cm^5); **AND**
- Baseline assessment of 6-minute walk distance (6MWD) and/or B-type natriuretic peptide plasma levels (NT-proBNP)

Inadequate Clinical Response Criteria
Inadequate clinical response for patients who were initially in WHO Functional Class II or III: • Resulting clinical status defined as stable and not satisfactory; **OR** • Resulting clinical status defined as unstable and deteriorating Inadequate clinical response for patients who were initially in WHO Functional Class IV: • No rapid improvement to WHO Functional Class III or better; **OR** • Resulting clinical status defined as stable and not satisfactory
Reference charts
WHO classification of pulmonary hypertension (PH): • Group 1 PAH: Pulmonary arterial hypertension (PAH) • Group 2 PH: Pulmonary hypertension owing to left heart disease • Group 3 PH: Pulmonary hypertension owing to lung diseases and/or hypoxia • Group 4 PH: Chronic thromboembolic pulmonary hypertension (CTEPH) • Group 5 PH: Pulmonary hypertension with unclear multifactorial mechanisms **NYHA Functional Classification:** • Class I: No symptoms with ordinary physical activity. • Class II: Symptoms with ordinary activity. Slight limitation of activity. • Class III: Symptoms with less than ordinary activity. Marked limitation of activity. • Class IV: Symptoms with any activity or even at rest. **WHO Functional Assessment Classification:** • Class I: Patients with PH but without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope. • Class II: Patients with PH resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope. • Class III: Patients with PH resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope. • Class IV: Patients with PH with inability to carry out any physical activity without symptoms. These patients manifest signs of right-heart failure. Dyspnea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

CLINICAL CRITERIA FOR RENEWAL

- Disease response as determined by one or more of the following:
  - Progress towards an improvement in WHO functional class status
  - Improvement in right ventricular function (based on echocardiogram or cardiac MRI)
  - Improvement (from baseline) on the 6-minute walk distance (6MWD)
  - Improvement in B-type natriuretic peptide plasma levels (NT-proBNP)
  - Increase in time to first clinical worsening event (e.g., hospitalization due to worsening of disease) (**Orenitram® and Tyvaso® ONLY**); **AND**
- Absence of unacceptable toxicity from the drug.

REVATIO® AND ADCIRCA®

- Absence of unacceptable toxicity from the drug (e.g., pulmonary edema, worsening of pulmonary veno-occlusive disease [PVOD], hearing loss, visual loss, hypotension; epistaxis; priapism)

FLOLAN®, VELETRI®

- Absence of unacceptable toxicity from the drug (e.g., anticoagulation abnormalities/risk of bleeding, pulmonary edema, vasodilation reactions [hypotension, flushing, nausea, vomiting, dizziness, or headache])

ORENITRAM®

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: worsening PAH symptoms after abrupt discontinuation or large dose reductions and potential for tablets getting lodged in the diverticulum in patients with diverticulosis

REMODULIN®

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include catheter-blood stream infections (BSIs), sepsis, symptomatic hypotension, anticoagulation abnormalities/risk of bleeding, etc.

TYVASO®

- Absence of unacceptable toxicity from the drug (e.g., symptomatic hypotension; anticoagulation abnormalities [bleeding])

VENTAVIS®

- Absence of unacceptable toxicity from the drug (e.g., hypotension [systolic BP < 85 mm Hg]; pulmonary edema)

TRACLEER®, LETAIRIS™, AND OPSUMIT®

- Absence of unacceptable toxicity from the drug (e.g., hepatic impairment; fluid retention; pulmonary edema/pulmonary veno-occlusive disease [PVOD]; decreased hemoglobin and hematocrit)

ADEMPAS

- Absence of unacceptable toxicity from the drug (e.g., symptomatic hypotension, bleeding, and pulmonary edema/pulmonary veno-occlusive disease [PVOD])

UPTRAVI

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include pulmonary edema/pulmonary veno-occlusive disease (PVOD), etc.

PULMONARY FIBROSIS

Length of Authorization:	Esbriet: 6 months; may be renewed every 6 months thereafter. Ofev: 6 months; may be renewed every 6 months thereafter
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Idiopathic Pulmonary Fibrosis (IPF)**

- Patient is at least 18 years old; **AND**
- Therapy will not be used in combination with other disease modifying drug therapy (e.g., nintedanib); **AND**
- Confirmation that the patient will NOT smoke while on therapy; **AND**
- For Esbriet:
  - Patient will avoid concomitant therapy with any of the following:
    - Coadministration with strong or moderate CYP1A2 inhibitors (e.g., fluvoxamine, ciprofloxacin, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
    - Coadministration with moderate or strong CYP1A2 inhibitors and one or more other CYP isoenzymes involved in the metabolism of pirfenidone (i.e., CYP2C9, 2C19, 2D6, and 2E1); **AND**
    - Coadministration with CYP1A2 inducers (e.g., montelukast, phenytoin, omeprazole, etc.); **AND**
- For Ofev:
  - Patient will avoid coadministration with P-gp and CYP3A4 inhibitors (e.g., ketoconazole, erythromycin, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Patient will avoid coadministration with P-gp and CYP3A4 inducers (e.g., rifampicin, carbamazepine, phenytoin, St. John's wort, etc.); **AND**
- Other known causes of the patient's interstitial lung disease have been ruled out (e.g., domestic and occupational environmental exposures, connective tissue disease, and drug toxicity); **AND**
- Patient has a confirmed diagnosis of IPF by surgical lung biopsy and/or high-resolution computed tomography (HRCT); **AND**
- Baseline percent forced vital capacity (%FVC) is between 50-80%; **AND**
- Baseline percent predicted diffusing capacity of the lungs for carbon monoxide (%DL_{CO}, corrected for hemoglobin) ≥ 30%
- For Esbriet: Patient does not have severe (Child Pugh C) hepatic impairment
- For Esbriet: Patient does not have end stage renal disease requiring dialysis
- For Ofev: Patient does not have moderate (Child Pugh B) or more severe hepatic impairment; **AND**
- For Ofev: Negative pregnancy test for women of child-bearing potential

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Systemic Sclerosis-Associated Interstitial Lung disease (SSc-ILD) – OFEV**

- Patient is 18 years or older; **AND**
- Therapy will not be used be used in combination with other disease modifying drug therapy (e.g., Esbriet); **AND**
- Confirmation the patient will **not** smoke while on therapy; **AND**
- Negative pregnancy test for women of child-bearing potential; **AND**
- Patient will avoid coadministration with P-gp and CYP3A4 inhibitors (e.g., ketoconazole, erythromycin, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid coadministration with P-gp and CYP3A4 inducers (e.g., rifampicin, carbamazepine, phenytoin, St. John's wort, etc.); **AND**
- Patient does not have moderate (Child Pugh B) or more severe hepatic impairment; **AND**
- Patient has a confirmed diagnosis of systemic sclerosis with an American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) classification criteria score ≥ 9; **AND**
- Patient has ≥ 10% fibrosis on a chest high resolution computed tomography (HRCT) scan conducted within the previous 12 months; **AND**
- Onset of disease (first non-Raynaud symptom) of less than 7 years; **AND**
- Baseline percent forced vital capacity (%FVC) ≥ 40%; **AND**
- Baseline percent predicted diffusing capacity of the lungs for carbon monoxide (%DL_{CO}, corrected for hemoglobin) 30-89%; **AND**
- Patient has worsening disease despite use of low-dose corticosteroids (i.e., prednisone ≤ 10 mg/day) and/or stable doses of immunosuppressant therapy (i.e., mycophenolate, methotrexate, etc.)

Diagnosis of **Chronic Fibrosing Interstitial Lung Disease with a Progressive Phenotype – OFEV**

- Patient is 18 years or older; **AND**
- Therapy will not be used be used in combination with other disease modifying drug therapy (e.g., Esbriet); **AND**
- Confirmation the patient will **not** smoke while on therapy; **AND**
- Negative pregnancy test for women of child-bearing potential; **AND**
- Patient will avoid coadministration with P-gp and CYP3A4 inhibitors (e.g., ketoconazole, erythromycin, etc.). If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid coadministration with P-gp and CYP3A4 inducers (e.g., rifampicin, carbamazepine, phenytoin, St. John's wort, etc.); **AND**
- Patient does not have moderate (Child-Pugh B) or more severe hepatic impairment; **AND**
- Patient has a confirmed diagnosis of Progressive Fibrosing Interstitial Lung Disease (PF-ILD) by high resolution computed tomography (HRCT) showing either usual interstitial pneumonia (UIP)-like HRCT pattern or other HRCT fibrotic patterns; **AND**
- Patient has > 10% fibrosis on a chest high resolution computed tomography (HRCT) scan conducted within the previous 12 months; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient has at least one of the following clinical signs of disease progression in the 24 months prior to screening for the disease:
  - FVC decline ≥ 10%
  - FVC decline ≥ 5% and < 10% with worsening symptoms or imaging
  - Worsening symptoms and worsening imaging; **AND**
- Baseline percent forced vital capacity (%FVC) ≥ 45%; **AND**
- Baseline percent predicted diffusing capacity of the lungs for carbon monoxide (%DL_{CO}, corrected for hemoglobin) of 30% to less than 80%; **AND**
- Patient has worsening disease despite use of standard therapy for chronic fibrosing ILD with progressive phenotype (i.e. corticosteroids, immunosuppressants)

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

- Patient continues to meet criteria above; **AND**
- Patient has been adherent to therapy; **AND**
- Absence of unacceptable toxicity from the drug (e.g., elevated liver enzymes [ALT, AST, and bilirubin], drug-induced liver injury, severe gastrointestinal disorders [i.e., severe attacks of nausea, vomiting, diarrhea], gastrointestinal perforation, arterial thromboembolic events, severe bleeding)

Idiopathic Pulmonary Fibrosis

- Disease response to therapy including, but not limited to, one or more of the following:
  - Reduction in the rate of decline in forced vital capacity (%FVC) compared to pre-treatment baseline
  - Improvement or delay in time to acute IPF exacerbation compared to pre-treatment baseline
  - Patient does not have evidence of disease progression defined as an absolute decline of 10% or more in predicted FVC within any 12-month period

Systemic Sclerosis Associated with Interstitial Lung Disease

- Disease response as indicated by a reduction in the rate of decline in forced vital capacity (%FVC) compared to pre-treatment baseline

Chronic Fibrosing Interstitial Lung Disease with a Progressive Phenotype

- Disease response as indicated by a reduction in the rate of decline in forced vital capacity (%FVC) compared to pre-treatment baseline

PULMOZYME® (DORNASE ALFA)

Length of Authorization:	1 year, may be renewed
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cystic fibrosis (CF)**

- Patient is at least 3 months of age; **AND**
- Patient has baseline forced vital capacity (FVC) ≥ 40% predicted; **AND**
- Patient will receive treatment in conjunction with standard cystic fibrosis therapies, such as oral, inhaled and/or parenteral antibiotics (e.g., tobramycin, aztreonam, azithromycin); chest physiotherapy; cystic fibrosis transmembrane conductance regulator (CFTR) potentiators (e.g., lumacaftor/ivacaftor, ivacaftor); bronchodilators (e.g., albuterol solution/HFA, pirbuterol MDI, levalbuterol solution/HFA); enzyme supplements (e.g., pancrelipase); vitamins; analgesics or anti-inflammatory therapy (e.g., ibuprofen, oral or inhaled corticosteroids)

CLINICAL CRITERIA FOR RENEWAL

- Disease response as indicated by a significant decrease in respiratory tract infection, improved pulmonary function, etc.; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hypersensitivity allergic reaction, etc..

QBREXZA® (GLYCOPYRRONIUM TOSYLATE)

Length of Authorization:	Initial: 3 months, Renewal: 12 months
Initiative:	MNC: Miscellaneous PA required (IE 2462/ 75 NCPDP)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient age is 9 years of age or older; **AND**
- Prescribed by, or in consultation with, a dermatologist; **AND**
- Patient has documented diagnosis of primary axillary hyperhidrosis; **AND**
- Hyperhidrosis Disease Severity Scale (HDSS) grade of 3 or 4; **AND**
- Documented that diagnosis negatively impacts activities of daily living (e.g., household chores, performance at school/work); **AND**
- Not be diagnosed with a medical condition exacerbated by the anticholinergic effects (e.g., glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, or Sjögren's syndrome); **AND**
- Not be taking any additional anticholinergic medications; **AND**
- All other causes of secondary hyperhidrosis must be ruled out (e.g., exposure to excessive heat, systemic diseases [e.g., cancer], spinal cord injury, medications).

CLINICAL CRITERIA FOR RENEWAL

Patients must:

- Report at least 1-point reduction in sweating severity using the Hyperhidrosis Disease Severity Scale (HDSS); **AND**
- No documented dysregulation of temperature control; **AND**
- Not be taking any additional anticholinergic medications; **AND**
- Not have any new diagnosis with a medical condition exacerbated by the anticholinergic effects (e.g., glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, or Sjögren's syndrome).

QINLOCK™ (RIPRETINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is 18 years or older; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong CYP3A inhibitors (e.g., fluconazole, itraconazole), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with moderate CYP3A inducers (e.g., bosentan, efavirenz, etravirine), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient's left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will have a dermatologic evaluation prior to initiating therapy and routinely during treatment; **AND**
- Patient does not have uncontrolled hypertension; **AND**
- Patient must not have had a surgical procedure within the preceding 14 days or have a surgical wound that has not fully healed; **AND**
- Patient does not have active CNS metastases**; AND**
- Patient has unresectable, recurrent, locally advanced, or metastatic disease; **AND**
- Patient's disease progressed after an adequate trial or intolerance to three or more prior therapies (e.g., imatinib, sunitinib, regorafenib), with one being imatinib

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: palmar-plantar erythrodysesthesia syndrome (≥ grade 3), new primary cutaneous malignancies (**Note**: suspicious skin lesions are managed with excision and dermato-pathologic evaluation with continuation of Qinlock® therapy), uncontrolled hypertension (≥ grade 4), severe arthralgia or myalgia, impaired wound healing and complications, left-ventricular systolic dysfunction (grade 3 or 4), etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

QUADRAMET® (SAMARIUM SM 153 LEXIDRONAM)

Length of Authorization:	1 treatment course and may be renewed, one-time only, after 60 days
Initiative:	SPC: Miscellaneous PA required (IE 2462/ 75 NCPDP)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Pain related to metastatic bone lesions**

- Patient is at least 16 years old; **AND**
- Women of child-bearing age must have a negative pregnancy test; **AND**
- Lactating women should discontinue breast feeding at least 6 weeks prior to administration; **AND**
- Patient will not use in combination with or has not had a treatment course of strontium-89 chloride within the previous 90 days; **AND**
- Patient has not had a treatment course of samarium-sm-153 lexidronam within the previous 60 days; **AND**
- Patients of reproductive potential will use effective contraception during treatment with therapy and for at least six months after the last dose; **AND**
- Patient does not have significant bone marrow suppression (e.g., neutropenia, leukopenia, thrombocytopenia); **AND**
- Patient does not have disseminated intravascular coagulation; **AND**
- Used for palliative treatment of metastatic skeletal bone pain; **AND**
- Patient has had a positive (enhancement) radionuclide bone scan confirming osteoblastic metastatic bone lesions; **AND**
- Therapy will not be used for spinal cord compression pain; **AND**
- Patient has failed other conventional treatments for bone pain due to skeletal metastases (e.g., chemotherapy, hormonal therapy, external beam radiation, opioid analgesics); **AND**
- Patient has a life-expectancy of at least 6 months

Diagnosis of **Osteosarcoma**

- Patient is at least 16 years old; **AND**
- Women of child-bearing age must have a negative pregnancy test; **AND**
- Lactating women should discontinue breast feeding at least 6 weeks prior to administration; **AND**
- Patient will not use in combination with or has not had a treatment course of strontium-89 chloride within the previous 90 days; **AND**
- Patient has not had a treatment course of samarium-sm-153 lexidronam within the previous 60 days; **AND**
- Patients of reproductive potential will use effective contraception during treatment with therapy and for at least six months after the last dose; **AND**
- Patient does not have significant bone marrow suppression (e.g., neutropenia, leukopenia, thrombocytopenia); **AND**
- Patient does not have disseminated intravascular coagulation; **AND**
- Used for recurrent or refractory disease beyond second-line therapy

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe leukopenia, severe thrombocytopenia, severe neutropenia, etc.; **AND**
- Patient has experienced hematological recovery since administration of the initial dose; **AND**

Pain related to metastatic bone lesions

- Patient had an inadequate response or recurrence of bone pain after the initial dose

Osteosarcoma

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

QUANTITY LIMITS

Length of Authorization:	See specific criteria below
Initiative FirstRx:	MNC: quantity limit per day exceeded (15110) MNC: quantity limit: IE 7001 (IE 7001 / NCPDP 76)
Initiative DST:	MNC: Quantity Limit Exception (IE 145)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- **Technicians:**
  - **PPI TWICE DAILY THERAPY:**
    - Diagnosis of Helicobacter Pylori (H. Pylori)
      - Approve BID dosing for 1 month
    - Diagnosis of gastrointestinal bleeding (GI bleed) or hemorrhagic gastritis
      - Approve BID dosing for up to 1 year
    - ANY OTHER Diagnosis
      - Patient has failed at least a 30-day trial of once daily PPI therapy (check fax, ask caller, review claims for previous trials, previous PA notes if available)
      - **Note**: If trial length is less than 30 days, call the pharmacists' line for consult before escalating or faxing back
      - Approve 6 months initial; 1 year for renewals.
    - If any of the above criteria have not been met, escalate to the Pharmacist for further review.
    - Note: some medications may need to meet step therapy with another PPI due to their status on the formulary (e.g., Dexilant). That will need to be reviewed along with the quantity limit criteria.
  - **TITRATION**
    - A gradual **increase** to desired effective dose for a patient
    - Must not exceed FDA max daily dose
    - **Approve for 1 month**
    - Note: If titration period extends beyond 1 month, call the pharmacists' line for a consult. Pharmacist may approve an extension of more than one month.
  - **TAPERING**
    - A gradual **decrease** to reduce the daily dose for a patient
    - Must not exceed FDA max daily dose
    - **Approve for 1 month**
    - Note: If the taper extends more than a month, call the pharmacists' line and to consult whether an extension of the taper can be made.
  - **DOSE ALTERNATING SCHEDULE**
    - The use of varying doses or strengths on alternating days
    - Must not exceed FDA max daily dose
    - **Approve for 1 year**
    - Note: call the pharmacists' line for a consult if it looks like a challenging dose schedule
  - **ALL OTHER QUANTITY LIMIT REJECTS (REFERENCE TABLE BELOW)**
    - If the requested dose does not exceed the FDA max dose; **AND**
    - Reject Code is **15110 or 145 (DST)**
    - **Approve for 1 year**

*If above criteria are not met, escalate to MAP-Pharmacist queue for further review

QUANTITY LIMITS (CONTINUED)

Please use the table below to locate medications and their associated max daily dose

***The table below includes several medications for reference but is not all inclusive**

Drug	HICL	FDA Max Dose	How Supplied
Amlodipine	006494	10 mg/day	2.5 mg, 5 mg, 10 mg tablet
Citalopram	010321	40 mg/day	10 mg, 20 mg, 40 mg tablet; 10 mg/5 mL and 20 mg/10 mL sol
Desvenlafaxine ER	035420	400 mg/day	25 mg, 50 mg, 100 mg extended release tablet
Duloxetine	026521	120 mg/day	20 mg, 30 mg, 40 mg, 60 mg delayed release capsule
Escitalopram	024022	20 mg/day	5 mg, 10 mg, 20 mg tablet; 5 mg/5 mL, 10 mg/10 mL oral solution
Fluoxetine	001655	80 mg/day	10 mg, 20 mg, 40 mg capsule; 10 mg, 20 mg, 60 mg tablet; 20 mg/5 mL sol
Lisinopril	000132	80 mg/day	2.5 mg, 5 mg, 10 mg, 20 mg, 30 mg, 40 mg
Mirtazapine	011505	45 mg/day	7.5 mg, 15 mg, 30 mg, 45 mg tablet
Modafinil	010865	400 mg/day	100 mg, 200 mg tablet
Nifedipine ER	000181	90 mg/day	30 mg, 60 mg, 90 mg ER capsules and tablets
Paroxetine	007344	60 mg/day	10 mg, 20 mg, 30 mg, 40 mg tablet; 12.5 mg, 25 mg, 37.5 mg CR tablet; 10 mg/5 mL solution
Pravastatin	006227	80 mg/day	10 mg, 20 mg, 40 mg, 80 mg
Quetiapine	014015	800 mg/day	25 mg, 50 mg, 100 mg, 200 mg, 300 mg, 400 mg IR tablet; 50 mg, 150 mg, 200 mg, 300 mg, 400 mg ER tablet
Sertraline	006324	200 mg/day	25 mg, 50 mg, 100 mg tablets; 20 mg/mL solution
Venlafaxine ER	008847	225 mg/day	37.5 mg, 75 mg, 150 mg ER capsule; 37.5 mg, 75 mg, 150 mg, 225 mg ER tablet
Verapamil ER/SR	000180	480 mg/day	100 mg, 120 mg, 180 mg, 200 mg, 240 mg, 200 mg, 360 mg ER capsules; 120 mg, 180 mg, 240 mg ER tablets
Viibryd	037597	40 mg/day	10 mg, 20 mg, 40 mg tablet
Ziprasidone	021974	160 mg/day	20 mg, 40 mg, 60 mg, 80 mg

CONTINUED ON NEXT PAGE

QUANTITY LIMITS (CONTINUED)

- **Pharmacists:**
  - Approval is based on the clinical judgment of the Magellan Pharmacy Solutions Clinical pharmacist; **AND**
  - Criteria listed for the technicians have been met based on type of request (PPI BID dosing, Titration, Tapering, Dose Alternating Schedule), Daily dose max=1. Approve up to 1 year; **OR**
    - Requested strength/dose is commercially unavailable and patient is too unstable to be adjusted to the commercial dose. Approve up to 1 year.
  - For topical applications, patient requires a larger quantity to cover a larger surface area. Approve DOS.

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

- If approved, medication is available to member at the current tier.
- If not approved, medication is still available to member at full price (pharmacy's U&C).
- Authorization will be issued for long-term therapy.
- Not to exceed FDA max approved dose.
- No override requested will be permitted for acetaminophen or acetaminophen-combinations that exceed 4 grams of acetaminophen per day.
- This guideline only applies in the absence of drug-specific quantity limit override guidelines.
- In general, mail order is triple the retail quantity, but confirm on CSID plan if custom quantity limit.

QUTENZA® (CAPSAICIN)

Length of Authorization:	3 months, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462/ 75 NCPDP)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Management of neuropathic pain associated with postherpetic neuralgia (PHN)**

- Patient is at least 18 years of age; **AND**
- Patient has a documented baseline Numerical Pain Rating Scale (NPRS) score; **AND**
- Patient has postherpetic neuralgia that has persisted for at least 6 months following healing of herpes zoster rash (i.e., crusting of the skin vesicles); **AND**
- Painful areas to be treated are not located on the face, above the hairline of the scalp, and/or in proximity to mucous membranes; **AND**
- Patient had an inadequate response (or contraindication) to ALL four of the following:
  - Tricyclic antidepressant (e.g., amitriptyline, nortriptyline, maprotiline, desipramine, etc.)
  - A gabapentinoid (e.g., pregabalin or gabapentin)

Diagnosis of **Treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet**

- Patient is at least 18 years of age; **AND**
- Patient has a documented baseline Numerical Pain Rating Scale (NPRS) score; **AND**
- Patient has painful, distal, symmetrical, sensorimotor polyneuropathy due to diabetes that has persisted for at least 1 year prior to screening; **AND**
- All other causes of pain in the feet have been ruled out; **AND**
- Patient had an inadequate response (or contraindication) to **ALL** of the following:
  - An antidepressant (e.g., duloxetine, venlafaxine, amitriptyline, nortriptyline, maprotiline, desipramine, etc.)
  - A gabapentinoid (e.g., pregabalin or gabapentin)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe application site pain and burning, hypertension, decrease in sensory function,; **AND**
- Patient has experienced an improvement in pain based on the Numerical Pain Rating Scale (NPRS) compared to baseline

Radicava® (edaravone)

Length of Authorization:	6 months; May be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462/ 75 NCPDP)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Amyotrophic lateral sclerosis (ALS):**

- Patient is at least 18 years of age; **AND**
- Patient has a diagnosis of clinically definite or probable ALS based on El Escorial revised criteria or Awaji criteria; **AND**
- Patient has a disease duration of 2 years or less; **AND**
- Patient has a percent-predicted forced vital capacity (%FVC) ≥ 80%; **AND**
- Baseline documentation of retained functionality for most activities of daily living [i.e., score of 2 points or better on each individual item of the ALS Functional Rating Scale – Revised (ALSFRS-R)]

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity reactions, sulfite allergic reactions); **AND**
- Patient has responded to therapy compared to pretreatment baseline with disease stability or mild progression indicating a slowing of decline on the ALSFRS-R (patient has not experienced rapid disease progression while on therapy); **AND**
- Patient does not have a cumulative score on the ALSFRS-R of ≤ 3

RAVICTI® (GLYCEROL PHENYLBUTYRATE)

Length of Authorization:	6 months initial; 1 year for renewal
Initiative:	SPC: Enzyme Deficiency (IE 2462/ 75 NCPDP)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Urea cycle disorders (UCDs):**

- Patient must have a confirmed diagnosis of UCD involving genetic deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamylase (OTC), argininosuccinate lyase (ASL), or argininosuccinate synthase (ASS), confirmed via enzymatic, biochemical, or genetic testing; **AND**
- Patient is 2 months of age or older; **AND**
- Patient has had an inadequate response to dietary protein restriction and/or amino acid supplementation alone for the reduction of plasma ammonia levels; **AND**
- Must be used in conjunction with dietary protein restriction and/or amino acid supplementation (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements); **AND**
- Must be used for chronic management of urea cycle disorders (UCDs); **AND**
- Must not be used to treat *N*-acetylglutamate synthase (NAGS) deficiency; **AND**
- Must not be used to treat acute hyperammonemia; **AND**
- Patient has a baseline plasma ammonia level determined prior to therapy

CLINICAL CRITERIA FOR RENEWAL

- Patient has received a beneficial response to therapy; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include pancreatic insufficiency, intestinal malabsorption, neurotoxicity associated with phenylacetate [PAA], etc.; **AND**
- Patient has received a beneficial response to therapy (i.e., reduction in venous ammonia levels compared to pretreatment baseline)

RAYOS® (PREDNISONE, DELAYED-RELEASE)

Length of Authorization:	1 Year (initial and renewal)
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Prescribed for **one** of the following conditions:
  - Allergic (atopic dermatitis, drug hypersensitivity reactions, seasonal or perennial allergic rhinitis, serum sickness)
  - Dermatologic "(bullous dermatitis herpetiformis, contact dermatitis, exfoliative erythroderma, mycosis fungoides, pemphigus, severe erythema multiforme [Stevens-Johnson syndrome])
  - Endocrine (congenital adrenal hyperplasia, hypercalcemia of malignancy, nonsuppurative thyroiditis, primary or secondary adrenocortical insufficiency)
  - Gastrointestinal (Crohn's disease, ulcerative colitis)
  - Hematologic (acquired [autoimmune] hemolytic anemia, Diamond-Blackfan anemia, idiopathic thrombocytopenic purpura in adults, pure red cell aplasia, secondary thrombocytopenia in adults)
  - Neoplastic (acute leukemia, aggressive lymphomas)
  - Nervous system (acute exacerbations of multiple sclerosis, cerebral edema associated with primary or metastatic brain tumor, craniotomy or head injury)
  - Ophthalmic (sympathetic ophthalmia, uveitis and ocular inflammatory conditions unresponsive to topical steroids)
  - Acute or chronic solid organ rejection
  - Pulmonary (acute exacerbations of chronic obstructive pulmonary disease [COPD], allergic bronchopulmonary aspergillosis, aspiration pneumonitis, asthma, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate chemotherapy, hypersensitivity pneumonitis, idiopathic bronchiolitis obliterans with organizing pneumonia, idiopathic eosinophilic pneumonias, idiopathic pulmonary fibrosis, pneumocystis carinii pneumonia [PCP] associated with hypoxemia occurring in an HIV[+] individual who is also under treatment with appropriate anti-PCP antibiotics)
  - Renal (nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus)
  - Rheumatologic (acute gouty arthritis, exacerbation or maintenance therapy in cases of ankylosing spondylitis, dermatomyositis/polymyositis, polymyalgia rheumatic, psoriatic arthritis, relapsing polychondritis, rheumatoid arthritis, Sjogren's syndrome, systemic lupus erythematosus, vasculitis)
  - Infectious diseases (trichinosis with neurologic or myocardial involvement, tuberculous meningitis with subarachnoid block or impending block used concurrently with appropriate antituberculous chemotherapy)
  - Any other new FDA indication; **AND**
- Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to generic prednisone tablets which is unable to be resolved with attempts to minimize the adverse effects where appropriate; **AND**
- Documented history of failure, contraindication, or intolerance to **TWO** of the following:
  - Dexamethasone tablet/oral solution
  - Hydrocortisone tablet
  - Methylprednisolone tablet
  - Prednisolone tablet/syrup/oral solution; **AND**
- Dose is optimized

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient is free of unacceptable toxicity from the drug.

REBLOZYL (LUSPATERCEPT-AAMT)

Length of Authorization:	Beta Thalassemia: Coverage will be provided initially for 15 weeks (5 initial doses) and may be renewed annually thereafter. Myelodysplastic Syndrome: Coverage will be provided initially for 21 weeks (7 initial doses) and may be renewed every 6 months thereafter
Initiative:	SPC: Miscellaneous PA required (IE 2462/ 75 NCPDP)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Beta Thalassemia:**

- Patient must be 18 years or older*; **AND**

  ***Note:** Request for patients < 18 years will be considered on a case by case basis for those with high transfusion burden and symptomatic iron overload, history of alloimmunization, or history of transfusion reactions
- Females of reproductive potential have a negative pregnancy test prior to start of therapy and will use an effective method of contraception during treatment and at least for 3 months after treatment; **AND**
- Patient has a documented diagnosis of beta thalassemia (excludes alpha-thalassemia and hemoglobin S/ß-thalassemia variants) as outlined by the following
  - Patient diagnosis is confirmed by HBB sequence gene analysis showing biallelic pathogenic variants; **OR**
  - Patient has severe microcytic/hypochromic anemia, anisopoikilocytosis with nucleated red blood cells on peripheral blood smear, and hemoglobin analysis that reveals decreased amounts or complete absence of hemoglobin A and increased amounts of hemoglobin F; **AND**
- Patient is red blood cell (RBC) transfusion dependent as defined by requiring 6-20 RBC units per 24 weeks; **AND**
- Patient does not have major end organ damage*, defined as any of the following:
  - Liver disease with an ALT > 3x the ULN or history of evidence of cirrhosis; **OR**
  - Heart disease, heart failure NYHA classification 3 or higher, or significant arrhythmia requiring treatment, or recent myocardial infarction within 6 months of treatment; **OR**
  - Lung disease, including pulmonary fibrosis or pulmonary hypertension which are clinically significant (i.e., ≥ Grade 3); **OR**
  - Creatinine clearance < 60 mL/min; **AND**
- Patient has not had a deep vein thrombosis or a thrombotic stroke which required medical intervention within 6 months prior to therapy; **AND**
- Patient has a baseline Hemoglobin (Hb) < 11.5 g/dL (if Hb is 11.5 g/dL or higher, the dose must be delayed until the Hb is 11 g/dL or less) (**Note:** If an RBC transfusion occurred prior to dosing, the pretransfusion Hgb must be considered for dosing purposes. Lab values are obtained within 7 days of the date of administration); **AND**
- Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency) have been ruled out; **AND**
- Reblozyl is not being used as a substitute for RBC transfusions in patients requiring immediate correction of anemia

***Note**: Request for patients deemed to have any major end organ damage will be reviewed on a case-by-case basis.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Myelodysplastic Syndrome

- Patient must be 18 years or older; **AND**
- Females of reproductive potential have a negative pregnancy test prior to start of therapy and will use an effective method of contraception during treatment and at least for 3 months after treatment; **AND**
- Patient does not have major end organ damage*, defined as any of the following:
  - Liver disease with an ALT > 3x the ULN or history of evidence of cirrhosis; **OR**
  - Heart disease, heart failure NYHA classification 3 or higher, or significant arrhythmia requiring treatment, or recent myocardial infarction within 6 months of treatment; **OR**
  - Lung disease, including pulmonary fibrosis or pulmonary hypertension which are clinically significant (i.e., ≥ Grade 3); **OR**
  - Creatinine clearance < 60 mL/min; **AND**
- Patient has not had a deep vein thrombosis or a thrombotic stroke which required medical intervention within 6 months prior to therapy; **AND**
- Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency) have been ruled out; **AND**
- Reblozyl is not being used as a substitute for RBC transfusions in patients requiring immediate correction of anemia; **AND**
- Patient has required 2 or more red blood cell units over an 8 week timeframe; **AND**
- Patient has a diagnosis of one of the following:
  - Myelodysplastic syndrome with ring sideroblasts (MDS-RS); **OR**
  - Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T; **AND**
- Patient has very low to intermediate risk disease defined as any one of the following:
  - IPSS-R: very low, low, or intermediate; **OR**
  - IPSS: low/intermediate-1; **OR**
  - WPSS: very low, low, or intermediate; **AND**
- Patient has symptomatic anemia with ring sideroblasts ≥ 15% (or ring sideroblasts ≥5% with an SF3B1 mutation); **AND**
  - Serum erythropoietin > 200 mU/mL; **OR**
  - Patient has had an inadequate response to prior treatment with an erythropoiesis-stimulating agent (i.e. epoetin alpha > 40,000 units/week for at least 8 doses or darbepoetin alpha > 500 mcg every 3 weeks for at least 4 doses); **OR**
  - Patient has a documented contraindication or intolerance to the use of an erythropoiesis-stimulating agent

***Note**: Request for patients deemed to have any major end organ damage will be reviewed on a case-by-case basis.

CLINICAL CRITERIA FOR RENEWAL

- Patient will not receive doses < 21 days apart; **AND**
- Absence of unacceptable toxicity from the drug (e.g., thromboembolic events, severe hypertension); **AND**
- Other causative factors (e.g., a bleeding event) have been ruled out; **AND**
- Reblozyl® is not being used as a substitute for RBC transfusions in patients requiring immediate correction of anemia; **AND**
- Hemoglobin (Hb) < 11.5 g/dL (if Hb is 11.5 g/dL or higher, the dose must be delayed until the Hb is 11 g/dL or less) (**Note:** If an RBC transfusion occurred prior to dosing, the pretransfusion Hgb must be considered for dosing purposes. Lab values are obtained within 7 days of the date of administration); **AND**

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

(For **Beta Thalassemia**)

- Patient is experiencing disease response as evidenced by a decrease in the number of RBC transfusions; **OR**
- **For new starts**: Patient has not achieved a reduction in RBC transfusion burden after at least 2 consecutive, initial (1 mg/kg), doses (6 weeks) and requires a dose increase to 1.25 mg/kg; **OR**
- Patient experienced a response followed by a lack/loss of response and requires a dose increase to 1.25 mg/kg (from 1 mg/kg)

(For **Myelodysplastic Syndrome**)

- Patient is experiencing disease response as evidenced by a decrease in the number of RBC transfusions; **OR**
- **For new starts:** Patient has not achieved a reduction in RBC transfusion burden after at least 2 consecutive, initial (1 mg/kg), doses (6 weeks) and requires a dose increase to 1.33 mg/kg; **OR**
- Patient has not achieved a reduction in RBC transfusion burden after at least 2 consecutive, 1.33 mg/kg doses (6 weeks) and requires a dose increase to 1.75 mg/kg; **OR**
- Patient experienced a response followed by a lack/loss of response and requires a dose increase to 1.33 mg/kg (from 1 mg/kg)

***Note**: Discontinue Reblozyl if a patient does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose level or if unacceptable toxicity occurs at any time.

RELISTOR® (METHYLNALTREXONE BROMIDE) INJECTION

Length of Authorization:	Up to 1 year
Initiative:	MNC: Gastrointestinals: IBS Agents (IE 2462/ NCPCP 75)

STANDARD FORMULARY CRITERIA

Diagnosis of **Opioid-Induced Constipation in Adult Patients with Advanced Illness**

- Patient must have opioid-induced constipation with advanced illness (including incurable cancer, end stage COPD/emphysema, cardiovascular disease/heart failure, Alzheimer's Disease/dementia, or HIV/AIDS); **AND**
- Adult patients with advanced illness with a life expectancy of less than 6 months; **AND**
- Confirmed diagnosis of opioid-induced constipation; **AND**
- History of failure, contraindication, or intolerance to an osmotic laxative (e.g., lactulose, polyethylene glycol)
- Response to standard laxative therapy is inadequate (< 3 bowel movements in preceding 7 days); **AND**
- Standard therapy is defined as routine, scheduled use of 3 or more of the following; **AND**
  - Dietary changes
  - Stool softeners
  - Stimulant laxatives
  - Osmotic or saline laxatives
  - Bulk forming laxatives
  - Lubricants
- Patient does not have known or suspected mechanical gastrointestinal obstruction; **AND**
- Patient is not pregnant or breastfeeding.

Diagnosis of **Opioid-Induced Constipation in Adult Patients with Chronic Non-Cancer Pain**

- Confirmed diagnosis of opioid-induced constipation; **AND**
- Response to standard laxative therapy is inadequate (< 3 bowel movements in preceding 7 days); **AND**
- Standard therapy is defined as routine, scheduled use of 3 or more of the following; **AND**
  - Dietary changes
  - Stool softeners
  - Stimulant laxatives
  - Osmotic or saline laxatives
  - Bulk forming laxatives
  - Lubricants
- ***Patient must try ONE of the following generics: lactulose or polyethylene glycol; AND***
- ***Patient must have failed a trial of Movantik or Symproic; AND***
- Patient does not have known or suspected mechanical gastrointestinal obstruction; **AND**
- Patient is not pregnant or breastfeeding.

RETEVMO® (SELPERCATINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years old; **AND**
- Must be used as a single agent; **AND**
- Patient does not have uncontrolled hypertension; **AND**
- Patient does not have clinically significant active cardiovascular disease or a recent myocardial infarction (i.e., within 6 months prior to start of therapy); **AND**
- Patient does not have a history of prolongation of the QT-interval > 470 msec; **AND**
- Patient has not had recent major surgery within the previous 14 days; **AND**
- Therapy will not be used concomitantly with other RET-type targeted therapies (e.g., cabozantinib, vandetanib, parlsetinib)
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with acid-reducing agents, if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **OR**
  - Coadministration with strong or moderate CYP3A4 inhibitors (e.g., fluconazole, itraconazole), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **OR**
  - Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient disease has the presence of a RET gene fusion as detected by an FDA-approved or CLIA compliant test; **AND**
- Patient has recurrent, advanced, or metastatic disease *(excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease)* or mediastinal lymph node recurrence with prior radiation therapy

Diagnosis of **Thyroid Cancer**

- Must be used as a single agent; **AND**
- Patient does not have uncontrolled hypertension; **AND**
- Patient does not have clinically significant active cardiovascular disease or a recent myocardial infarction (i.e., within 6 months prior to start of therapy); **AND**
- Patient does not have a history of prolongation of the QT-interval > 470 msec; **AND**
- Patient has not had recent major surgery within the previous 14 days; **AND**
- Therapy will not be used concomitantly with other RET-type targeted therapies (e.g., cabozantinib, vandetanib, pralsetinib)
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with acid-reducing agents, if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **OR**
  - Coadministration with strong or moderate CYP3A4 inhibitors (e.g., fluconazole, itraconazole), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **OR**
  - Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient has RET-fusion positive Follicular, Hürthle Cell, or Papillary carcinoma; **AND**
  - Patient is at least 12 years of age; **AND**
  - Patient has metastatic, advanced, or unresectable locoregional recurrent or persistent disease; **AND**
  - Patient is radioactive iodine (RAI) therapy refractory or is not amenable to RAI therapy; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient has RET-mutation positive medullary thyroid cancer (MTC); **AND**
  - Patient is at least 12 years of age; **AND**
  - Patient has symptomatic or progressive unresectable locoregional disease; **OR**
  - Patient has advanced or metastatic disease; **OR**
- Patient has RET-fusion positive Anaplastic carcinoma; **AND**
  - Patient is at least 18 years old; **AND**
  - Used as neoadjuvant therapy for borderline resectable locoregional disease; **OR**
  - Used as first- or second-line therapy for metastatic disease

Diagnosis of **Histiocytic Neoplasms**

- Patient is at least 18 years old; **AND**
- Must be used as a single agent; **AND**
- Patient does not have uncontrolled hypertension; **AND**
- Patient does not have clinically significant active cardiovascular disease or a recent myocardial infarction (i.e., within 6 months prior to start of therapy); **AND**
- Patient does not have a history of prolongation of the QT-interval > 470 msec; **AND**
- Patient has not had recent major surgery within the previous 14 days; **AND**
- Therapy will not be used concomitantly with other RET-type targeted therapies (e.g., cabozantinib, vandetanib, parlsetinib)
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with acid-reducing agents, if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **OR**
  - Coadministration with strong or moderate CYP3A4 inhibitors (e.g., fluconazole, itraconazole), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **OR**
  - Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient disease has the presence of a RET gene fusion; **AND**
- Patient has one of the following sub-types of disease:
  - Langerhans Cell Histiocytosis (LCH); **AND**
    - Used for multisystem disease with symptomatic or impending organ dysfunction; **OR**
    - Used for pulmonary LCH; **OR**
    - Patient has multifocal single system bone disease not responsive to treatment with a bisphosphonate and more than 2 lesions; **OR**
    - Patient has CNS lesions; **OR**
    - Used for relapsed/refractory disease; **OR**
  - Erdheim-Chester Disease; **AND**
    - Patient has symptomatic disease; **OR**
    - Used for relapsed or refractory disease; **OR**
  - Rosai-Dorfman Disease; **AND**
    - Patient has symptomatic disease that is multifocal or unresectable unifocal; **OR**
    - Used for relapsed or refractory disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hepatotoxicity, severe hypersensitivity, QT interval prolongation, impaired wound healing, severe or life-threatening hemorrhagic events, uncontrolled hypertension, tumor lysis syndrome, etc.

REVCOVI™ (ELAPEGADEMASE-LVLR)

Length of Authorization:	1 year, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Adenosine Deaminase (ADA) deficiency**

- Must not be used in combination with pegademase-bovine; **AND**
- Patient does not have severe thrombocytopenia (<50,000/microL); **AND**
- Patient has severe combined immunodeficiency disease (SCID) with a definitive diagnosis of adenosine deaminase deficiency as determined by one of the following:
  - Deficient ADA catalytic activity (<1% of normal) in hemolysates (in untransfused individuals) or in extracts of other cells (e.g., blood mononuclear cells, fibroblasts); **OR**
  - Detection of biallelic pathogenic mutations in the *ADA* gene by molecular genetic testing; **AND**
- Patient has a marked elevation of the metabolite deoxyadenosine triphosphate (dATP) or total deoxyadenosine nucleotides (dAXP) in erythrocytes; **AND**
- Patient is not a candidate for or has failed bone marrow transplantation (BMT); **AND**
- Baseline values for trough plasma ADA activity, red blood cell deoxyadenosine triphosphate (dATP), trough deoxyadenosine nucleotide (dAXP) and/or total lymphocyte counts have been obtained.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., injection site bleeding in patients with thrombocytopenia, severe thrombocytopenia); **AND**
- Adequate documentation of disease stability and/or improvement as indicated by one or more of the following:
  - Increase in plasma ADA activity (target trough level ≥ 15 mmol/hr/L)
  - Red blood cell dATP level decreased (target ≤ 0.005 to 0.015 mmol/L)
  - Improvement in immune function with diminished frequency/complications of infection as evidenced in improvement in the ability to produce antibodies
  - Improvement in red blood cell dAXP levels (target trough level ≤ 0.02 mmol/L)

REVLIMID® (LENALIDOMIDE)

Length of Authorization:	6 Months, may be renewed Previously untreated Follicular lymphoma may be renewed for up to 18 cycles Previously treated Follicular lymphoma and Marginal zone lymphoma may be renewed for up to 12 cycles.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Myelodysplastic Syndrome (MDS)**

- Both patient **and** prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Patient has myelodysplastic/myeloproliferative neoplasms with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) overlap disease; **AND**
  - Used as a single agent or in combination with a hypomethylating agent (e.g., azacitidine, decitabine, etc.); **OR**
- Patient has lower risk disease (defined as IPSS-R [Very Low, Low, Intermediate], IPSS [Low/Intermediate-1], WPSS [Very Low, Low, Intermediate]); **AND**
  - Patient has symptomatic anemia; **AND**
    - Used as a single agent for del(5q) **†**; **OR**
    - Patient does not have del(5q); **AND**
      - Patient has ring sideroblasts < 15% (or < 5% with an SF3B1 mutation); **AND**
        - Patient has a serum erythropoietin (EPO) ≤ 500 mU/mL; **AND**
          - Used as a single agent if no response to an ESA AND no response to an ESA with G-CSF; **OR**
          - Used with ESA following failure of ESA alone; **OR**
        - Patient has a serum EPO > 500 mU/mL; **AND**
          - Patient had no response, intolerance, or a poor probability of response to immunosuppressive therapy (i.e., antithymocyte globulin [ATG] ± cyclosporine); **OR**
      - Patient has ring sideroblasts ≥ 15% (or ring sideroblasts ≥5% with an SF3B1 mutation); **AND**
        - Patient has a serum EPO ≤ 500 mU/mL with no response to ESA with G-CSF AND no response to luspatercept; **OR**
        - Patient has a serum EPO > 500 mU/mL and no response to luspatercept

Diagnosis of **Multiple Myeloma**

- Both patient and prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Used in combination with dexamethasone; **OR**
- Used as primary therapy for newly diagnosed disease in combination with dexamethasone **AND** one of the following:
  - bortezomib: **OR**
  - carfilzomib; **OR**
  - daratumumab; **OR**
  - cyclophosphamide; **OR**
  - combination therapy with daratumumab and bortezomib; **OR**
- Used as maintenance therapy after response to primary myeloma therapy or following autologous hematopoietic stem cell transplant (auto-HSCT) as a single agent or in combination with bortezomib; **OR**
- Used for previously treated multiple myeloma for relapsed or progressive disease in combination with dexamethasone or as a single agent if patient is steroid-intolerant; **OR**
- Used in combination with dexamethasone for POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Systemic light chain amyloidosis**

- Both patient **and** prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Used in combination with dexamethasone with or without bortezomib or cyclophosphamide; **AND**
- Used for newly diagnosed or relapsed or refractory disease.

Diagnosis of **Hodgkin Lymphoma (HL)**

- Used as a single agent; **AND**
- Used as third-line or greater therapy for relapsed or refractory disease; **AND**
- Both patient **and** prescriber are enrolled in the Revlimid REMS™ program.

Diagnosis of **B-Cell Non-Hodgkin Lymphoma (NHL)**

- Both patient **and** prescriber are enrolled in the Revlimid REMS™ program; **AND**
  - Mantle Cell Lymphoma
    - Used in combination with rituximab for initial/induction therapy or in non-transplant candidates; **OR**
    - Used as a single agent after two prior therapies, one of which included bortezomib; **OR**
    - Used as a single agent or in combination with rituximab; **AND**
      - Used as second-line therapy for stable disease; **OR**
      - Used for partial response with substantial disease after induction therapy; **OR**
      - Used for relapsed or progressive disease.
  - Follicular Lymphoma
    - Used as first-line therapy in combination with rituximab; **OR**
    - Used as subsequent therapy in patients with refractory or progressive disease in combination with rituximab or obinutuzumab or as a single agent if not a candidate for anti-CD20 therapy
  - AIDS-Related Cell Lymphoma
    - Used as subsequent therapy, with or without rituximab, for relapsed non-germinal center diffuse large B-cell lymphoma in patients who are not transplant candidates

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **B-Cell Non-Hodgkin Lymphoma (NHL)** ***(Continued)***

- Diffuse Large B-Cell Lymphoma (DLBCL) (including Histologic Transformation)
  - Used in combination with tafasitamab for non-transplant candidates; **AND**
    - Patient had histologic transformation from Nodal Marginal Zone Lymphoma OR from Follicular Lymphoma (without translocations of MYC and BCL2 and/or BCL6); **AND**
      - Patient received at least two lines of chemoimmunotherapy for indolent or transformed disease; **OR**
      - Patient received minimal or no chemoimmunotherapy prior to histologic transformation and had no response or progressive disease after chemoimmunotherapy (e.g., anthracycline- or anthracenedione-based regimen unless contraindicated); **OR**
    - Patient had partial response, no response, relapsed, progressive, or refractory disease; **OR**
  - Used with or without rituximab; **AND**
    - Patient had histologic transformation from Nodal Marginal Zone Lymphoma OR from Follicular Lymphoma; **AND**
      - Patient had transformation to non-geminal center disease; **AND**
      - Patient received multiple lines of chemoimmunotherapy for indolent or transformed disease; **OR**
    - Patient had partial response, no response, relapsed, progressive, or refractory non-germinal center disease
- High-Grade B-Cell Lymphoma (DLBCLC)
  - Used as subsequent therapy, with or without rituximab, in non-transplant candidate patients with a partial response, no response, relapsed, progressive, or refractory disease.
- Marginal Zone Lymphoma (includes Nodal or Splenic MZL & Gastric or Non-Gastric MALT)
  - Used as subsequent therapy for recurrent, refractory, or progressive disease in combination with rituximab.
- Multicentric Castleman's Disease
  - Both patient **and** prescriber are enrolled in the Revlimid REMS™ program; **AND**
  - Used as subsequent therapy, with or without rituximab, for disease that has progressed following treatment of relapsed/refractory or progressive disease.
- Post-Transplant Lymphoproliferative Disorders (PTLD)
  - Used as subsequent therapy, following first-line chemoimmunotherapy, in patients with partial response, persistent or progressive disease to first-line therapy; **AND**
    - Patient has monomorphic PTLD (non-germinal center B-cell type)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of Primary Cutaneous Non-Hodgkin's Lymphoma (NHL)

- Both patient and prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Mycosis Fungoides (MF)/Sézary Syndrome (SS)
  - Used as a single agent; **AND**
    - Used as primary systemic therapy; **AND**
      - Patient has stage IV non-Sézary or visceral disease; **OR**
      - Patient has large cell transformation (LCT) with generalized cutaneous or extracutaneous lesions; **OR**
    - Used as systemic therapy for subsequent treatment
- Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders
  - Used as a single agent for relapsed or refractory disease; **AND**
    - Patient has primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions; **OR**
    - Patient has cutaneous ALCL with regional nodes (excludes systemic ALCL).

Diagnosis of T-Cell Non-Hodgkin's Lymphoma (NHL)

- Both patient and prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Peripheral T-Cell Lymphoma (includes all of the following: peripheral T-cell lymphoma not otherwise specified, angioimmunoblastic T-cell lymphoma, enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma with TFH phenotype, or follicular T-cell lymphoma):
  - Used as a single agent as initial palliative therapy or as subsequent therapy
- Adult T-cell Leukemia/Lymphoma
  - Used as a single agent subsequent therapy for non-responders to first-line treatment for acute or lymphoma subtypes
- Hepatosplenic T-Cell Lymphoma
  - Used as a single agent therapy for refractory disease after two prior primary treatment regimens

Diagnosis of **Primary CNS Lymphoma**

- Both patient and prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Used as a single-agent or in combination with rituximab; **AND**
  - Used as induction therapy for intolerance to, or patient is not a candidate for, high-dose methotrexate; **OR**
  - Used for relapsed or refractory disease; **AND**
    - Patient previously received whole brain radiation therapy; **OR**
    - Patient previously received high-dose methotrexate-based regimen; **OR**
    - Patient received prior high-dose chemotherapy with stem cell rescue (HDT/ASCR)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)**

- Both patient **and** prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Used for relapsed or refractory disease; **OR**
- Used as maintenance therapy following a complete or partial response to second-line therapy in patients without del(17p)TP53 mutation; **OR**
- Used as maintenance therapy after first-line therapy in patients without del(17p)/TP53 mutation; **AND**
  - Patient has high-risk minimal residual disease (MRD) $\geq 10^{-2}$ or $\geq 10^{-4}$ and $< 10^{-2}$ with unmutated immunoglobulin heavy-chain variable region gene (IGHV)

Diagnosis of **Myelofibrosis**

- Both patient **and** prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Must be used as a single agent or in combination with prednisone for management of myelofibrosis-associated anemia; **AND**
  - Patient has a serum EPO ≥ 500 mU/mL; **OR**
  - Patient has a serum EPO < 500 mU/mL and no response or loss of response to erythropoietic stimulating agents.

Diagnosis of **AIDS-Related Kaposi Sarcoma**

- Both patient **and** prescriber are enrolled in the Revlimid REMS™ program; **AND**
- Used as subsequent therapy with antiretroviral therapy following progression on first-line and alternative first-line therapy; **AND**
- Patient has advanced cutaneous, oral, visceral, or nodal disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment defined as stabilization or disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., secondary primary malignancies, pulmonary embolism; deep vein thrombosis, hematologic toxicity [neutropenia, thrombocytopenia], tumor lysis syndrome, hepatic failure, severe cutaneous reactions, severe hypersensitivity reactions)

REYVOW® (LASMIDITAN)

Length of Authorization:	12 months and renewable
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient must be ≥ 18 years of age; **AND**
- Patient must have a diagnosis of migraine, with or without aura; **AND**
- Patient must NOT have headache frequency ≥ 15 headache days per month during the prior 6 months [indication is for acute use only]; **AND**
- Prescriber attests patient has been educated about need to refrain from driving or operating machinery for ≥ 8 hours after dose; **AND**
- Patient must have tried and failed at least one of the following: NSAID, non-opioid analgesic, acetaminophen OR caffeinated analgesic combination; **AND**
- Patient must have tried and failed or have a contraindication or intolerance to 2 preferred triptans; **AND**
- ***Patient must have tried and failed or have a contraindication or intolerance to BOTH Nurtec AND Ubrelvy***

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet initial criteria; **AND**
- Patient is experiencing symptom improvement; **AND**
- The patient is not experiencing any treatment-limiting adverse reactions of the medication

REZUROCK™ (BELUMOSUDIL)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Graft versus Host Disease (cGVHD)**

- Patient is at least 12 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with proton-pump inhibitors (PPIs), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.) or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Will not be used in combination with ibrutinib (subsequent therapy is allowed); **AND**
- Patient is post-allogeneic stem cell transplant (generally 3 or more months); **AND**
- Patient does not have histologic relapse of underlying cancer or post-transplant lymphoproliferative disease; **AND**
- Patient has failed two or more previous lines of systemic therapy for the treatment of cGVHD (e.g., corticosteroids, immunosuppressants, etc.); **AND**
- Used in combination with stable doses of systemic therapies for GVHD, which can include corticosteroids (e.g., calcineurin inhibitors [cyclosporine; tacrolimus], sirolimus, mycophenolate mofetil, methotrexate, rituximab, etc.)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include grade 4 hepatotoxicity, etc.; **AND**
- Response to therapy with an improvement in one or more of the following:
  - Clinician assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score, etc.)
  - Patient-reported symptoms (e.g., Lee Symptom Scale, etc.)

RITUXAN HYCELA® (RITUXIMAB AND HYALURONIDASE HUMAN)

Length of Authorization:	• 6 months, may be renewed (unless otherwise specified) • Maintenance therapy for mantle cell lymphoma may be renewed until disease progression or intolerable toxicity • Hairy cell leukemia may not be renewed • Maintenance therapy for all other indications may be renewed for up to a maximum of 2 years
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Note: These criteria are only for Rituxan Hycela®. Refer to the Immunomodulator section for other Rituxan® products.

***Note**: Patient must meet relevant initial criteria and receive at least **one** dose of the intravenous formulation of rituximab prior to initiating therapy with the subcutaneous formulation.

Diagnosis of **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)**

- Patient age is 18 years or older; **AND**
- Patient has been screened for the presence of hepatitis B virus (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient is CD20 antigen expression positive; **AND**
- Patient has received at least one full dose of a rituximab product by intravenous infusion prior to initiating therapy; **AND**
- Rituxan Hycela® will not be used with intravenous chemotherapy agents; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- **For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Ruxience®**

Note: For Core Formulary, Rituxan Hycela is non-formulary.

Diagnosis of **B-Cell Lymphomas**

- Patient age is 18 years or older; **AND**
- Patient has been screened for the presence of hepatitis B virus (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient is CD20 antigen expression positive; **AND**
- Patient has received at least one full dose of a rituximab product by intravenous infusion prior to initiating therapy; **AND**
- Rituxan Hycela® will not be used with intravenous chemotherapy agents; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- One of the following:
  - Follicular lymphoma (FL)
  - Diffuse large B-cell lymphoma (DLBCL)
  - High grade B-cell lymphomas
  - Castleman disease
  - Gastric and non-gastric MALT lymphoma
  - Mantle cell lymphoma
  - Nodal and splenic marginal zone lymphoma
  - Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma
  - Post-transplant lymphoproliferative disorder (PTLD)

Diagnosis of **Hairy Cell Leukemia**

- Patient age is 18 years or older; **AND**
- Patient has been screened for the presence of hepatitis B virus (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient is CD20 antigen expression positive; **AND**
- Patient has received at least one full dose of a rituximab product by intravenous infusion prior to initiating therapy; **AND**
- Rituxan Hycela® will not be used with intravenous chemotherapy agents
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment

Diagnosis of **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma**

- Patient age is 18 years or older; **AND**
- Patient has been screened for the presence of hepatitis B virus (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient is CD20 antigen expression positive; **AND**
- Patient has received at least one full dose of a rituximab product by intravenous infusion prior to initiating therapy; **AND**
- Rituxan Hycela® will not be used with intravenous chemotherapy agents
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Primary Cutaneous B-Cell Lymphoma**

- Patient age is 18 years or older; **AND**
- Patient has been screened for the presence of hepatitis B virus (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient is CD20 antigen expression positive; **AND**
- Patient has received at least one full dose of a rituximab product by intravenous infusion prior to initiating therapy; **AND**
- Rituxan Hycela® will not be used with intravenous chemotherapy agents; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment
- **For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Ruxience®**

Note: For Core Formulary, all rituximab products are non-formulary.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hypersensitivity or other administration reactions (i.e., local cutaneous reactions), tumor lysis syndrome (TLS), severe mucocutaneous reactions, progressive multifocal leukoencephalopathy (PML), hepatitis B virus reactivation, serious bacterial, fungal, or viral infections, cardiac adverse reactions, renal toxicity, bowel obstruction or perforation, etc.

ROZLYTREK® (ENTRECTINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Solid Tumors with *NTRK* Gene Fusion**

- Patient is 12 years or older; **AND**
- Patients with symptoms or known risk factors for congestive heart failure (CHF) have had left ventricular ejection fraction (LVEF) assessed prior to therapy; **AND**
- Patient does not have signs and symptoms of hyperuricemia as evidenced by a baseline serum acid level as tested prior to initiation of therapy; **AND**
- Will not be used in combination with another *NTRK*-inhibitor (i.e., larotrectinib) or ROS1-directed (e.g., crizotinib) therapy; **AND**
- Patient will have an electrocardiogram (ECG) at baseline and will be assessed periodically during therapy; **AND**
- Patient will avoid concomitant therapy with all the following:
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with moderate or strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, bosentan); **AND**
  - Coadministration with moderate or strong CYP3A inhibitors (e.g., erythromycin, itraconazole, fluconazole, grapefruit juice), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented (**Note**: Complete avoidance must be implemented in pediatric patients with BSA ≤ 1.50 m^2); **AND**
- Patient has a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion or fusion partner tumors without a known acquired resistance mutation*; **AND**
- Used as single agent therapy; **AND**
- Patient has one of the following solid tumors:
  - Breast cancer
    - Patient has no satisfactory alternative treatments or disease has progressed following treatment; **AND**
      - Patient has recurrent unresectable (local or regional) or stage IV (M1) disease; **OR**
      - Patient has not responded to preoperative systemic therapy
  - Central nervous system cancers
    - Patient has recurrent or progressive low-grade (WHO grade 1 or 2) glioma; **AND**
      - Patient is at least 18 years of age; **AND**
      - Patient has received prior fractionated external beam radiation therapy; **OR**
    - Patient has recurrent anaplastic glioma or glioblastoma; **OR**
    - Patient has brain metastases from NTRK-gene fusion positive tumors*; **AND**
      - Used as initial treatment in patients with small, asymptomatic brain metastases; **OR**
      - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
      - Patient has recurrent limited brain metastases; **OR**
      - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Colorectal adenocarcinoma
  - Used as subsequent therapy for progression of metastatic disease
- Cutaneous melanoma
  - Used for unresectable or metastatic disease; **AND**
  - Used as subsequent therapy for disease progression or after maximum clinical benefit from BRAF targeted therapy
- Gastric adenocarcinoma **or** esophageal/esophago-gastric Junction (GEJ) adenocarcinoma/squamous cell carcinoma
  - Used palliatively as subsequent therapy; **AND**
  - Patient has unresectable (or is not a surgical candidate) locally advanced, recurrent, or metastatic disease
- Gastrointestinal Stromal Tumors (GIST)
  - Patient has unresectable, recurrent, or metastatic disease; **AND**
  - Used after failure on approved therapies including each of the following: imatinib, sunitinib, regorafenib, and ripretinib
- Head and neck cancer
  - Patient has salivary gland tumors; **AND**
  - Used for one of the following:
    - Recurrent disease with distant metastases; **OR**
    - Unresectable locoregional recurrence with prior radiation therapy (RT); **OR**
    - Unresectable second primary with prior RT
- Hepatobiliary cancer
  - Patient has gallbladder cancer or cholangiocarcinoma (Intra/Extra – hepatic); **AND**
    - Patient has unresectable or metastatic disease; **OR**
  - Patient has hepatocellular carcinoma; **AND**
    - Used as subsequent treatment for progressive disease; **AND**
      - Patient has unresectable disease and is not a transplant candidate; **OR**
      - Patient has metastatic disease or extensive liver tumor burden; **OR**
      - Patient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease
- Histiocytic Neoplasms – Langerhans Cell Histiocytosis (LCH)
  - Patient has multisystem LCH with symptomatic or impending organ dysfunction; **OR**
  - Patient has pulmonary LCH; **OR**
  - Patient has multifocal single system bone disease not responsive to treatment with a bisphosphonate and > 2 lesions; **OR**
  - Patient has CNS lesions; **OR**
  - Patient has relapsed/refractory disease
- Histiocytic Neoplasms – Erdheim-Chester Disease (ECD)
  - Patient has symptomatic or relapsed/refractory disease
- Histiocytic Neoplasms – Rosai-Dorfman Disease
  - Patient has symptomatic unresectable unifocal disease; **OR**
  - Patient has symptomatic multifocal disease; **OR**
  - Patient has relapsed/refractory disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Ovarian cancer (Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer)
  - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without evidence of radiographic disease); **AND**
  - Patient has persistent, relapsed, or recurrent disease
- Pancreatic adenocarcinoma
  - Used as subsequent therapy for locally advanced, metastatic, or recurrent disease in patients with a PS of ≤ 2
- Small Bowel Adenocarcinoma/Advanced Ampullary Cancer
  - Used as subsequent therapy for metastatic disease
- Soft tissue sarcoma
  - Will not be used as adjuvant therapy for non-metastatic disease; **AND**
    - Used for solitary fibrous tumors; **OR**
    - Used for angiosarcoma; **OR**
    - Used as first-line therapy for one of the following:
      - Advanced or metastatic pleomorphic rhabdomyosarcoma
      - Advanced, unresectable, recurrent, or metastatic disease of the extremity/body wall/head-neck
      - Advanced, unresectable, or metastatic disease or post-operatively for sarcoma of the retroperitoneal or intra-abdominal area
- Thyroid carcinoma
  - Patient has follicular, Hürthle cell, or papillary carcinoma; **AND**
    - Patient has unresectable locoregional recurrent or persistent disease **or** metastatic disease; **AND**
    - Disease is not susceptible to radioactive iodine (RAI) therapy; **OR**
  - Patient has anaplastic carcinoma; **AND**
    - Patient has metastatic disease

Diagnosis of **Non-Small Cell Lung Cancer**

- Patient is at least 18 years of age **(unless otherwise specified)**; **AND**
- Patients with symptoms or known risk factors for congestive heart failure (CHF) have had left ventricular ejection fraction (LVEF) assessed prior to therapy; **AND**
- Patient does not have signs and symptoms of hyperuricemia as evidenced by a baseline serum acid level as tested prior to initiation of therapy; **AND**
- Will not be used in combination with another *NTRK*-inhibitor (i.e., larotrectinib) or ROS1-directed (e.g., crizotinib) therapy; **AND**
- Patient will have an electrocardiogram (ECG) at baseline and will be assessed periodically during therapy; **AND**
- Patient will avoid concomitant therapy with all the following:
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with moderate or strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, bosentan); **AND**
  - Coadministration with moderate or strong CYP3A inhibitors (e.g., erythromycin, itraconazole, fluconazole, grapefruit juice), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented (**Note**: Complete avoidance must be implemented in pediatric patients with BSA ≤ 1.50 m^2); **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Used as a single agent; **AND**
  - Patient's tumor is *ROS1*-positive❖; **OR**
  - Patient has NTRK 1/2/3 gene fusion-positive disease*; **AND**
    - Patient is at least 12 years of age; **AND**
    - Used as first line therapy or as subsequent therapy following progression on first-line systemic therapy in patients who did not receive an NTRK1/2/3-targeted regimen in a previous line of therapy

* An FDA-approved test for the detection of NTRK gene fusion is not currently available. NTRK gene fusions can be identified by means of the following testing methodologies: next-generation sequencing (NGS), fluorescence in situ hybridization (FISH), or reverse transcription-polymerase chain reactions (RT-PCR), etc.
❖ An FDA-approved test for the detection of ROS1 gene fusions is not currently available. ROS1 gene fusions can be identified by means of the following testing methodologies: NGS, FISH, etc.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., congestive heart failure, hepatotoxicity, CNS effects [e.g., cognitive impairment, mood disorders, dizziness, and sleep disturbances], skeletal fractures, hyperuricemia, QT-interval prolongation, visual disturbances)

RSV Prophylaxis – Synagis®

Length of Authorization:	• November through April • APPROVE UNTIL 04/30/2022 • **Note:** in infants and children < 24 months, already on prophylaxis and eligible, 1 post-op dose can be approved after cardiac bypass or after extracorporeal membrane oxygenation (ECMO). • **Note:** Synagis® season can vary based on state/region; please refer to CDC trends (https://www.cdc.gov/surveillance/nrevss/rsv/state.html) to determine if the approval timeframe needs to be different for a particular patient. You can also refer to Medicaid plans on MRx Docs for assistance on dates their states use.
Initiative:	SPC: RSV Prophylaxis (IE 2462 & 3024 / NCPDP 75 & 78)

INFORMATION ON RSV SEASON AND PATIENT POPULATIONS

- In August 2021, the American Academy of Pediatrics (AAP) issued an interim guidance and strongly supports consideration for use of palivizumab in patients who would be candidates per current eligibility recommendations. The AAP recognizes the need for flexible approaches that may include early initiation of palivizumab for the respiratory syncytial virus (RSV) prior to the typically fall onset. Clinicians should evaluate the need for palivizumab on at least a monthly basis. https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/
- There is variability in the onset and offset of RSV season. Generally, it runs from November to April* within the continental US. A maximum of 5 doses during RSV season provides 6 months of RSV prophylaxis.
- In regions experiencing high rates of RSV circulation, consistent with a typical fall-winter season, coverage may be provided if surveillance data from the CDC indicate a high percent positivity rate for RSV testing in the area.
- The RSV season is determined when RSV is detected at high rates. High rates are defined by statewide or local positivity rates of:
  - > 3% polymerase chain reaction (PCR) positivity rate average over 2 consecutive weeks AND/OR
  - > 10% antigen test positivity rate average over 2 consecutive weeks
- A total of 5 monthly doses beginning in November* will provide protection for most infants through April* and is recommended for most areas in the US.
- Alaska:
  - Due to the varied epidemiology of RSV infection, clinicians can use RSV surveillance data by the state of Alaska to determine the onset and offset of RSV season.
- Florida:
  - Data from the Florida Department of Health can be used to determine the onset and offset of RSV season in different regions of Florida.
- Native American Indian infants:
  - There is limited information about the burden of RSV infection among American Indian populations. Prophylaxis can be considered for Navajo and White Mountain Apache infants in the first year of life.
- Despite differences in onset and offset of RSV infection in some states or regions, only a maximum of 5 doses will be approved during RSV season. If prophylaxis is initiated later in the RSV season, the infant or child will receive less than 5 doses. For example, if prophylaxis is initiated in January, the fourth and final dose will be administered in April. For eligible infants born during RSV season, fewer than 5 monthly doses may be needed.

* *The typical RSV season may not be applicable in all locations for the reasons above.*

CLINICAL CRITERIA FOR APPROVAL

- **Technicians**: Do not approve. You may obtain the requested criteria information listed and escalate to pharmacist for review.
- **Pharmacists**: Approve the correct strength based on patient weight (15 mg/kg).

Synagis may be approved in the following scenarios:

Infant/Child Age at Start of RSV Season	Criteria
< 12 months (1st year of life)	• GA < 29 wks, 0 d (otherwise healthy); **OR** • Profoundly immunocompromised
≤ 12 months (1st year of life)	• CHD (hemodynamically *significant*) with *acyanotic* HD on CHF medications and will require cardiac surgery or with moderate to severe PH. For *cyanotic* heart defects consult a pediatric cardiologist; **OR** • CLD of prematurity (GA < 32 wks, 0 d and > 21% O2 x first 28 d after birth); **OR** • Anatomic pulmonary abnormalities, or neuromuscular disorder, or congenital anomaly that impairs the ability to clear upper airway secretions; **OR** • CF with CLD and/or nutritional compromise
> 12 months (2nd year of life)	• CLD of prematurity (GA < 32 wks, 0 d and > 21% O2 x first 28 d after birth) and medical support (chronic steroids, diuretic therapy, or supplemental O2) within 6 months before start of 2nd RSV season; **OR** • CF with severe lung disease* or weight for length < 10th percentile
< 24 months (2nd year of life)	• Cardiac transplant during RSV season; **OR** • Already on prophylaxis and eligible: give post-op dose after cardiac bypass or after ECMO; **OR** • Profoundly immunocompromised

GA=gestational age; d=day; CF=cystic fibrosis; CHD=congenital heart disease; CHF=congestive heart failure; CLD=chronic lung disease; ECMO=extracorporeal membrane oxygenation; HD=heart disease; O_2=oxygen; PH=pulmonary hypertension; wks=weeks

*Examples of severe lung disease: previous hospitalization for pulmonary exacerbation in the first year of life, abnormalities on chest radiography (chest X-ray), or chest computed tomography (chest CT) that persist when stable.

*Examples of profoundly immunocompromised: HIV, Cancer - receiving chemotherapy, organ transplant receiving immunosuppressant therapy.

ADDITIONAL INFORMATION TO AID IN THE FINAL DETERMINATION

Synagis® will **not** be approved in the following scenarios:

Infant/Child Age at Start of RSV Season	Deny
> 12 months (2nd year of life)	• Based on prematurity alone • CLD *without* medical support (chronic systemic steroids, diuretic therapy, or supplemental O2) • CHD • Otherwise healthy children in 2nd year of life
Any age	• Outpatient RSV infection or breakthrough RSV hospitalization** • Hemodynamically *insignificant* CHD*** • CHD lesions corrected by surgery (unless on CHF meds) • CHD and mild cardiomyopathy not on medical therapy • CHD in 2nd year of life
No specific age defined	• GA ≥ 29 wks, 0 d (otherwise healthy) • Asthma prevention • Reduce wheezing episodes • Down Syndrome • CF (otherwise healthy) • Healthcare-associated RSV disease****

CLD=chronic lung disease; CHD=congenital heart disease; CHF=congestive heart failure; GA=gestational age; CF=cystic fibrosis

**If any infant or child is receiving palivizumab prophylaxis and experiences an outpatient RSV infection of breakthrough RSV hospitalization, discontinue palivizumab, because the likelihood of a second RSV hospitalization in the same season is extremely low.

***Examples of hemodynamically *insignificant* CHD: secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, patent ductus arteriosus.

**** No rigorous data exist to support palivizumab use in controlling outbreaks of health care-associated disease; palivizumab use is not recommended for this purpose.

RUBRACA® (RUCAPARIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Ovarian Cancer (epithelial ovarian, fallopian tube, or primary peritoneal cancer)**

- Patient must be 18 years of age or older; **AND**
- Patient has not received prior treatment with a PARP-inhibitor inhibitor (i.e., olaparib, niraparib, talazoparib) prior to initiating therapy; **AND**
- Patient must not have untreated or symptomatic CNS metastases; **AND**
- Must be used as a single agent; **AND**
- Patient must have a deleterious BRCA mutation (germline and/or somatic) as detected by an FDA-approved test; **AND**
  - Patient has advanced, persistent or recurrent disease; **AND**
  - Patient must have received treatment with two or more prior lines of chemotherapy; **OR**
- Patient is in complete or partial response to platinum-based chemotherapy (e.g., platinum-sensitive); **AND**
  - Used for maintenance treatment of recurrent disease

Diagnosis of **Prostate Cancer**

- Patient must be 18 years of age or older; **AND**
- Patient has not received prior treatment with a PARP-inhibitor inhibitor (i.e., olaparib, niraparib, talazoparib) prior to initiating therapy; **AND**
- Patient must not have untreated or symptomatic CNS metastases; **AND**
- Must be used as a single agent; **AND**
- Patient must have a deleterious BRCA mutation (germline and/or somatic) as detected by an FDA-approved test; **AND**
- Patient has metastatic castration-resistant prostate cancer (mCRPC); **AND**
- Patient has been previously treated with androgen receptor-directed therapy (e.g., enzalutamide, abiraterone, etc.); **AND**
  - Patient has been treated with taxane-based chemotherapy; **OR**
  - Patient is not fit for taxane-based chemotherapy; **AND**
    - Patient received prior novel hormone therapy; **AND**
    - Patient had no prior docetaxel OR patient received prior docetaxel and has no visceral metastases present; **AND**
- Patient is receiving a gonadotropin-releasing hormone (GnRH) analog concurrently or had a prior bilateral orchiectomy

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., Development of myelodysplastic syndrome/acute myeloid leukemia [MDS/AML]), etc.

RUXIENCE (RITUXIMAB-PVVR)

Length of Authorization:	6 months, may be renewed • Maintenance therapy for oncology indications (excluding mantle cell lymphoma and hairy cell leukemia) may be renewed for up to a maximum of 2 years – Mantle cell lymphoma may be renewed until disease progression or intolerable toxicity – Hairy cell leukemia may not be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Note: For Core Formulary, Ruxience is non-formulary.

Diagnosis of **chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)**

- Patient age is 18 years or older; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive; **AND**
- Used in combination with fludarabine and cyclophosphamide (FC); **OR**
- Patient has disease that is ***without*** del(17p)/TP53 mutation; **AND**
  - Used as first-line therapy in combination with **ONE** of the following:
    - Bendamustine (*patients ≥ 65 years, or younger patients with or without significant comorbidities; excluding use in frail patients [i.e., not able to tolerate purine analogs]*);
    - Fludarabine (patient is without del(11q) and is < 65 years without significant comorbidities); **OR**
  - Used as subsequent therapy in one of the following settings or in combination with one of the following:
    - Alemtuzumab
    - Bendamustine (patients < 65 years without significant comorbidities)
    - Chlorambucil (patients ≥ 65 years or younger patients with significant comorbidities)
    - High-dose Methylprednisolone
    - Idelalisib
    - Lenalidomide
    - Venetoclax
    - PCR (pentostatin, cyclophosphamide, and rituximab); **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient has disease **WITH** del(17p)/TP53 mutation; **AND**
  - Used as first-line therapy in one of the following settings or in combination with:
    - Alemtuzumab
    - High-dose Methylprednisolone; **OR**
  - Used as subsequent therapy in one of the following settings or in combination with:
    - Alemtuzumab
    - High-dose Methylprednisolone
    - Idelalisib
    - Lenalidomide
    - Venetoclax; **OR**
- Used as first line therapy for histologic (Richter's) transformation to diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, and vincristine-based regimens or as a component of OFAR (oxaliplatin, fludarabine, cytarabine, and rituximab).

Diagnosis of **Non-Hodgkin lymphomas (NHL), including the following:**

- Patient age is 18 years or older (unless otherwise noted); **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive; **AND**
- AIDS-related B-Cell Lymphoma
  - Disease is related to Burkitt Lymphoma or diffuse large B-cell lymphoma (including HHV-8 DLBCL, not otherwise specified)
- Burkitt Lymphoma
  - Used in combination with other chemotherapy.
- Castleman Disease
  - Patient has multicentric disease; **OR**
  - Patient has unicentric disease; **AND**
    - Used as second-line therapy for relapsed or refractory disease; **OR**
    - Used for unresectable disease or patients with symptoms after resection.
- Diffuse large B-cell lymphoma
- Low-grade or follicular lymphoma
- Gastric and non-gastric MALT lymphoma
- High-grade B-cell lymphoma
- Mantle cell lymphoma
- Nodal and splenic marginal zone lymphoma
- Histologic transformation of follicular or nodal marginal zone lymphoma to diffuse large B-cell lymphoma
- Post-transplant lymphoproliferative disorder (PTLD) (B-cell type)
  - Patient has had solid organ transplant or allogeneic hematopoietic stem cell transplantation

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Pediatric Aggressive Mature B-Cell Lymphomas
  - Patient age is 18 years and under*; **AND**
  - Used in combination with chemotherapy

  * Pediatric aggressive mature B-cell lymphoma may be applicable to adolescent and young adult (AYA) patients older than 18 years of age and less than 39 years of age, who are treated in the pediatric oncology setting.
- Primary cutaneous B-cell lymphomas

Diagnosis of **Hairy Cell Leukemia**

- Patient age is 18 years old or older; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive; **AND**
- Used in combination with cladribine as initial therapy; **OR**
- Used for relapsed or refractory disease or in patients with a less than complete response (CR) to initial therapy

Diagnosis of **Granulomatosis with Polyangiitis (GPA) (Wegener's granulomatosis) and Microscopic Polyangiitis (MPA)**

- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast tofacitinib, baricitinib, upadacitinib); **AND**
- Patient is at least 2 years of age; **AND**
- Used in combination with glucocorticoids (e.g., prednisone, methylprednisolone).

Diagnosis of **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma**

- Patient age is 18 years or older; **AND**
- Patient does not have a severe, active infection**; AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infusion-related reactions, tumor lysis syndrome (TLS), severe mucocutaneous reactions, progressive multifocal leukoencephalopathy (PML), hepatitis B virus reactivation, serious bacterial, fungal, or viral infections, cardiovascular adverse reactions (e.g., ventricular fibrillation, myocardial infarction, cardiogenic shock, cardiac arrhythmias), renal toxicity, bowel obstruction or perforation, etc.; **AND**

Oncology Indications

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **OR**

Granulomatosis with Polyangiitis (GPA) (Wegener's granulomatosis) and Microscopic Polyangiitis (MPA)

- Disease response as indicated by disease control and improvement in signs and symptoms of condition compared to baseline; **AND**
- A decrease frequency in the occurrence of major relapses (defined by the reappearance of clinical and/or laboratory signs of vasculitis activity that could lead to organ failure or damage, or could be life threatening)

RUZURGI® (AMIFAMPRIDINE)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Lambert- Eaton Myasthenic Syndrome (LEMS)**

- Patient is at least 6 years or older; **AND**
- Will be used as a single agent or in combination with stable doses of peripherally acting cholinesterase inhibitors (e.g., pyridostigmine) or oral immunosuppressants (e.g., glucocorticoids); **AND**
- Patient has no past medical history of seizures or comorbidities increasing the risk of seizure (e.g., no active brain metastases, etc.); **AND**
- Patient is not on other medications which lower the seizure threshold (e.g., bupropion, clozapine, fluoroquinolones, etc.); **AND**
- Will not be used in combination with other aminopyridine type potassium-channel-blocker medications (e.g., dalfampridine, amifampridine, etc.); **AND**
  - Patient does not have a concurrent diagnosis of small cell lung cancer (SCLC); **OR**
  - Patient has SCLC that was previously treated and continues to have symptomatic disease; **AND**
- Patient has symptoms including progressive proximal lower extremity weakness, oculobulbar findings, recovery of lost deep tendon reflexes or improvement in muscle strength with brief muscle activation; **AND**
- Patient diagnosis is confirmed based on the following neurophysiological-electrodiagnostic and antibody testing:
  - Patient has a normal sensory study with low compound motor action potential (CMAP) which increase in amplitude ≥60% following 10s maximal isometric muscle activation (i.e., post-exercise facilitation) or during high-frequency nerve stimulation (RNS) testing; **AND**
  - Positive anti-P/Q type voltage-gated calcium channel (VGCC) antibody test; **AND**
- Patient is ambulatory and/or able to ambulate; **AND**
- Physician has assessed baseline disease severity including muscle weakness, reflexes, and using either the Quantitative Myasthenia Gravis (QMG) score or the triple-timed up-and-go [3TUG] test

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., seizures, severe hypersensitivity); **AND**
- Disease response as indicated by an improvement, stabilization or slowing in decline, when compared to baseline, in either the signs and symptoms of disease such as muscle weakness, reflexes, autonomic dysfunction **or** as evidenced on a disease activity scoring tool (e.g., QMG score, 3TUG time).

RYBREVANT™ (AMIVANTAMAB-VMJW)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years of age; **AND**
- Patient has been instructed/counseled on limiting sun exposure and the use of protective clothing and/or broad-spectrum UVA/UVB sunscreen; **AND**
- Patient does not have untreated brain metastases (clinically stable asymptomatic brain metastases are allowed); **AND**
- Patient has locally advanced or metastatic disease; **AND**
- Patient disease has epidermal growth factor receptor (EGFR) exon 20 insertion mutations as detected by an FDA-approved or CLIA compliant test; **AND**
- Patient has disease progression on or subsequent to platinum-based chemotherapy

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, interstitial lung disease, pneumonitis, dermatologic reactions (e.g., acneiform dermatitis and toxic epidermal necrolysis), ocular toxicity, etc.

RYDAPT® (MIDOSTAURIN)

Length of Authorization:	• Acute Myeloid Leukemia and Myeloid/Lymphoid Neoplasms: coverage will be provided for six months and may not be renewed – Patients with residual disease requiring re-induction may repeat two cycles of induction therapy for a total of 8 cycles of therapy (4 cycles of induction and 4 cycles of consolidation) • Systemic Mastocytosis and MDS/MPN Overlap Neoplasms: 6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Acute Myeloid Leukemia (AML)**

- Patient must be 18 years of age or older; **AND**
- Not used in combination with other FMS-like tyrosine kinase (FLT)-inhibitors (e.g., gilteritinib, sorafenib); **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., ketoconazole, grapefruit juice, clarithromycin, diltiazem), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient must be diagnosed with AML (excluding acute promyelocytic leukemia); **AND**
- Patient's disease is FMS-like tyrosine kinase-3 (FLT3) mutation-positive (**includes ITD or TKD positive mutations**), as confirmed by an FDA-cleared or CLIA-compliant test; **AND**
  - Used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation therapy; **OR**
  - Used in combination with cytarabine and daunorubicin as re-induction therapy after induction with cytarabine for patients with residual disease; **OR**
  - Used post-remission in combination with cytarabine; **OR**
  - Used for relapsed/refractory disease as a component of repeating the initial induction regimen if there has been a late relapse (≥ 12 months)

Diagnosis of **Systemic Mastocytosis**

- Patient must be 18 years of age or older; **AND**
- Not used in combination with other FMS-like tyrosine kinase (FLT)-inhibitors (e.g., gilteritinib, sorafenib); **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., ketoconazole, grapefruit juice, clarithromycin, diltiazem), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as single agent therapy; **AND**
- Patient has a diagnosis of one of the following:
  - Aggressive systemic mastocytosis (ASM); **OR**
  - Systemic mastocytosis with associated hematologic neoplasm (SM-AHN); **OR**
  - Mast cell leukemia (MCL)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Myelodysplastic/Myeloproliferative MDS/MPN) Overlap Neoplasms**

- Patient must be 18 years of age or older; **AND**
- Not used in combination with other FMS-like tyrosine kinase (FLT)-inhibitors (e.g., gilteritinib, sorafenib); **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., ketoconazole, grapefruit juice, clarithromycin, diltiazem), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as single agent therapy; **AND**
- Used for the treatment of chronic myelomonocytic leukemia (i.e., CMML-0, CMML-1, CMML-2); **AND**
- Patient has CMML-associated systemic mastocytosis (SM-AHN) and KIT816V mutation

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**

- Patient must be 18 years of age or older; **AND**
- Not used in combination with other FMS-like tyrosine kinase (FLT)-inhibitors (e.g., gilteritinib, sorafenib); **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., ketoconazole, grapefruit juice, clarithromycin, diltiazem), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used for myeloid or lymphoid neoplasms with eosinophilia; **AND**
  - Patient has FGFR1 or FLT3 rearrangements in chronic phase; **AND**
    - Used as a single agent; **OR**
  - Patient has FGFR1 or FLT3 rearrangements in blast phase (**Note: May be used in mixed lineage neoplasms as well**); **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic transplant in transplant eligible patients

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: pulmonary toxicity (interstitial lung disease or pneumonitis) **AND**

Systemic Mastocytosis and MDS/MPN Overlap Neoplasms

- Disease response with treatment as defined by stabilization of disease or decrease in the size of tumor or tumor spread.

Acute Myeloid Leukemia (AML)/ Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes

- Coverage may NOT be renewed (**Note**: Patients with residual AML disease requiring re-induction may repeat two cycles of induction for a total of 8 cycles of therapy).

RYLAZE™ (ASPARAGINASE ERWINIA CHRYSANTHEMI [RECOMBINANT]-RYWN)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Acute lymphoblastic leukemia (ALL)/lymphoblastic lymphoma (LBL)**

- Patient is at least 1 month of age; **AND**
- Patient must not have a history of serious pancreatitis, thrombosis, or hemorrhagic events with prior L-asparaginase therapy; **AND**
- Used as a component of multi-agent chemotherapy; **AND**
- Used as a substitute for E. coli-derived asparaginase (e.g., pegaspargase) in cases of hypersensitivity

CLINICAL CRITERIA FOR RENEWAL

- Disease stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hypersensitivity reactions including anaphylaxis, pancreatitis, thrombosis, hemorrhage, hepatotoxicity, etc.

RYPLAZIM® (PLASMINOGEN, HUMAN-TVMH)

Length of Authorization:	12 weeks initially • In patients with complete response, coverage will be renewed annually thereafter. • In patients with less than complete response, coverage will be renewed for an additional 12 weeks to optimize frequency of administration
Initiative:	SPC: Miscellaneous: Pa Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Plasminogen Deficiency Type 1 (Hypoplasminogenemia)**

- Patient is at least 11 months of age; **AND**
- Patient's blood pressure is controlled prior to initiation of treatment**; AND**
- Patient has healing of lesions or wounds suspected as a source of a recent bleeding event prior to initiating therapy**; AND**
- Patient has had baseline plasminogen activity measured prior to therapy and plasminogen activity level is ≤ 45% (**Note**: If patient is receiving plasminogen supplementation with fresh frozen plasma, allow for a 7-day washout period before obtaining baseline plasminogen activity level)**; AND**
- Patients on concomitant therapy with anticoagulants, antiplatelet drugs, or other agents which may interfere with normal coagulation will be monitored during and for 4 hours after infusion of Ryplazim®; **AND**
- Patient has a history of visible or non-visible lesions (e.g., confirmed by computed tomography, magnetic resonance imaging, ultrasound)

CLINICAL CRITERIA FOR RENEWAL

- Patient has demonstrated a beneficial response to therapy (i.e., resolution of lesions); **OR**
- Patient's lesions have not resolved after an initial 12 weeks of therapy **or** there are new or recurrent lesions; **AND**
  - Patient may increase dosage frequency, as outlined below, in one day increments every 4–8 weeks up to the max dosing frequency (i.e., every two days); **AND**
  - Re-assess trough plasminogen activity level if, after 12 additional weeks of dose optimization, no clinical effect has been noted; **AND**
    - If trough plasminogen activity level is < 10% above baseline, repeat trough. If low plasminogen is confirmed **and** no clinical effect has been demonstrated, consider treatment discontinuation
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe bleeding, respiratory distress, anaphylaxis and severe allergic reactions, etc.

SAMSCA® (TOLVAPTAN)

Length of Authorization:	30 days; may be renewed
Initiative:	SPC: Miscellaneous: PA required (IE 2462/ NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Hyponatremia**:

- Patient is at least 18 years of age; **AND**
- Documentation the medication was initiated or re-initiated in a hospital; **AND**
- Confirmation the patient does not have liver disease (including cirrhosis); **AND**
- Patient will not be on concomitant therapy with **strong** CYP3A–inhibitors (e.g., ketoconazole, nefazodone, clarithromycin, etc.); **AND**
- Patient will not be on concomitant therapy with a V2-agonist (e.g., desmopressin (DDAVP)); **AND**
- Patient will not be on concomitant therapy with a **strong** CYP3A– inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifampin, etc) [*Note: Patients taking Samsca, if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented*]; **AND**
- Patient will not be on concomitant therapy with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented:
  - **Moderate** CYP3A–inhibitors (e.g., atazanavir, ciprofloxacin, erythromycin, grapefruit juice, fluconazole, etc.
  - P-gp inhibitors (e.g., cyclosporine, etc); **AND**
- Patient is able to sense or respond to thirst; **AND**
- Patient does not have hypovolemia or hypovolemic hyponatremia; **AND**
- Patient does not have anuria; **AND**
- Patient does NOT need intervention to raise serum sodium urgently to prevent or treat serious neurological symptoms; **AND**
- Confirmation the patient has not been on continuous therapy which exceeds 30 consecutive days; **AND**
- Confirmation the patient has clinically significant hypervolemic or euvolemic hyponatremia as evidenced by one of the following:
  - Serum sodium < 125 mEq/L; **OR**
  - Patient is symptomatic (dizziness, gait disturbances, forgetfulness, confusion, lethargy, seizures, impaired mental status or coma) and resisted correction with fluid restriction

CLINICAL CRITERIA FOR RENEWAL

- Patient has responded to therapy (achieved the desired level of serum sodium); **AND**
- Confirmation the patient has not been on continuous therapy which exceeds 30 consecutive days**; AND**
- Absence of unacceptable toxicity from the drug (e.g., osmotic demyelination, liver injury or ALT/AST ever exceeded 3 times the ULN during treatment, dehydration, hypovolemia)

SAPHNELO™ (ANIFROLUMAB-FNIA)

Length of Authorization:	12 months, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Systemic Lupus Erythematosus (SLE)**

- Patient is 18 years of age or older; **AND**
- Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
- Patient must not have a clinically significant active infection; **AND**
- Patient will not receive a live or live-attenuated vaccine concurrently with treatment; **AND**
- Will not be used in combination with other biologic therapies, including B-cell targeted therapies (e.g., belimumab), cyclophosphamide, or voclosporin; **AND**
- Will be used in combination with standard therapy (e.g., anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives); **AND**
- Patient does not have any of the following exclusion criteria:
  - Severe active central nervous system lupus
  - Severe active lupus nephritis; **AND**
- Patient has a confirmed diagnosis of SLE with at least 4 diagnostic features (see list of diagnostic SLE criteria below*), one of which must include a positive autoantibody test (e.g., anti-nuclear antibody [ANA] greater than laboratory reference range and/or anti-double-stranded DNA [anti-dsDNA] greater than twice the laboratory reference range if tested by ELISA); **AND**
- Patient has failed to respond adequately to at least one (1) standard therapy such as anti-malarials, corticosteroids, or immunosuppressives; **AND**
- Patient has moderate to severe disease as evidenced by ALL of the following:
  - Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI 2K) score of ≥ 6
  - British Isles Lupus Assessment Group-2004 (BILAG) B organ domain score of ≥ 2
  - Physician's Global Assessment [PGA] score of ≥ 1

*Systemic Lupus Erythematosus Diagnostic Criteria
Patient must have at least 4 out of 11 diagnostic SLE features:

1. Malar rash
2. Discoid rash
3. Photosensitivity
4. Oral ulcers
5. Nonerosive arthritis (involving 2 or more peripheral joints)
6. Pleuritis/pericarditis
   - Pleuritis – history of pleuritic pain or rubbing heard by a physician or evidence of pleural effusion
   - Pericarditis – documented by electrocardiogram or rubbing heard by a physician or evidence of pericardial effusion
7. Renal disorder
   - Persistent proteinuria > 0.5 grams/day or > 3+ on urine dipstick
   - Cellular casts (red cell, hemoglobin, granular, tubular, or mixed)
8. Seizures/psychosis
9. Hematologic disorder
   - Hemolytic anemia with reticulocytosis
   - Leukopenia < 4,000/mm^3 on ≥ 2 occasions
   - Lymphopenia < 1,500/mm^3 on ≥ 2 occasions
   - Thrombocytopenia < 100,000/mm^3 in the absence of offending drugs
10. Immunologic disorder
    - Presence of anti-Sm or antiphospholipid antibodies
    - Presence of anti-double-stranded DNA [anti-dsDNA] greater than twice the laboratory reference range if tested by ELISA
11. Positive anti-nuclear antibody [ANA] greater than laboratory reference range

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: serious infections, malignancy, severe hypersensitivity reactions/anaphylaxis, etc.; **AND**
- Adequate documentation of disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline:
  - No worsening in the SLEDAI-2K score where worsening is defined as > 0 point increase; **OR**
  - Reduction of baseline BILAG-2004 B to C/D, and no BILAG-2004 worsening in other organ systems, as defined by ≥ 2 new BILAG-2004 B; **OR**
  - No worsening (< 0.30-point increase) in Physician's Global Assessment (PGA) score; **OR**
  - Seroconverted (negative)

SARCLISA® (ISATUXIMAB-IRFC)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma**

- Patient is at least 18 years of age; **AND**
- Patient is not refractory to previous treatment with anti-CD38 therapy (i.e., daratumumab) (**Note**: refractory is defined as progression on or within 60 days after the end of prior anti-CD38 treatment OR failure to achieve at least minimum response to treatment); **AND**
- Patient has relapsed, refractory, or progressive disease; **AND**
  - Used in combination with pomalidomide and dexamethasone after at least two prior therapies including lenalidomide and a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib, etc.); **OR**
  - Used in combination with carfilzomib and dexamethasone in patients who have received 1 to 3 prior lines therapy

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe infusion-related reactions, neutropenia, secondary primary malignancies, etc.

SCENESSE (AFAMELANOTIDE)

Length of Authorization:	Initial: 6 months, renewal: 12 months
Initiative:	SPC: Miscellaneous: PA required (IE 2462/ NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Erythropoietic Protoporphyria (EPP):**

- Patient must be 18 years or older; **AND**
- Patient does not have any malignant or premalignant skin lesions (e.g., melanoma, dysplastic nevus syndrome, Bowen's disease, basal cell or squamous cell carcinomas, etc.) as evidenced by a baseline full body skin examination for pre-existing skin lesions; **AND**
- Patient has a definitive diagnosis of erythropoietic protoporphyria as confirmed by elevated free protoporphyrin in peripheral erythrocytes and/or by the identification of pathogenic variants in ferrochelatase (FECH) on molecular genetic testing; **AND**
- Used to increase the pain free light exposure in patients with a history of phototoxic reactions; **AND**
- Patient will continue to maintain sun and light protection measures during treatment to prevent phototoxic reactions.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe skin darkening); **AND**
- Disease response as evidenced by an increase in pain free time during light exposure and/or a decrease in the number of phototoxic reactions; **AND**
- Patient is monitored with full body skin examinations for pre-existing or new lesions.

SCULPTRA® (INJECTABLE POLY-L-LACTIC ACID)

Length of Authorization:	12 months
Initiative:	SPC: Miscellaneous (IE 2462/ NCPDP 75)

CLINICAL CRITERIA FOR APPROVAL

Patient has a diagnosis of facial fat loss (lipoatrophy) due to human immunodeficiency virus (HIV).

SEDATIVE HYPNOTIC AGENTS

Length of Authorization:	6 Months Hetlioz: 3 months, may be renewed
Initiative:	MNC: Sedative Hypnotics (IE 2462/ NCPDP 75, 50081 and 2194) SPC: Sedative Hypnotics (IE 2462/ NCPDP 75, 50081 and 2194)- Hetlioz

CLINICAL CRITERIA FOR INITIAL APPROVAL

HETLIOZ

Diagnosis of **Non-24-Hour Sleep-Wake Disorder (Non-24)**

- Patient age is 18 years of age or older; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP1A2 inhibitors (e.g., fluvoxamine, ciprofloxacin, etc.); **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has complete blindness (i.e., no perception of light); **AND**
- Patient has a documented diagnosis of Non-24-Hour Sleep-Wake Disorder* (aka Free Running Disorder); **AND**
- Documented baseline nighttime sleep time and daytime nap time per sleep log or diary (renewal will require current log/diary results); **AND**
- Must be prescribed by a sleep specialist, psychiatrist, or neurologist, or sleep specialist, neurology, or psychiatry consult; **AND**
- Documented failure, contraindication, or ineffective response to a minimum (3) month trial on previous therapy with melatonin **AND** ramelteon.

Diagnosis of **Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)**

- Patient is at least 3 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP1A2 inhibitors (e.g., fluvoxamine, ciprofloxacin, etc.); **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, etc.); **AND**
- Patient has a documented diagnosis of SMS**; **AND**
- Documented baseline nighttime total sleep time and nighttime sleep quality per sleep log or diary (renewal will require current log/diary results)

* Diagnostic criteria for Non-24-Hour Sleep-Wake Rhythm Disorder (all of the following)
• There is a history of insomnia, excessive daytime sleepiness, or both, which alternate with asymptomatic episodes, due to misalignment between the 24-hour light-dark cycle and the non-entrained endogenous circadian rhythm of sleep-wake propensity • Symptoms persist over the course of at least three months. • Daily sleep logs and actigraphy for at least 14 days, preferably longer for blind persons, demonstrate a pattern of sleep and wake times that typically delay each day, with a circadian period that is usually longer than 24 hours. • The sleep disturbance is not better explained by another current sleep disorder, medical or neurological disorder, mental disorder, medication use, or substance use disorder.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

HETLIOZ (*CONTINUED*)

** Diagnostic criteria for Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS) [11]
• One or more of the following clinical features: – Subtly distinctive facial appearance that becomes more evident with age (e.g. broad square-shaped face, brachycephaly, prominent forehead, synophrys, mildly upslanted palpebral fissures, deep-set eyes, broad nasal bridge, midfacial retrusion, short, full-tipped nose with reduced nasal height, micrognathia in infancy changing to relative prognathia with age, distinct appearance of the mouth with fleshy everted vermilion of the upper lip) – Mild-to-moderate infantile hypotonia with feeding difficulties and failure to thrive – Peripheral neuropathy – Some level of developmental delay and/or intellectual disability, including early speech delays with or without associated hearing loss – A distinct neurobehavioral phenotype that includes stereotypic and maladaptive behaviors and sleep disturbance – Short stature (prepubertal) – Minor skeletal anomalies, including brachydactyly – Ophthalmologic abnormalities – Otolaryngologic abnormalities; **AND** • Molecular genetic testing that reveals: – A heterozygous deletion of 17p11.2; **OR** – A heterozygous pathogenic variant involving RAI1

STEP THERAPY (NO GRANDFATHERING)

AMBIEN, AMBIEN CR AND SONATA [BRAND NAME AGENTS]

- Trial of eszopiclone; **AND**
- Trial and failure of zolpidem and/or zaleplon.

EDLUAR SL AND INTERMEZZO

- Patient trial and failure of Zolpidem or Ambien.

LUNESTA

- Patient trial and failure of Zolpidem or Zaleplon.

BELSOMRA, DAYVIGO, AND ROZEREM

- Patient trial and failure of Zolpidem, Zaleplon or eszopiclone; **OR**
- Patient has a history of substance abuse (For Rozerem only).

CLINICAL CRITERIA FOR RENEWAL

HETLIOZ

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: impairment of activities requiring complete mental alertness, etc.; **AND**

Non-24-Hour Sleep-Wake Disorder (Non-24)

- Disease response as indicated by improvement in nighttime sleep time compared to baseline **or** reduction in daytime nap time compared to baseline per current sleep log or diary.

Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)

- Disease response as indicated by improvement in nighttime sleep time compared to baseline OR improvement in nighttime sleep quality compared to baseline per current sleep log or diary

SENSIPAR® (CINACALCET)

Length of Authorization:	3 months initial, 1 year for renewals
Initiative:	SPC: Miscellaneous: PA required (IE 2462/ NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Secondary Hyperparathyroidism (HPT):**

- Patient is at least 18 years of age; **AND**
- Patient has a diagnosis of chronic kidney disease (CKD); **AND**
- Patient is currently undergoing dialysis; **AND**
- Baseline(pre-treatment) intact parathyroid hormone (iPTH) >300 pg/ml **or** bio-intact parathyroid hormone(biPTH) >160 pg/ml; **AND**
- Baseline serum calcium (Ca) >8.4 mg/dL (corrected for albumin); **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with **one** of the following vitamin D agents (e.g., calcitriol, doxercalciferol, paricalcitol, etc.); **AND**
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with **one** of the following phosphate binders: (e.g., calcium carbonate, calcium acetate, sevelamer hydrochloride, sevelamer carbonate, lanthanum carbonate, etc.); **AND**
- Must be prescribed by a nephrologist or endocrinologist, or by nephrology or endocrinology consult.

Diagnosis of **Parathyroid Carcinoma (PC):**

- Patient is at least 18 years of age; **AND**
- Confirmation the patient has a diagnosis of Parathyroid Carcinoma; **AND**
- Confirmation the patient has hypercalcemia as defined by baseline serum calcium (Ca) >10 mg/dL (corrected for albumin); **AND**
- Must be prescribed by or in consultation with an oncologist, nephrologist, or endocrinologist.

Diagnosis of **Primary Hyperparathyroidism (HPT):**

- Patient is at least 18 years of age; **AND**
- Confirmation the patient has severe hypercalcemia as defined by baseline (pre-treatment) serum calcium (Ca) > 12 mg/dL (corrected for albumin); **AND**
- Confirmation the parathyroidectomy is indicated but patient is unable to undergo parathyroidectomy; **AND**
- Must be prescribed by or in consultation with a nephrologist or endocrinologist.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., hypocalcemia, seizures, hypotension, worsening heart failure, arrhythmia, adynamic bone disease); **AND**

Secondary Hyperparathyroidism (HPT)

- Adequate documentation of disease response as indicated by improvement of intact parathyroid hormone (iPTH) levels from baseline; **AND**
- Current intact parathyroid hormone (iPTH) >150 pg/ml; **AND**
- Current serum calcium (Ca) >7.5 mg/dL **and** the patient does not have symptoms of hypocalcemia

Parathyroid Carcinoma (PC)

- Adequate documentation of disease response as indicated by improvement of serum calcium (Ca) from baseline; **AND**
- Current serum calcium (Ca) >8.4 mg/dL

Primary Hyperparathyroidism (HPT)

- Adequate documentation of disease response as indicated by improvement of serum calcium (Ca) from baseline; **AND**
- Current serum calcium (Ca) >8.4 mg/dL

SIGNIFOR®/SIGNIFOR® LAR (PASIREOTIDE)

Length of Authorization:	6 Months, may be renewed
Initiative:	SPC: Hormonal Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cushing's disease**

- Request is for Signifor®; **AND**
- Patient is at least 18 years old; **AND**
- Will not be used in combination with the intramuscular formulation of pasireotide (i.e., Signifor® LAR); **AND**
- Confirmed diagnosis of endogenous Cushing's disease in which the patient's hypercortisolism is not a result of chronic administration of high dose glucocorticoids; **AND**
- Treatment of patient's disease with pituitary surgery has not been curative **or** the patient is not a candidate for or has refused pituitary surgery; **AND**
- Documentation of baseline 24-hour urinary free cortisol (UFC), fasting plasma glucose, hemoglobin A1c, liver tests, electrocardiogram (ECG), and gallbladder ultrasound prior to initiation of therapy; **AND**
- Patient baseline pituitary function (e.g., thyroid-stimulating hormone (TSH)/free T4, GH/IGF-1) has been evaluated prior to starting therapy; **AND**
- Patient is **not** Child-Pugh Class C

Diagnosis of **Cushing's disease**

- Request is for Signifor® LAR; **AND**
- Patient is at least 18 years old; **AND**
- Confirmation fasting plasma glucose, hemoglobin A1c, liver enzyme tests, ECG, serum magnesium and serum potassium have been evaluated prior to starting; **AND**
- Patients with diabetes mellitus have stable glycemic control and are on optimized anti-diabetic treatment prior to start of therapy; **AND**
- Patient does not have severe hepatic impairment (i.e., Child-Pugh Class C); **AND**
- Patient has not received a long-acting somatostatin analogue (e.g., octreotide LAR, lanreotide SR, lanreotide autogel, pasireotide LAR) within the last 4 weeks; **AND**
- Confirmed diagnosis of endogenous Cushing's disease in which the patient's hypercortisolism is not a result of chronic administration of high dose glucocorticoids or other physiologic conditions; **AND**
- Treatment of patient's disease with pituitary surgery has not been curative **OR** the patient is not a candidate for pituitary surgery; **AND**
- Baseline 24-hour UFC, Adrenocorticotropic hormone (ACTH), and/or serum cortisol level have been obtained (renewal will require reporting of current levels)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Acromegaly**

- Request is for Signifor® LAR; **AND**
- Patient is at least 18 years old; **AND**
- Confirmation fasting plasma glucose, hemoglobin A1c, liver enzyme tests, ECG, serum magnesium and serum potassium have been evaluated prior to starting; **AND**
- Patients with diabetes mellitus have stable glycemic control and are on optimized anti-diabetic treatment prior to start of therapy; **AND**
- Patient does not have severe hepatic impairment (i.e., Child-Pugh Class C); **AND**
- Patient has not received a long-acting somatostatin analogue (e.g., octreotide LAR, lanreotide SR, lanreotide autogel, pasireotide LAR) within the last 4 weeks; **AND**
- Patient diagnosis confirmed by elevated (age-adjusted) or equivocal serum IGF-1 as well as inadequate suppression of GH after a glucose load; **AND**
- Patient has a documented inadequate response to surgery and/or radiotherapy, or it is not an option for the patient **AND**
- Patient's tumor has been visualized on imaging studies (i.e., MRI or CT-scan); **AND**
- Baseline growth hormone (GH) and IGF-I blood levels have been obtained (renewals will require reporting current levels)

CLINICAL CRITERIA FOR RENEWAL

- Signifor®
  - Disease response as indicated by reduction in 24-hour UFC from baseline; **AND**
  - Absence of unacceptable toxicity from the drug (e.g., severe hypocortisolism [evidenced by weakness, fatigue, anorexia, nausea, vomiting, hypotension, hyponatremia, or hypoglycemia], uncontrolled hyperglycemia, bradycardia, QT prolongation, liver test elevations [elevations of alanine transaminase (ALT) of 5 times the upper limit of normal (ULN) or 5 times baseline], gallstones [cholelithiasis], pituitary hormone deficiency [evidenced by inadequate levels of (TSH)/free T4, GH/IGF-1])
- Signifor® LAR
  - Absence of unacceptable toxicity from the drug (e.g., severe adrenal insufficiency [evidenced by weakness, fatigue, anorexia, nausea, vomiting, hypotension, hyponatremia, or hypoglycemia]; uncontrolled hyperglycemia; bradycardia; QT prolongation; liver test elevations [elevations of ALT of 5 times the ULN or 5 times baseline]; or gallstones[cholelithiasis]); **AND**

Acromegaly

- Disease response as indicated by an improvement in signs and symptoms compared to baseline; **AND**
  - Reduction of GH by random testing to < 1.0 mcg/L; **OR**
  - Age-adjusted normalization of serum IGF-1

Cushing's disease

- Disease response indicated by reduction in UFC, plasma ACTH, and/or serum cortisol levels from baseline

SIRTURO® (BEDAQUILINE)

Length of Authorization:	6 months
Initiative:	MNC: Antimicrobial: TB (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Tuberculosis**, multi-drug resistant infection (MDR-TB) when other medications fail.

- Confirmation of failure of triple therapy or isolate is resistant.
- Must be administered in combination with AT LEAST 3 anti-TB drugs proven to be or at least 4 other drugs suspected of being effective against Mycobacterium tuberculosis isolate.

SKELETAL MUSCLE RELAXANTS

STANDARD FORMULARY CRITERIA

Length of Authorization:	1 year
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

AMRIX

- The patient must try and fail cyclobenzaprine

SMOKING CESSATION

Length of Authorization:	12 weeks
Initiative:	MNC: smoking cessation (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

CHANTIX

- Medication is prescribed for **Smoking Cessation**
- Patient is at least 18 years of age; **AND**
- Document any current or known history of depression, Generalized Anxiety Disorder, suicide attempt, or suicidal ideation; **AND**
- Prescriber is aware of the Black Box warning regarding serious neuropsychiatric events with use of Chantix®; **AND**
- Patient is enrolled in a smoking cessation program **OR** is receiving smoking cessation counseling (verbal or written attestation of participation in a program or counseling may be accepted from the prescriber, or from a pharmacist rendering the counseling). Pharmacist may call in for the prescriber to verify patient has been counseled and has met all criteria.

CLINICAL CRITERIA FOR RENEWAL

- Patient has completed 12 weeks of treatment **AND** continues to meet criteria above (A); **AND**
- Patient is free of any new or worsening symptoms of depression, anxiety, suicide attempts, or suicidal ideation; **AND**
- Patient is free of any hypersensitivity reactions or severe skin reactions (e.g., Stevens-Johnson or erythema multiform)

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

- If the diagnosis/indication provided is Tobacco Use Disorder or Nicotine Dependence, please confirm that the requested medication will be used for Smoking Cessation. Technicians: If Chantix® is being requested for cessation of any other nicotine product (e.g., chew, dip, e-cigarettes, gum, lozenge, snuff, spray, vaporizers, etc.), document and escalate the request to a clinical pharmacist.

SOGROYA® (SOMAPACITAN-BECO)

Length of Authorization:	12 months, may be renewed
Initiative:	SPC: Growth Hormone (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Growth Hormone Deficiency (GHD)**

- Patient is at least 18 years of age; **AND**
- Patient does not have a current acute critical illness after open heart surgery, abdominal surgery, or multiple accidental trauma; **AND**
- Patient does not have acute respiratory failure; **AND**
- Patient does not have severe hepatic impairment; **AND**
- Patient does not have active malignancy; **AND**
- Patient does not have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
- Patient has had a fundoscopic examination prior to initiating therapy and will be assessed at regular intervals thereafter; **AND**
- Patient has organic GHD with ≥ 3 documented pituitary hormone deficiencies and low serum IGF-1 levels (<-2.0 standard deviation score [SDS]); **OR**
- Patient has organic GHD with ≤ 2 documented pituitary hormone deficiencies, low serum IGF-1 levels (< 0 SDS), and deficient GH levels; **OR**
- Patient has a history of one of the following: hypothalamic-pituitary tumors, surgery, cranial irradiation, empty sella, pituitary apoplexy, traumatic brain injury, subarachnoid hemorrhage, autoimmune hypophysitis, or Rathke's cleft cyst; **AND**
  - Patient has high clinical suspicion of GHD; **AND**
  - Patient has low serum IGF-1 levels (< 0 SDS); **AND**
  - Patient has deficient GH levels; **OR**
- Patient is in transition from child-onset GHD; **AND**
  - Patient has organic GHD or congenital and/or genetic hypothalamic-pituitary defects with ≥ 3 documented pituitary hormone deficiencies and low serum IGF-1 levels (<-2.0 SDS); **OR**
  - Patient has organic GHD**§** with ≤ 2 documented pituitary hormone deficiencies, low serum IGF-1 levels (< 0 SDS), and deficient GH levels; **OR**
  - Patient has idiopathic isolated childhood GHD or suspected hypothalamic GHD; **AND**
    - Patient has high clinical suspicion of GHD; **AND**
    - Patient has low serum IGF-1 levels (< 0 SDS); **AND**
    - Patient has deficient GH levels

Examples of Organic, Congenital, or Genetic Hypothalamic Pituitary Defects
Organic: • Suprasellar mass with previous surgery and cranial irradiation **Congenital/Genetic:** • Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2) • GHRH receptor-gene defects • GH-gene defects • GH-receptor/post-receptor defects • Associated with brain structural defects • Single central incisor • Cleft lip/palate • Perinatal insults
Examples of Pituitary Hormones
• Adrenocorticotropic hormone (ACTH) • Antidiuretic hormone (ADH) • Follicle stimulating hormone (FSH) • Growth hormone (GH) • Luteinizing hormone (LH) • Thyroid stimulating hormone (TSH) • Prolactin
Adult GH Deficiency Determination/Testing
• Patient has deficient GH levels as confirmed by any one of the following tests: – Insulin tolerance test (ITT): < 5 mcg/L; **OR** – Macimorelin-stimulation test: < 2.8 mcg/L; **OR** – Glucagon-stimulation test: • ≤ 3 mcg/L for patients with BMI < 25 kg/m^2 • ≤ 3 mcg/L for patients with BMI 25-30 kg/m^2 with a high pre-test probability • ≤ 1 mcg/L for patients with BMI 25-30 kg/m^2 with a low pre-test probability • ≤ 1 mcg/L for patients with BMI > 30 kg/m^2

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include increased risk of neoplasms, intracranial hypertension, pancreatitis, glucose intolerance/development of diabetes mellitus, hypothyroidism, hypoadrenalism, severe hypersensitivity, fluid retention, lipohypertrophy/lipoatrophy, etc.; **AND**
- Patient has shown a beneficial response to treatment as evidenced by at least one of the following:
  - Improvement in quality of life based on Quality of Life in Adult Growth Hormone Deficiency Assessment (QoL-AGHDA); **OR**
  - Objective improvements in biochemistry, body composition, or bone mineral density

SOLIRIS® (ECULIZUMAB)

Length of Authorization:	**PNH and aHUS**: Coverage will be provided for twelve months and may be renewed **gMG and NMOSD**: Initial coverage will be provided for 6 months and may be renewed annually thereafter
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Paroxysmal nocturnal hemoglobunuria (PNH)**

- Patient is at least 18 years of age; **AND**
- Prescriber is enrolled in the Soliris® Risk Evaluation and Mitigation Strategy (REMS); **AND**
- Patient must be vaccinated against meningococcal disease at least two weeks prior to initiation of therapy and will continue to be revaccinated according to current medical guidelines for vaccine use (**If urgent Soliris® therapy is indicated in an unvaccinated patient, administer meningococcal vaccine(s) as soon as possible and provide patients with two weeks of antibacterial drug prophylaxis**); **AND**
- Patient does not have an unresolved, serious systemic infection (e.g., *Neisseria meningitidis*); **AND**
- Will not be used in combination with another complement-inhibitor therapy (i.e., ravulizu mab, pegcetacoplan) [**Note**: a 4-week run-in period is allowed when transitioning from eculizumab to pegcetacoplan]; **AND**
- Diagnosis must be accompanied by detection of PNH clones of at least 10% by flow cytometry diagnostic test; **AND**
  - Demonstrate the presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59) within at least 2 different cell lines (i.e., granulocytes, monocytes, erythrocytes); **AND**
- Patient has laboratory evidence of significant intravascular hemolysis (i.e., lactate dehydrogenase [LDH] ≥ 1.5 x upper limit of normal [ULN]) and at least one other indication for therapy from the following:
  - Presence of a thrombotic event
  - Presence of organ damage secondary to chronic hemolysis (i.e., renal insufficiency, pulmonary insufficiency, or hypertension)
  - Patient is pregnant and potential benefit outweighs potential fetal risk
  - Patient has symptomatic anemia (regardless of transfusion dependence)
  - Patient has disabling fatigue
  - Patient has abdominal pain requiring admission or opioid analgesia; **AND**
- Documented baseline values for one or more of the following (necessary for renewal): LDH, hemoglobin level, packed red blood cell (RBC) transfusion requirement, and history of thrombotic events

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Atypical Hemolytic uremic syndrome (aHUS)**

- Patient is at least 2 months of age; **AND**
- Prescriber is enrolled in the Soliris® Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
- Patient must be vaccinated against meningococcal disease at least two weeks prior to initiation of therapy and will continue to be revaccinated according to current medical guidelines for vaccine use (**If urgent Soliris® therapy is indicated in an unvaccinated patient, administer meningococcal vaccine(s) as soon as possible and provide patients with two weeks of antibacterial drug prophylaxis**); **AND**
- Patient does not have an unresolved, serious systemic infection (e.g., *Neisseria meningitidis*); **AND**
- Will not be used in combination with another complement-inhibitor therapy (i.e., ravulizumab, pegcetacoplan) [**Note**: a 4-week run-in period is allowed when transitioning from eculizumab to pegcetacoplan]; **AND**
- Patient shows signs of thrombotic microangiopathy (TMA) (e.g., changes in mental status, seizures, angina, dyspnea, thrombosis, increasing blood pressure, decreased platelet count, increased serum creatinine, increased LDH); **AND**
- Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS-13 level (ADAMTS-13 activity level ≥ 10%); **AND**
- Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS) has been ruled out; **AND**
- Other causes have been ruled out, such as coexisting diseases or conditions (e.g., bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug-induced, malignant hypertension, human immunodeficiency virus [HIV] infection), *Streptococcus pneumoniae* or influenza A (H1N1) infection, or cobalamin deficiency; **AND**
- Documented baseline values for one or more of the following (necessary for renewal): serum LDH; serum creatinine/eGFR, platelet count and plasma exchange/infusion requirement

Diagnosis of **Generalized Myasthenia Gravis (gMG)**

- Patient is at least 18 years of age; **AND**
- Prescriber is enrolled in the Soliris Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
- Patient must be vaccinated against meningococcal disease at least two weeks prior to initiation of therapy and will continue to be revaccinated according to current medical guidelines for vaccine use (**If urgent Soliris® therapy is indicated in an unvaccinated patient, administer meningococcal vaccine(s) as soon as possible and provide patients with two weeks of antibacterial drug prophylaxis**); **AND**
- Patient does not have an unresolved, serious systemic infection (e.g., *Neisseria meningitidis*); **AND**
- Will not be used in combination with another complement-inhibitor therapy (i.e., ravulizumab, pegcetacoplan) (**Note**: a 4-week run-in period is allowed when transitioning from eculizumab to pegcetacoplan); **AND**
- Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; **AND**
- Patient has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies; **AND**
- Physician has assessed the baseline Quantitative Myasthenia Gravis (QMG) score; **AND**
- Patient has a MG-activities of Daily Living (MG-ADL) total score of ≥ 6; **AND**
- Patient had an inadequate response after a minimum one-year trial with either:
  - Two (2) or more immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate); **OR**
  - One (1) immunosuppressive therapy **and** required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Neuromyelitis Optica Spectrum Disorder (NMOSD)**

- Patient is at least 18 years of age; **AND**
- Prescriber is enrolled in the Soliris Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
- Patient must be vaccinated against meningococcal disease at least two weeks prior to initiation of therapy and will continue to be revaccinated according to current medical guidelines for vaccine use (**If urgent Soliris® therapy is indicated in an unvaccinated patient, administer meningococcal vaccine(s) as soon as possible and provide patients with two weeks of antibacterial drug prophylaxis**); **AND**
- Patient does not have an unresolved, serious systemic infection (e.g., *Neisseria meningitidis*); **AND**
- Will not be used in combination with another complement-inhibitor therapy (i.e., ravulizumab, pegcetacoplan) (**Note**: a 4-week run-in period is allowed when transitioning from eculizumab to pegcetacoplan); **AND**
- Patient has a confirmed diagnosis based on the following:
  - Patient was found to be seropositive for aquaporin-4 (AQP4) IgG antibodies; **AND**
  - Patient has at least one core clinical characteristic §**; AND**
  - Alternative diagnoses have been excluded (e.g., multiple sclerosis, sarcoidosis, cancer, chronic infection); **AND**
- Patient has a history of at least 2 relapses in the last 12 months **or** 3 relapses in the last 24 months, with at least 1 relapse in the last 12 months; **AND**
- Patient has an Expanded Disability Status Score (EDSS) of ≤ 7 (i.e., presence of at least limited ambulation with aid); **AND**
- Patient is receiving concurrent corticosteroid therapy of 20 mg per day or less and those receiving immunosuppressive therapy (e.g., azathioprine, glucocorticoids, mycophenolate) are on a stable dose regimen; **AND**
- Patient has not received therapy with rituximab or mitoxantrone in the last 3 months; **AND**
- Patient has not received IVIG in the last 3 weeks; **AND**
- Patient had an inadequate response or has a contraindication or intolerance to rituximab **or** inebilizumab; **AND**
- Patient will not concomitantly receive therapy with any of the following:
  - IL6-inhibitor (e.g., satralizumab); **AND**
  - Anti-CD20-directed antibody (e.g., rituximab); **AND**
  - Anti-CD19-directed antibody (e.g., inebilizumab)

§ Core Clinical Characteristics of NMOSD
• Optic neuritis • Acute myelitis • Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting • Acute brainstem syndrome • Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions • Symptomatic cerebral syndrome with NMOSD-typical brain lesions

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., serious meningococcal infections [septicemia and/or meningitis], infusion reactions, serious infections, thrombotic microangiopathy complications [TMA]); **AND**
- Disease response as indicated by one or more of the following:
  - For PNH:
    - Decrease in serum LDH from pretreatment baseline
    - Stabilization/improvement in hemoglobin level from pretreatment baseline
    - Decrease in packed RBC transfusion requirement from pretreatment baseline
    - Reduction in thromboembolic events
  - For aHUS:
    - Decrease in serum LDH from pretreatment baseline
    - Stabilization/improvement in serum creatinine/eGFR from pretreatment baseline
    - Increase in platelet count from pretreatment baseline
    - Decrease in plasma exchange/infusion requirement from pretreatment baseline
  - For gMG:
    - Improvement of at least 3-points from baseline in the MG-ADL total score
    - Improvement of at least 5-points from baseline in the QMG total score
  - For NMOSD:
    - Stabilization/improvement of neurologic symptoms as evidenced by a decrease in acute relapses, EDSS, hospitalizations or plasma exchange treatments

SPINRAZA® (NUSINERSEN)

Length of Authorization:	1 year, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Submission of medical records related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation via direct upload through the PA web portal or by fax.

Diagnosis of **Spinal Muscular Atrophy (SMA)**

- Patient must not have previously received treatment with SMA gene therapy (e.g., onasemnogene abeparvovec-xioi); **AND**
- Patient will not use in combination with other agents for SMA (e.g., onasemnogene abeparvovec, risdiplam); **AND**
- Patient must not have advanced disease (e.g., complete limb paralysis, permanent ventilation support); **AND**
- Patient must have the following laboratory tests at baseline and prior to each administration*: platelet count, prothrombin time; activated partial thromboplastin time, and quantitative spot urine protein testing; **AND**
- Patient retains meaningful voluntary motor function (e.g., manipulate objects using upper extremities, ambulate); **AND**
- Patient must have a diagnosis of 5q spinal muscular atrophy confirmed by either homozygous deletion of the SMN1 gene or dysfunctional mutation of the SMN1 gene; **AND**
- Patient must have a diagnosis of SMA phenotype I, II, or III; **AND**
  - Patient has ≤ 3 copies of the *SMN2* gene; **OR**
  - Patient has symptomatic disease (i.e., impaired motor function and/or delayed motor milestones); **AND**
- Baseline documentation of one or more of the following:
  - Motor function/milestones, including but not limited to, the following validated scales: Hammersmith Infant Neurologic Exam (HINE), Hammersmith Functional Motor Scale Expanded (HFMSE), Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), Bayley Scales of Infant and Toddler development Third Ed. (BSID-III), 6-minute walk test (6MWT), upper limb module (ULM), motor function measure 32 (MFM32), revised upper limb module (RULM), etc.
  - Respiratory function tests (e.g., forced vital capacity [FVC])
  - Exacerbations necessitating hospitalization and/or antibiotic therapy for respiratory infection in the preceding year/timeframe
  - Patient weight (for patients without a gastrostomy tube)
- *Laboratory tests should be obtained within several days prior to administration

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity which would preclude safe administration of the drug (e.g., significant renal toxicity, thrombocytopenia, coagulation abnormalities); **AND**
- Patient has responded to therapy compared to pretreatment baseline in one or more of the following:
  - Stability or improvement in net motor function/milestones, including but not limited to, the following validated scales: Hammersmith Infant Neurologic Exam (HINE), Hammersmith Functional Motor Scale Expanded (HFMSE), Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) Bayley Scales of Infant and Toddler development Third Ed. (BSID-III), 6-minute walk test (6MWT), upper limb module (ULM), motor function measure 32 (MFM32), revised upper limb module (RULM), etc.
  - Stability or improvement in respiratory function tests (e.g., forced vital capacity [FVC])
  - Reduction in exacerbations necessitating hospitalization and/or antibiotic therapy for respiratory infection in the preceding year/timeframe
  - Stable or increased patient weight (for patients without a gastrostomy tube)
  - Slowed rate of decline in the aforementioned measures

SPRAVATO® (ESKETAMINE)

Length of Authorization:	Initial: 4 weeks Renewal: 4 weeks for first renewal; 3 months for subsequent renewals
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Major Depressive Disorder (MDD)

- Patient is ≥ 18 years old; **AND**
- Patient must have a baseline depression assessment using any validated depression rating scale (e.g., Montgomery-Asberg Depression Rating Scale [MADRS], Hamilton Depression Rating Scale [HAM-D], Patient Health Questionnaire Depression Scale [PHQ-9], Beck Depression Inventory [BDI]); **AND**
- Esketamine is prescribed by or in consultation with a psychiatrist or psychiatric mental health nurse practitioner (PMHNP); **AND**
- Patient must **not** have a current or prior DSM-5 diagnosis of any of the following:
  - Concomitant psychotic disorder; **OR**
  - MDD with psychosis; **OR**
  - Bipolar or related disorders; **OR**
  - Obsessive-compulsive disorder (OCD); **OR**
  - History of moderate to severe substance or alcohol use disorder; **OR**
  - Personality disorder; **AND**
- Patient must **not** have any of the following conditions:
  - Aneurysmal vascular disease; **OR**
  - Arteriovenous malformation; **OR**
  - History of intracerebral hemorrhage; **OR**
  - Uncontrolled hypertension (> 140/90 mmHg in patients < 65 years old or > 150/90 mmHg in patients ≥ 65 years); **AND**
- Patient must **not** be pregnant; **AND**
- Patient must **not** have intellectual disability; **AND**
- Patient must **not** have known hypersensitivity to any component of the product; **AND**
- Patient is **not** receiving concomitant ketamine therapy; **AND**
- Patient must be taking esketamine in conjunction with an antidepressant medication (esketamine is not to be used as monotherapy); **AND**
- Attestation that prescriber's healthcare setting is certified in the Spravato Risk Evaluation and Mitigation Strategies (REMS) program; **AND**
- Attestation that the prescriber will check blood pressure prior to each visit **and** is capable of monitoring patient as directed following administration, ensuring patient has been stable for ≥ 2 hours, with baseline or decreasing blood pressure, prior to cessation of monitoring; **AND**
- Prescriber attestation that he/she has reviewed the dosing schedule with the patient; **AND**
- Prescriber attestation that patient understands and is committed to receiving scheduled doses **and** has the capability of being available twice a week with adequate transportation to and from treatment facility; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

- If used for **treatment-resistant depression (TRD)**, patient meets the following criteria:
  - Patient has a history of adherence with oral therapy (compliant with ≥ 80% of their doses as demonstrated by refill history or prescriber attestation during current depressive episode); **AND**
  - Patient has failed a trial of antidepressant augmentation therapy for a duration of ≥ 6 weeks in the *current* depressive episode with ≥ 1 of the following, unless contraindicated or clinically significant adverse effects are experienced (failed trial as defined above):
    - An atypical antipsychotic; **OR**
    - Lithium; **OR**
    - An antidepressant from a different class; **AND**
  - Patient has tried psychotherapy alone or in combination with oral antidepressants, if psychotherapy resource is available; **AND**
  - Patient must **not** have failed prior ketamine treatment for MDD; **AND**
  - Patient is **not** receiving concomitant electroconvulsive therapy (ECT), vagus nerve stimulation (VNS), transcranial magnetic stimulation (TMS), or deep brain stimulation (DBS); **AND**
  - Patient has failed a trial of ≥ 2 antidepressants of *different* classes for a duration of ≥ 6 weeks each at generally accepted doses in the current depressive episode, unless contraindicated or clinically significant adverse effects are experienced (failed trial defined as < 50% reduction in symptom severity using any validated depression rating scale); **AND**
- If used for **depressive symptoms in patients with Major Depressive Disorder (MDD) with acute suicidal ideation/behavior**, patient meets the following criteria:
  - Patient must meet criteria for acute inpatient hospitalization per prescriber attestation; OR
  - Patient has recently been discharged from a hospital in which treatment with esketamine has been initiated.
    -

CLINICAL CRITERIA FOR RENEWAL

- Patient must demonstrate disease improvement and/or stabilization as a result of the medication, as documented by a 50% reduction in symptom severity using a validated depression rating scale; **AND**
- Patient has not experienced unacceptable toxicity (e.g., dissociation, cognitive impairment); **AND**
- Prescriber attestation that patient has committed to receiving all scheduled doses thus far in treatment and will continue to do so

SPRYCEL® (DASATINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myelogenous Leukemia**

- *For Standard and Precision* ***for CML, for new starts only: patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic imatinib OR Bosulif®**** *(***following the NCCN guidelines surrounding genetic mutations)*

- Patient is at least 18 years of age (unless otherwise noted); **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Patient's disease is confirmed by either a Philadelphia chromosome-positive (Ph+) or *BCR-ABL1* positive laboratory test result; **AND**
- Patient does not have any of the following BCR-ABL1 mutations: T315I/A, F317L/V/I/C, or V299L (****Note**: This does **NOT** apply to patients receiving first-line or continued therapy); **AND**
  - Patient has chronic phase disease and is at least 1 year of age; **OR**
  - Patient is resistant, intolerant, or had an inadequate response to prior therapy consisting of a 3-month trial or longer with a tyrosine kinase inhibitor (e.g., imatinib, bosutinib, ponatinib, nilotinib); **AND**
    - Patient has chronic, accelerated, or blast phase disease; **OR**
  - Used as primary treatment; **AND**
    - Used as single agent for newly diagnosed chronic or accelerated or myeloid blast phase disease; **OR**
    - Used in combination with corticosteroids for lymphoid blast phase disease; **OR**
    - Used in combination with induction chemotherapy for disease in lymphoid blast phase or myeloid blast phase; **OR**
  - Used as switch therapy; **AND**
    - Patient received initial therapy with one of the following: imatinib, bosutinib or nilotinib
    - Patient has *BCR-ABL1* transcript levels:
      - > 0.1% to 1% at 12 months (if treatment goal is treatment-free remission); **OR**
      - > 1% to 10% at 12 months; **OR**
      - > 10% at any response milestone; **OR**
  - Used as continued therapy; **AND**
    - Patient has *BCR-ABL1* transcript levels:
      - ≤ 10% at any response milestone; **OR**
      - > 10% at 3 months; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Chronic Myelogenous Leukemia** *(Continued)*

- Used post-allogeneic hematopoietic stem cell transplant (HCT); **AND**
  - Used for at least one year in patients with prior complete cytogenetic response (CCyR) for accelerated or blast phase disease; **OR**
  - Used as follow-up therapy in patients with molecular relapse (BCR-ABL1 transcript positive) following CCyR; **OR**
  - Used as follow-up therapy in patients with relapse or those who are not in CCyR

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 18 years of age (unless otherwise noted); **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Patient's disease is Philadelphia chromosome-positive (Ph+); **AND**
  - Used for newly diagnosed disease in patients at least 1 year of age in combination with chemotherapy; **OR**
  - Patient has relapsed/refractory disease; **AND**
    - Patient does not have any of the following *BCR-ABL1* mutations: T315I/A, F317L/V/I/C, or V299L; **AND**
      - Patient is resistant, or intolerant, or had an inadequate response to prior therapy, consisting of a 3-month trial or longer, with any of the following: imatinib, bosutinib, ponatinib, nilotinib, etc.; **OR**
      - Used as a single agent therapy; **OR**
      - Used in combination with an induction therapy not previously used; **OR**
      - Used in combination with blinatumomab ; **OR**
  - Used as maintenance therapy; **AND**
    - Used in combination with vincristine and prednisone with or without methotrexate and mercaptopurine; **OR**
    - Used post-hematopoietic stem cell transplant; **OR**
  - Patient is at least 15 years of age and < 65 years of age; **AND**
    - Used in a multiagent chemotherapy regimen for induction or consolidation therapy; **OR**
    - Used in combination with a corticosteroid for induction or consolidation therapy; **OR**
    - Used in combination with vincristine and dexamethasone for induction therapy; **OR**
    - Used in combination with blinatumomab as consolidation therapy for persistent/rising minimal residual disease following a complete response (CR) to induction therapy; **OR**
  - Patient is ≥ 65 years of age or with substantial comorbidities; **AND**
    - Used as induction therapy as part of one of the following regimens:
      - As a single agent or in combination with a corticosteroid; **OR**
      - In combination with vincristine and dexamethasone; **OR**
      - In combination with a multiagent chemotherapy regimen; **OR**
    - Used as consolidation therapy; **AND**
      - Patient has persistent/rising minimal residual disease following a complete response to induction therapy; **AND**
      - Used in combination with blinatumomab

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Pediatric Acute Lymphoblastic Leukemia (ALL)**

- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Patient is < 18 years of age; **AND**
  - Patient has Ph-like B-ALL with ABL class kinase fusion or Ph+ B-ALL; **AND**
    - Used as part of a cytotoxic chemotherapy regimen as induction or consolidation therapy; **OR**
  - Patient has Ph+ B-ALL; **AND**
    - Used as part of a cytotoxic chemotherapy regimen for relapsed or refractory disease; **OR**
  - Patient has T-ALL with ABL-class translocation; **AND**
    - Used as part of a TKI-based regimen for relapsed/refractory disease

Diagnosis of **Gastrointestinal stromal tumors (GIST)**

- Patient is 18 years old or older; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Patient has unresectable, recurrent, or metastatic disease; **AND**
- Used as a single agent; **AND**
- Patient's BCR-ABL KD mutational analysis contains the PDGFRA D842V mutation; **AND**
- Used after failure on approved therapies including each of the following: imatinib, avapritinib, sunitinib, regorafenib, and ripretinib

Diagnosis of **Bone Cancer (Chondrosarcoma and Chordoma)**

- Patient is 18 years old or older; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Used as single agent; **AND**
  - Patient has chondrosarcoma and widespread metastatic disease: **OR**
  - Patient has conventional or chondroid chordoma and recurrent disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**

- Patient is 18 years old or older; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Patient has eosinophilia and ABL1 rearrangement; **AND**
  - Patient has chronic phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

CLINICAL CRITERIA FOR RENEWAL

- Patient has been adherent to therapy; **AND**
- Absence of unacceptable toxicity from the drug (e.g., pulmonary arterial hypertension, severe myelosuppression [neutropenia, anemia, thrombocytopenia], fluid retention, cardiovascular events [ischemia, conduction system abnormalities, arrhythmia/palpitations], cardiac dysfunction, QT prolongation, severe dermatologic reactions, tumor lysis syndrome); **AND**
- Acute lymphoblastic leukemia (ALL) and pediatric ALL only:
  - Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH
- Chronic myelogenous leukemia (CML) only:
  - Treatment response as indicated by one of the following *BCR-ABL1* transcript levels:
    - > 0.1% to 10% at 3 months or 6 months; **OR**
    - > 0.1% to 1% at 12 months and beyond (if treatment goal is long-term survival); **OR**
    - ≤ 0.1% at 12 months and beyond (if treatment goal is treatment-free remission)

    Note: cytogenetic assessment of response may be used if quantitative RT-PCR (QPCR) using International Scale (IS) for BCR-ABL1 is not available

    Note: For patients who are within the first year of treatment with Sprycel® and are not meeting the levels under the renewal criteria for CML, the levels under initial sections "Continued Therapy" may be utilized. If the patient has been on therapy for longer than a year, they must meet the levels mentioned in the renewal criteria.
- Gastrointestinal stromal tumors (GIST) only:
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread
- Bone cancer (chondrosarcoma and chordoma) only:
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

- Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes only:
  - Disease response as evidenced by at least one of the following:
    - Decrease in spleen size or improvements in other myelofibrosis symptoms (e.g., fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding)
    - Stabilization or improvement as evidenced by a complete response (CR) (i.e., morphologic, cytogenetic, or molecular complete response CR), complete hematologic response, or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

ENHANCED FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myelogenous Leukemia (CML)**

- *For Enhanced Formulary **for CML, Sprycel® is a preferred product***

- Patient is at least 18 years of age (unless otherwise noted); **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Patient's disease is confirmed by either a Philadelphia chromosome-positive (Ph+) or BCR-ABL1 positive laboratory test result; **AND**
- Patient does not have any of the following BCR-ABL1 mutations: T315I/A, F317L/V/I/C, or V299L (****Note**: This does **NOT** apply to patients receiving first-line or continued therapy); **AND**
  - Patient has chronic phase disease and is at least 1 year of age; **OR**
  - Patient is resistant, intolerant, or had an inadequate response to prior therapy consisting of a 3-month trial or longer with a tyrosine kinase inhibitor (e.g., imatinib, bosutinib, ponatinib, nilotinib); **AND**
    - Patient has chronic, accelerated, or blast phase disease;
  - Used as primary treatment; **AND**
    - Used as single agent for newly diagnosed chronic or accelerated or myeloid blast phase disease; **OR**
    - Used in combination with corticosteroids for lymphoid blast phase disease; **OR**
    - Used in combination with induction chemotherapy for disease in lymphoid blast phase or myeloid blast phase; **OR**
  - Used as switch therapy; **AND**
    - Patient received initial therapy with one of the following: imatinib, bosutinib or nilotinib
    - Patient has *BCR-ABL1* transcript levels:
      - > 0.1% to 1% at 12 months (if treatment goal is treatment-free remission); **OR**
      - > 1% to 10% at 12 months; **OR**
      - > 10% at any response milestone; **OR**
  - Used as continued therapy; **AND**
    - Patient has *BCR-ABL1* transcript levels:
      - ≤ 10% at any response milestone; **OR**
      - > 10% at 3 months; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Used post-allogeneic hematopoietic stem cell transplant (HCT); **AND**
  - Used for at least one year in patients with prior complete cytogenetic response (CCyR) for accelerated or blast phase disease; **OR**
  - Used as follow-up therapy in patients with molecular relapse (BCR-ABL1 transcript positive) following CCyR; **OR**
  - Used as follow-up therapy in patients with relapse or those who are not in CCyR

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 18 years of age (unless otherwise noted); **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Patient's disease is Philadelphia chromosome-positive (Ph+); **AND**
  - Used for newly diagnosed disease in patients at least 1 year of age in combination with chemotherapy; **OR**
  - Patient has relapsed/refractory disease; **AND**
    - Patient does not have any of the following *BCR-ABL1* mutations: T315I/A, F317L/V/I/C, or V299L; **AND**
      - Patient is resistant, or intolerant, or had an inadequate response to prior therapy, consisting of a 3-month trial or longer, with any of the following: imatinib, bosutinib, ponatinib, nilotinib, etc.; **OR**
      - Used as a single agent therapy; **OR**
      - Used in combination with an induction therapy not previously used; **OR**
      - Used in combination with blinatumomab ; **OR**
  - Used as maintenance therapy; **AND**
    - Used in combination with vincristine and prednisone with or without methotrexate and mercaptopurine; **OR**
    - Used post-hematopoietic stem cell transplant; **OR**
  - Patient is at least 15 years of age and < 65 years of age; **AND**
    - Used in a multiagent chemotherapy regimen for induction or consolidation therapy; **OR**
    - Used in combination with a corticosteroid for induction or consolidation therapy; **OR**
    - Used in combination with vincristine and dexamethasone for induction therapy; **OR**
    - Used in combination with blinatumomab as consolidation therapy for persistent/rising minimal residual disease following a complete response (CR) to induction therapy; **OR**
  - Patient is ≥ 65 years of age or with substantial comorbidities; **AND**
    - Used as induction therapy as part of one of the following regimens:
      - As a single agent or in combination with a corticosteroid; **OR**
      - In combination with vincristine and dexamethasone; **OR**
      - In combination with a multiagent chemotherapy regimen; **OR**
    - Used as consolidation therapy; **AND**
      - Patient has persistent/rising minimal residual disease following a complete response to induction therapy; **AND**
      - Used in combination with blinatumomab

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Pediatric Acute Lymphoblastic Leukemia (ALL)**

- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Patient is < 18 years of age; **AND**
  - Patient has Ph-like B-ALL with ABL class kinase fusion or Ph+ B-ALL; **AND**
    - Used as part of a cytotoxic chemotherapy regimen as induction or consolidation therapy; **OR**
  - Patient has Ph+ B-ALL; **AND**
    - Used as part of a cytotoxic chemotherapy regimen for relapsed or refractory disease; **OR**
  - Patient has T-ALL with ABL-class translocation; **AND**
    - Used as part of a TKI-based regimen for relapsed/refractory disease

Diagnosis of **Gastrointestinal stromal tumors (GIST)**

- Patient is 18 years old or older; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Patient has unresectable, recurrent, or metastatic disease; **AND**
- Used as a single agent; **AND**
- Patient's BCR-ABL KD mutational analysis contains the PDGFRA D842V mutation; **AND**
- Used after failure on approved therapies including each of the following: imatinib, avapritinib, sunitinib, regorafenib, and ripretinib

Diagnosis of **Bone Cancer (Chondrosarcoma and Chordoma)**

- Patient is 18 years old or older; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Used as single agent; **AND**
  - Patient has chondrosarcoma and widespread metastatic disease; **OR**
  - Patient has conventional or chondroid chordoma and recurrent disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**

- Patient is 18 years old or older; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Patient has eosinophilia and ABL1 rearrangement; **AND**
  - Patient has chronic phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

CLINICAL CRITERIA FOR RENEWAL

- Patient has been adherent to therapy; **AND**
- Absence of unacceptable toxicity from the drug (e.g., pulmonary arterial hypertension, severe myelosuppression [neutropenia, anemia, thrombocytopenia], fluid retention, cardiovascular events [ischemia, conduction system abnormalities, arrhythmia/palpitations], cardiac dysfunction, QT prolongation, severe dermatologic reactions, tumor lysis syndrome); **AND**
- Acute lymphoblastic leukemia (ALL) and Pediatric ALL only:
  - Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH
- Chronic myelogenous leukemia (CML) only:
  - Treatment response as indicated by one of the following *BCR-ABL1* transcript levels:
    - > 0.1% to 10% at 3 months or 6 months; **OR**
    - > 0.1% to 1% at 12 months and beyond (if treatment goal is long-term survival); **OR**
    - ≤ 0.1% at 12 months and beyond (if treatment goal is treatment-free remission)

    Note: cytogenetic assessment of response may be used if quantitative RT-PCR (QPCR) using International Scale (IS) for BCR-ABL1 is not available

    Note: For patients who are within the first year of treatment with Sprycel® and are not meeting the levels under the renewal criteria for CML, the levels under initial sections "Continued Therapy" may be utilized. If the patient has been on therapy for longer than a year, they must meet the levels mentioned in the renewal criteria.
- Gastrointestinal stromal tumors (GIST) only:
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread
- Bone cancer (chondrosarcoma and chordoma) only:
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

CLINICAL CRITERIA FOR RENEWAL

- Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes only:
  - Disease response as evidenced by at least one of the following:
    - Decrease in spleen size or improvements in other myelofibrosis symptoms (e.g., fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding)
    - Stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic, or molecular complete response CR), complete hematologic response, or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

CORE FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myelogenous Leukemia (CML)**

- ***For Core Formulary for CML, for new starts only: patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic imatinib****** *(***following the NCCN guidelines surrounding genetic mutations)*
- Patient is at least 18 years of age (unless otherwise noted); **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Patient's disease is confirmed by either a Philadelphia chromosome-positive (Ph+) or BCR-ABL1 positive laboratory test result; **AND**
- Patient does not have any of the following BCR-ABL1 mutations: T315I/A, F317L/V/I/C, or V299L (****Note**: This does **NOT** apply to patients receiving first-line or continued therapy); **AND**
  - Patient has chronic phase disease and is at least 1 year of age; **OR**
  - Patient is resistant, intolerant, or had an inadequate response to prior therapy consisting of a 3-month trial or longer with a tyrosine kinase inhibitor (e.g., imatinib, bosutinib, ponatinib, nilotinib); **AND**
    - Patient has chronic, accelerated, or blast phase disease; **OR**
  - Used as primary treatment; **AND**
    - Used as single agent for newly diagnosed chronic or accelerated or myeloid blast phase disease; **OR**
    - Used in combination with corticosteroids for lymphoid blast phase disease; **OR**
    - Used in combination with induction chemotherapy for disease in lymphoid blast phase or myeloid blast phase; **OR**
  - Used as switch therapy; **AND**
    - Patient received initial therapy with one of the following: imatinib, bosutinib or nilotinib
    - Patient has *BCR-ABL1* transcript levels:
      - > 0.1% to 1% at 12 months (if treatment goal is treatment-free remission); **OR**
      - > 1% to 10% at 12 months; **OR**
      - > 10% at any response milestone; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Used as continued therapy; **AND**
  - Patient has *BCR-ABL1* transcript levels:
    - ≤ 10% at any response milestone; **OR**
    - > 10% at 3 months; **OR**
- Used post-allogeneic hematopoietic stem cell transplant (HCT); **AND**
  - Used for at least one year in patients with prior complete cytogenetic response (CCyR) for accelerated or blast phase disease; **OR**
  - Used as follow-up therapy in patients with molecular relapse (BCR-ABL1 transcript positive) following CCyR; **OR**
  - Used as follow-up therapy in patients with relapse or those who are not in CCyR

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 18 years of age (unless otherwise noted); **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead
- Patient's disease is Philadelphia chromosome-positive (Ph+); **AND**
  - Used for newly diagnosed disease in patients at least 1 year of age in combination with chemotherapy; **OR**
  - Patient has relapsed/refractory disease; **AND**
    - Patient does not have any of the following *BCR-ABL1* mutations: T315I/A, F317L/V/I/C, or V299L; **AND**
      - Patient is resistant, or intolerant, or had an inadequate response to prior therapy, consisting of a 3-month trial or longer, with any of the following: imatinib, bosutinib, ponatinib, nilotinib, etc.; **OR**
      - Used as a single agent therapy; **OR**
      - Used in combination with an induction therapy not previously used; **OR**
      - Used in combination with blinatumomab; **OR**
  - Used as maintenance therapy; **AND**
    - Used in combination with vincristine and prednisone with or without methotrexate and mercaptopurine; **OR**
    - Used post-hematopoietic stem cell transplant; **OR**
  - Patient is at least 15 years of age and < 65 years of age; **AND**
    - Used in a multiagent chemotherapy regimen for induction or consolidation therapy; **OR**
    - Used in combination with a corticosteroid for induction or consolidation therapy; **OR**
    - Used in combination with vincristine and dexamethasone for induction therapy; **OR**
    - Used in combination with blinatumomab as consolidation therapy for persistent/rising minimal residual disease following a complete response (CR) to induction therapy; **OR**
  - Patient is ≥ 65 years of age or with substantial comorbidities; **AND**
    - Used as induction therapy as part of one of the following regimens:
      - As a single agent or in combination with a corticosteroid; **OR**
      - In combination with vincristine and dexamethasone; **OR**
      - In combination with a multiagent chemotherapy regimen; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Used as consolidation therapy; **AND**
  - Patient has persistent/rising minimal residual disease following a complete response to induction therapy; **AND**
  - Used in combination with blinatumomab

Diagnosis of **Pediatric Acute Lymphoblastic Leukemia (ALL)**

- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Patient is <18 years of age; **AND**
  - Patient has Ph-like B-ALL with ABL class kinase fusion or Ph+ B-ALL; **AND**
    - Used as part of a cytotoxic chemotherapy regimen as induction or consolidation therapy; **OR**
  - Patient has Ph+ B-ALL; **AND**
    - Used as part of a cytotoxic chemotherapy regimen for relapsed or refractory disease; **OR**
  - Patient has T-ALL with ABL-class translocation; **AND**
    - Used as part of a TKI-based regimen for relapsed/refractory disease

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is 18 years old or older; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Patient has unresectable, recurrent, or metastatic disease; **AND**
- Used as a single agent; **AND**
- Patient's BCR-ABL KD mutational analysis contains the PDGFRA D842V mutation; **AND**
- Used after failure on approved therapies including each of the following: imatinib, avapritinib, sunitinib, regorafenib, and ripretinib

Diagnosis of **Bone Cancer (Chondrosarcoma and Chordoma)**

- Patient is 18 years old or older; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Used as single agent; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient has chondrosarcoma and widespread metastatic disease; **OR**
- Patient has conventional or chondroid chordoma and recurrent disease

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**

- Patient is 18 years old or older; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**
- Patient has eosinophilia and ABL1 rearrangement; **AND**
  - Patient has chronic phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

CLINICAL CRITERIA FOR RENEWAL

- Patient has been adherent to therapy; **AND**
- Absence of unacceptable toxicity from the drug (e.g., pulmonary arterial hypertension, severe myelosuppression [neutropenia, anemia, thrombocytopenia], fluid retention, cardiovascular events [ischemia, conduction system abnormalities, arrhythmia/palpitations], cardiac dysfunction, QT prolongation, severe dermatologic reactions, tumor lysis syndrome); **AND**
- Acute lymphoblastic leukemia (ALL) and pediatric ALL only:
  - Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH
- Chronic myelogenous leukemia (CML) only:
  - Treatment response as indicated by one of the following *BCR-ABL1* transcript levels:
    - > 0.1% to 10% at 3 months or 6 months; **OR**
    - > 0.1% to 1% at 12 months and beyond (if treatment goal is long-term survival); **OR**
    - ≤ 0.1% at 12 months and beyond (if treatment goal is treatment-free remission)

    Note: Cytogenetic assessment of response may be used if quantitative RT-PCR (QPCR) using International Scale (IS) for BCR-ABL1 is not available

    Note: For patients who are within the first year of treatment with Sprycel® and are not meeting the levels under the renewal criteria for CML, the levels under initial sections "Continued Therapy" may be utilized. If the patient has been on therapy for longer than a year, they must meet the levels mentioned in the renewal criteria.
- Gastrointestinal stromal tumors (GIST) only:
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread
- Bone cancer (chondrosarcoma and chordoma) only:
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

- Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes only:
  - Disease response as evidenced by at least one of the following:
    - Decrease in spleen size or improvements in other myelofibrosis symptoms (e.g., fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding)
    - Stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic, or molecular complete response CR), complete hematologic response, or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

STEP THERAPY

Length of Authorization:	1 year, may be renewed
Initiative:	Varies, utilize most appropriate to class (e.g., hypoglycemics, antipsychotics, etc.)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

Note: This section only applies to step therapy not documented elsewhere in the criteria document. This is for step therapy that is only available in the formulary look ups.

- For all medications, verify if there is criteria within the document to utilize for the review.
- If there is no criteria for the medication elsewhere in the document, use the look up tools for the specific formulary to see if there is step therapy listed.
  - Standard formulary: https://magellan.adaptiverx.com/webSearch/index?key=cnhmbGV4LnBsYW4uUGxhblBkZlR5cGUtNjU
  - Precision/Precision plus formulary: https://magellan.adaptiverx.com/webSearch/index?key=cnhmbGV4LnBsYW4uUGxhblBkZlR5cGUtNTg=
  - Enhanced formulary: magellan.adaptiverx.com/webSearch/index?key=cnhmbGV4LnBsYW4uUGxhblBkZlR5cGUtNjY2
  - Core Formulary:
  - https://magellan.adaptiverx.com/webSearch/index?key=cnhmbGV4LnBsYW4uUGxhblBkZlR5cGUtNjcx
- If there is no step in the look up tool, follow no criteria pa required drugs

STIVARGA® (REGORAFENIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Colorectal Cancer**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, phenytoin, carbamazepine, phenobarbital, St. John's Wort); **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, grapefruit juice, itraconazole, ketoconazole, nefazodone, posaconazole, telithromycin, and voriconazole); **AND**
- Patient has advanced or metastatic disease; **AND**
- Patient has not previously been treated with regorafenib; **AND**
- Used as a single agent; **AND**
- Used as subsequent therapy for disease progression through all available regimens besides regorafenib or trifluridine/tipiracil

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, phenytoin, carbamazepine, phenobarbital, St. John's Wort); **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, grapefruit juice, itraconazole, ketoconazole, nefazodone, posaconazole, telithromycin, and voriconazole); **AND**
- Patient has locally advanced, recurrent, unresectable, or metastatic disease; **AND**
  - Used as a single agent; **AND**
    - Patient was previously treated with single-agent imatinib and sunitinib; **OR**
  - Used in combination with everolimus after failure on approved therapies
    - Patient has had disease progression after previous treatment with single-agent imatinib, sunitinib, and regorafenib

Diagnosis of **Hepatocellular Carcinoma (HCC)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, phenytoin, carbamazepine, phenobarbital, St. John's Wort); **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, grapefruit juice, itraconazole, ketoconazole, nefazodone, posaconazole, telithromycin, and voriconazole); **AND**
- Used as a single agent; **AND**
- Patient is Child-Pugh Class A**; AND**
- Patient was previously treated with sorafenib

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

Diagnosis of **Soft Tissue Sarcoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, phenytoin, carbamazepine, phenobarbital, St. John's Wort, etc.); **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, grapefruit juice, itraconazole, ketoconazole, nefazodone, posaconazole, telithromycin, and voriconazole); **AND**
- Used as a single-agent as subsequent therapy; **AND**
  - Patient has advanced or metastatic pleomorphic rhabdomyosarcoma; **OR**
  - Patient has non-adipocytic retroperitoneal/intraabdominal disease that is recurrent unresectable or stage IV; **OR**
  - Patient has non-adipocytic disease of the extremity/body wall/head/neck that is advanced or metastatic with disseminated metastases; **OR**
  - Patient has angiosarcoma; **OR**
  - Patient has solitary fibrous tumor

Diagnosis of **Osteosarcoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, phenytoin, carbamazepine, phenobarbital, St. John's Wort); **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, grapefruit juice, itraconazole, ketoconazole, nefazodone, posaconazole, telithromycin, and voriconazole); **AND**
- Used as a single agent; **AND**
- Used as second-line therapy for relapsed/refractory or metastatic disease; **AND**
- Patient does not have dedifferentiated chondrosarcoma or high-grade undifferentiated pleomorphic sarcoma (UPS)

Diagnosis of G**lioblastoma – Central Nervous System Cancer**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, phenytoin, carbamazepine, phenobarbital, St. John's Wort); **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, grapefruit juice, itraconazole, ketoconazole, nefazodone, posaconazole, telithromycin, and voriconazole); **AND**
- Used as a single agent for recurrent disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hepatotoxicity, severe infections, hemorrhage, reversible posterior leukoencephalopathy syndrome (RPLS), gastrointestinal perforation or fistula, dermatologic toxicity, severe/uncontrolled hypertension, cardiac ischemia/infarction, impaired wound healing, etc.

STRENSIQ® (ASFOTASE ALFA)

Length of Authorization:	6 months
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **perinatal/infantile or juvenile-onset hypophosphatasia (HPP)**

- Diagnosis confirmed by ICD-10 code E83.39; **AND**
- Treatment is prescribed by (or in consultation with) an endocrinologist; **AND**
- Patient does **not** have a treatable form of rickets, current exposure to a bisphosphonate, hypocalcemia or hypophosphatemia, or a serum 25-hydroxyvitamin D level of less than 20ng/mL; **AND**
- Onset of disease prior to the age of 18 years; **AND**
- Do **not** use for osteomalacia due to causes other than HPP; **AND**
- Do **not** use the 80 mg/0.8 mL vial in pediatrics weighing < 40 kg

CLINICAL CRITERIA FOR RENEWAL

Documentation of clinical benefit as evidenced by z-scores or improvement in gait/mobility or radiographic results

SUCRAID® (SACROSIDASE)

Length of Authorization:	12 months; may be renewed
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Congenital Sucrase-Isomaltase Deficiency (CSID)**

- Patient is at least 5 months of age; **AND**
- Patient has a diagnosis of symptomatic genetic or congenital SI deficiency that has been confirmed by one of the following:
  - Patient has a mutation on chromosome 3 of the SI gene (e.g., G1073D, V577G, F1745C and R1124X) as determined by SI gene sequence analysis; **OR**
  - Disaccharidase assay (i.e., lactase, sucrase, isomaltase (palatinase), and maltase activity) of a small intestinal biopsy; **AND**
- Other causes of chronic diarrhea (e.g., diarrhea predominant IBS, malabsorption disorders, infectious, etc.) as well as congenital anatomic anomalies of the intestine have been ruled out; **AND**
- Patient is adhering to a reduced starch and/or sugar diet

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe allergic reactions, severe wheezing, etc.; **AND**
- Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline as evidenced by fewer total stools and a greater number of hard/formed stools; **AND**
- Patient has been re-evaluated to confirm symptomatic starch/sugar intolerance still persists

SUTENT® (SUNITINIB)

Length of Authorization:	6 months, may be renewed Adjuvant RCC may be renewed for up to nine 6-week cycles of therapy
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Renal cell carcinoma (RCC)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
  - Patient has advanced disease; **OR**
  - Used as adjuvant treatment for high-risk of recurrence, in patients with clear cell histology, following nephrectomy; **OR**
  - Patient has relapsed or stage IV disease; **AND**
    - Used as first-line or subsequent therapy for clear cell histology; **OR**
    - Used as systemic therapy for non-clear cell histology

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
  - Used for disease progression on, or intolerance to, imatinib; **OR**
  - Used as second-line therapy for unresectable, recurrent, or metastatic disease with limited progression; **OR**
- Used in combination with everolimus; **AND**
  - Patient has unresectable, recurrent, or metastatic disease; **AND**
  - Used after failure on approved therapies including each of the following: imatinib, sunitinib, regorafenib, and ripretinib

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Pancreatic Neuroendocrine Tumors (pNET)**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
- Patient has unresectable locally advanced or metastatic disease; **AND**
- Patient has progressive disease, significant tumor burden, or is symptomatic

Diagnosis of **Soft Tissue Sarcoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
- Patient has one of the following subtypes of disease:
  - Alveolar Soft Part Sarcoma (ASPS)
  - Angiosarcoma
  - Solitary Fibrous Tumor

Diagnosis of **Thymic Carcinomas**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
  - Patient is unable to tolerate first-line combination regimens; **AND**
    - Used as postoperative treatment after R1 (microscopic residual tumor) or R2 (macroscopic residual tumor) resection; **OR**
    - Used as first-line therapy for unresectable, locally advanced, or metastatic disease; **OR**
  - Used as second-line therapy; **AND**
    - Patient has unresectable or metastatic disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Thyroid Carcinoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has follicular, Hürthle cell, or papillary carcinoma; **AND**
  - Patient has unresectable, recurrent, persistent, or metastatic disease; **AND**
  - Treatment with clinical trials or other systemic therapies are not available or appropriate **AND**
  - Patient has progressive and/or symptomatic disease that is not susceptible to radioactive iodine (RAI) therapy; **OR**
- Patient has medullary carcinoma; **AND**
  - Patient has recurrent or persistent metastatic disease; **AND**
  - Disease is symptomatic or progressive; **AND**
    - Treatment with clinical trials, vandetanib, or cabozantinib are not available or appropriate; **OR**
    - Patient has progressed on vandetanib or cabozantinib

Diagnosis of **Bone Cancer** – **Chordoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as a single agent; **AND**
- Patient has recurrent disease with conventional or chondroid histology

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with all the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has eosinophilia and FLT3 rearrangement; **AND**
  - Patient has chronic phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hepatotoxicity, cardiovascular events (e.g., heart failure, cardiomyopathy, myocardial ischemia/infarction), QT prolongation and Torsades de Pointes, hypertension, hemorrhagic events and gastrointestinal perforation, tumor lysis syndrome (TLS), thrombotic microangiopathy (TMA), proteinuria and nephrotic syndrome, dermatologic toxicity (erythema multiforme [EM], Stevens-Johnsons syndrome [SJS], toxic epidermal necrolysis [TEN]), reversible posterior leukoencephalopathy syndrome (RPLS), thyroid dysfunction, hypoglycemia, osteonecrosis of the jaw, impaired wound healing, etc.; **AND**
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**
  - Disease response as evidenced by at least one of the following:
    - Decrease in spleen size or improvements in other myelofibrosis symptoms (e.g., fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding)
    - Stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic, or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH
- **Adjuvant renal cell carcinoma (RCC)**:
  - May be renewed for up to nine 6-week cycles of therapy
- **All Other Indications**
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

SYLATRON® (PEGINTERFERON ALFA-2B)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Melanoma**

- Patient is 18 years old or greater; **AND**
- Patient does not have autoimmune hepatitis or hepatic decompensation (Child-Pugh score >6 [class B and C]); **AND**
- Used as single agent adjuvant therapy; **AND**
- Patient has microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy

Diagnosis of **Myeloproliferative Neoplasms**

- Patient is 18 years old or greater; **AND**
- Patient does not have autoimmune hepatitis or hepatic decompensation (Child-Pugh score >6 [class B and C]); **AND**
- Myelofibrosis
  - Patient has symptomatic, low-risk disease
- Polycythemia Vera
  - Patient has high-risk or symptomatic low-risk disease,; **OR**
  - Patient had a loss or inadequate response to hydroxyurea or interferon therapy and is peginterferon alfa-2b naïve
- Essential Thrombocythemia
  - Patient has high-risk or symptomatic very-low, low, or intermediate disease; **OR**
  - Patient had a loss or inadequate response to hydroxyurea, interferon therapy or anagrelide and is peginterferon alfa-2b naïve

Diagnosis of Systemic Mastocytosis

- Patient is 18 years old or greater; **AND**
- Patient does not have autoimmune hepatitis or hepatic decompensation (Child-Pugh score >6 [class B and C]); **AND**
- Used as single agent or with prednisone for the treatment of aggressive disease or systemic mastocytosis associated with a hematologic neoplasm (SM-AHN), when the SM component requires more immediate treatment; **OR**
- Used for osteopenia/osteoporosis in patients with refractory bone pain and/or worsening bone mineral density on bisphosphonate therapy

CLINICAL CRITERIA FOR RENEWAL

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., persistent or worsening severe neuropsychiatric disorders, grade 4 non-hematologic toxicity, new or worsening retinopathy, new onset of ventricular arrhythmia, cardiovascular decompensation, hepatic failure, endocrinopathies [new onset or worsening of hypothyroidism, hyperthyroidism, and diabetes mellitus]); **AND**
- Total length of therapy does not exceed 5 years

SYLVANT® (SILTUXIMAB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multicentric Castleman's Disease (MCD)**

- Patient is human immunodeficiency virus (HIV) negative; **AND**
- Patient is human herpes virus-8 (HHV-8) negative; **AND**
- Patient is currently free of all clinically significant active infections; **AND**
- Patient will **not** receive any live vaccines during treatment with Sylvant; **AND**
- Must be used as a single agent

Diagnosis of **Unicentric Castleman's Disease (UCD)**

- Patient is human immunodeficiency virus (HIV) negative; **AND**
- Patient is human herpes virus-8 (HHV-8) negative; **AND**
- Patient is currently free of all clinically significant active infections; **AND**
- Patient will **not** receive any live vaccines during treatment with Sylvant; **AND**
- Must be used as a single agent; **AND**
- Must be used as second-line therapy for relapsed or refractory disease; **AND**
- Patient has plasmacytic/mixed histology

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., gastrointestinal perforation, severe infusion related reactions and severe hypersensitivity)

SYMDEKO® (TEZACAFTOR/IVACAFTOR AND IVACAFTOR)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cystic Fibrosis**

- Patient is at least 6 years old; **AND**
- Patient has a baseline percent predicted forced expiratory volume in 1 second (FEV_1)—**reported measurements may be used on renewal**; **AND**
- Patient is not receiving concurrent treatment with any other cystic fibrosis transmembrane conductance regulator (CFTR)-targeted therapy containing one or more of the following: ivacaftor, lumacaftor, tezacaftor, elexacaftor; **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, St. John's Wort); **AND**
- Patient will avoid concomitant use with strong or moderate CYP3A inhibitors (e.g., ketoconazole, fluconazole, erythromycin, itraconazole, grapefruit juice), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction, and/or dose modifications will be implemented; **AND**
- Patient has a baseline ophthalmological examination prior to initiation of therapy and will continue to have follow-up ophthalmological examinations periodically thereafter (**pediatric patients only**);**AND**
- Patient has a documented diagnosis of cystic fibrosis; **AND**
- Patient is homozygous (mutation is present on both alleles) for the *F508del* mutation or has at least one mutation in the *CFTR* gene, as confirmed by a Food and Drug Administration (FDA)-cleared or Clinical Laboratory Improvement Amendments (CLIA)-compliant CF mutation test, that is responsive to tezacaftor/ivacaftor based on clinical and/or in vitro assay data*****

***_CFTR_ Gene Mutations that produce CFTR Protein and are responsive to tezacaftor/ivacaftor – ivacaftor:**
546insCTA; E92K; G576A; L346P; R117G; S589N; 711+3A→G; E116K; G576A; R668C†; L967S; R117H; S737F; 2789+5G→A*; E193K; G622D; L997F; R117L; S912L; 3272-26A→G*; E403D; G970D; L1324P; R117P; S945L*; 3849+10kbC→T*; E588V; G1069R; L1335P; R170H; S977F*; A120T; E822K; G1244E; L1480P; R258G; S1159F; A234D; E831X; G1249R; M152V; R334L; S1159P; A349V; F191V; G1349D; M265R; R334Q; S1251N; A455E*; F311del; H939R; M952I; R347H*; S1255P; A554E; F311L; H1054D; M952T; R347L; T338I; A1006E; F508C; H1375P; P5L; R347P; T1036N; A1067T; F508C;S1251N†; I148T; P67L*; R352Q*; T1053I; D110E; F508del^; I175V; P205S; R352W; V201M; D110H*; F575Y; I336K; Q98R; R553Q; V232D; D192G; F1016S; I601F; Q237E; R668C; V562I; D443Y; F1052V; I618T; Q237H; R751L; V754M; D443Y; G576A; R668C†; F1074L; I807M; Q359R; R792G; V1153E; D579G*; F1099L; I980K; Q1291R; R933G; V1240G; D614G; G126D; I1027T; R31L; R1066H; V1293G; D836Y; G178E; I1139V; R74Q; R1070Q; W1282R; D924N; G178R; I1269N; R74W; R1070W*; Y109N; D979V; G194R; I1366N; R74W; D1270N†; R1162L; Y161S; D1152H*; G194V; K1060T; R74W; V201M†; R1283M; Y1014C; D1270N; G314E; L15P; R74W; V201M; D1270N†; R1283S; Y1032C; E56K; G551D; L206W*; R75Q; S549N; E60K; G551S; L320V; R117C*; S549R.*
* Clinical data for these mutations can be found in the prescribing information Clinical Studies. ^ A patient must have two copies of the F508del mutation or at least one copy of a responsive mutation presented in Table 6 to be indicated. † Complex/compound mutations where a single allele of the CFTR gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

Table may not be all-inclusive; verify gene mutations responsive to elexacaftor/tezacaftor/ivacaftor in the current prescribing information

CLINICAL CRITERIA FOR RENEWAL

- Disease response as indicated by one or more of the following:
  - Decreased pulmonary exacerbations compared to pretreatment baseline
  - Decrease in decline of lung function as measured by percent predicted FEV_1 within previous the 30 days compared to pre-treatment baseline
  - Improvement or stabilization of lung function as measured by percent predicted FEV_1 within the previous 30 days compared to pre-treatment baseline
  - Improvement in quality of life (e.g., Cystic Fibrosis Questionnaire-Revised [CFQ-R] score), weight gain, or growth; **AND**
- Patient has not received a lung transplant; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include elevated transaminases (ALT or AST), development of non-congenital cataracts or lens opacities, etc.

SYNAREL® (NAFARELIN ACETATE)

Length of Authorization:	Varies by diagnosis, see specific criteria below
Initiative:	SPC: Hormonal Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Endometriosis**

- Patient is 18 years of age or older; **AND**
- Female patients do not have undiagnosed abnormal vaginal bleeding; **AND**
- Patient does not have a hypersensitivity to GnRH or GnRH agonist analog type medications; **AND**
- Women of child-bearing age must have a negative pregnancy test; **AND**
- Patient is not currently breastfeeding; **AND**
- Diagnosis has been confirmed by a workup/evaluation (vs. presumptive treatment); **AND**
- Patient has not previously used Synarel® for endometriosis

Length of Authorization:	6 months, **not eligible for renewal**. Escalate renewal request to a pharmacist.

Diagnosis of **Central Precocious Puberty**

- Patient is less than 13 years old; **AND**
- Female patients do not have undiagnosed abnormal vaginal bleeding; **AND**
- Patient does not have a hypersensitivity to GnRH or GnRH agonist analog type medications; **AND**
- Onset of secondary sexual characteristics earlier than age 8 for girls and 9 for boys associated with pubertal pituitary gonadotropin activation; **AND**
- Diagnosis is confirmed by pubertal gonadal sex steroid levels and a pubertal LH response to stimulation by native GnRH; **AND**
- Bone age advanced greater than 2 standard deviations (SD) beyond chronological age; **AND**
- Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor); **AND**
- Will not be used in combination with growth hormone

Length of Authorization:	1 year

CLINICAL CRITERIA FOR RENEWAL

Diagnosis of **Central Precocious Puberty**

- Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, a decrease in the ratio of bone age to chronological age (BA:CA), and improvement in final height prediction; **AND**
- Absence of unacceptable toxicity from the drug (e.g., convulsions/seizures, development of ovarian cysts, psychiatric events, cerebrovascular disorder); **AND**
- Patient is less than 13 years old

Diagnosis of **Endometriosis**

- May not be renewed

SYNRIBO® (OMACETAXINE MEPESUCCINATE)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Chronic myelogenous leukemia (CML)

- Patient is at least 18 years of age; **AND**
- Patient's disease is confirmed by either a Philadelphia chromosome-positive (Ph+) or *BCR-ABL1* positive laboratory test result; **AND**
  - Used as single agent therapy for patients resistant, intolerant, or had an inadequate response after at least 3 months of therapy to TWO or more tyrosine kinase inhibitor (TKI) therapies (e.g., bosutinib, imatinib, dasatinib, ponatinib or nilotinib); **AND**
    - Patient has chronic phase CML; **OR**
    - Patient has advanced disease that has progressed to accelerated phase; **OR**
    - For post-allogeneic stem cell transplant follow-up therapy with molecular relapse (*BCR-ABL1* transcript positive) following complete cytogenetic response (CCyR); **OR**
    - For post-allogeneic stem cell transplant follow-up therapy with relapse or those who are not in CCyR; **OR**
    - Patient has T315I mutation positive disease.

CLINICAL CRITERIA FOR RENEWAL

Coverage can be renewed based upon the following criteria:

- Absence of unacceptable toxicity from the drug (e.g., myelosuppression [e.g., severe neutropenia, thrombocytopenia, or anemia], hemorrhage [including cerebral and gastrointestinal], uncontrolled hyperglycemia); **AND**
- Patient has been adherent to therapy; **AND**
- Treatment response as indicated by one of the following:
  - Patient has *BCR-ABL1* (IS) transcript levels:
    - ≤ 10% at 3 months; **OR**
    - ≤ 10% at 6 months; **OR**
    - ≤ 0.1% or a ≥ 3-log reduction in *BCR-ABL1* mRNA from the standardized baseline, if qPCR (IS) is not available
- **Note**: cytogenetic assessment of response may be used if quantitative RT-PCR (QPCR) using International Scale (IS) for *BCR-ABL1* is not available

TABRECTA® (CAPMATINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years old; **AND**
- Must be used as a single agent; **AND**
- Patient will avoid coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, efavirenz); **AND**
- Therapy will not be used concomitantly with other tyrosine-protein kinase mesenchymal-epithelial transition [cMET] or Hepatocyte Growth Factor Receptor [HGFR] -inhibitors (i.e., crizotinib); **AND**
- Patient has not previously failed treatment with cMET or HGF -inhibitors (e.g., crizotinib); **AND**
- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Patient's disease has a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved or CLIA compliant test; **OR**
  - Patient has disease with a high-level of MET-amplification that is amenable to therapy

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., interstitial lung disease [ILD], pneumonitis, severe hepatotoxicity, severe photosensitivity)

TAFINLAR® (DABRAFENIB)

Length of Authorization:	6 months, may be renewed. Adjuvant use in melanoma may be renewed for up to 1 year of therapy.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cutaneous Melanoma**

- Patient is at least 18 years of age; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib) unless otherwise specified; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole); if therapy is unavoidable, patient will be closely monitored for adverse reactions and/or dose modifications will be implemented
  - Strong CYP2C8 inhibitors (e.g., gemfibrozil, clopidogrel); if therapy is unavoidable, patient will be closely monitored for adverse reactions and/or dose modifications will be implemented; **AND**

- Patient has BRAF V600 mutation-positive disease as detected by a Food and Drug Administration (FDA)-approved or Clinical Laboratory Improvement Amendments (CLIA)-compliant test; **AND**
  - Used in combination with trametinib as adjuvant therapy; **AND**
    - Patient has lymph node involvement following complete resection, complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; **OR**
    - Patient has clinical satellite/in-transit metastases or local satellite/in-transit recurrence with no evidence of disease (NED) after complete excision to clear margins; **OR**
  - Used in combination with trametinib **or** as a single agent if BRAF/MEK inhibitor combination therapy is contraindicated; **AND**
    - Used as initial or subsequent therapy in patients with unresectable or metastatic** disease; **OR**
    - Used as re-induction therapy for patients who experience disease control (i.e., complete response, partial response, or stable disease) from prior BRAF inhibitor therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation

***Metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Non-Small Cell Lung Cancer**

- Patient is at least 18 years or older; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib) unless otherwise specified; **AND**
- LVEF is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole); if therapy is unavoidable, patient will be closely monitored for adverse reactions and/or dose modifications will be implemented
  - Strong CYP2C8 inhibitors (e.g., gemfibrozil, clopidogrel); if therapy is unavoidable, patient will be closely monitored for adverse reactions and/or dose modifications will be implemented; **AND**

- Patient has BRAF V600E mutation-positive disease as detected by an FDA-approved or CLIA-compliant test; **AND**
- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Used in combination with trametinib

Diagnosis of **Anaplastic Thyroid Cancer (ATC)**

- Patient is at least 18 years or older; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib) unless otherwise specified; **AND**
- LVEF is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole); if therapy is unavoidable, patient will be closely monitored for adverse reactions and/or dose modifications will be implemented
  - Strong CYP2C8 inhibitors (e.g., gemfibrozil, clopidogrel); if therapy is unavoidable, patient will be closely monitored for adverse reactions and/or dose modifications will be implemented; **AND**

- Patient has BRAF V600E mutation-positive disease; **AND**
- Used in combination with trametinib; **AND**
  - Patient has locally advanced disease with no satisfactory locoregional treatment options; **OR**
  - Patient has metastatic disease

Diagnosis of **Differentiated Thyroid Carcinoma (Papillary, Follicular, or Hurthle Cell)**

- Patient is at least 18 years or older; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib) unless otherwise specified; **AND**
- LVEF is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole); if therapy is unavoidable, patient will be closely monitored for adverse reactions and/or dose modifications will be implemented
  - Strong CYP2C8 inhibitors (e.g., gemfibrozil, clopidogrel); if therapy is unavoidable, patient will be closely monitored for adverse reactions and/or dose modifications will be implemented; **AND**

- Patient has progressive and/or symptomatic BRAF V600E mutation-positive disease ; **AND**
- Patient has unresectable locoregional recurrent disease, persistent disease, or distant metastases; **AND**
- Disease is not susceptible to radioactive-iodine (RAI) therapy; **AND**
- Alternative therapies (e.g., clinical trial or systemic therapy) are not available or appropriate; **AND**
- Used as a single agent

Diagnosis of **Central Nervous System (CNS) Cancers:**

- Patient is at least 18 years or older; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib) unless otherwise specified; **AND**
- LVEF is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole); if therapy is unavoidable, patient will be closely monitored for adverse reactions and/or dose modifications will be implemented
  - Strong CYP2C8 inhibitors (e.g., gemfibrozil, clopidogrel); if therapy is unavoidable, patient will be closely monitored for adverse reactions and/or dose modifications will be implemented; **AND**

- Patient has BRAF V600E mutation-positive disease; **AND**
  - Used in combination with trametinib; **AND**
    - Patient has pilocytic astrocytoma **or** pleomorphic xanthoastrocytoma (PXA) **or** ganglioglioma; **AND**
      - Used as adjuvant treatment for incomplete resection, biopsy, or surgically inaccessible location; **OR**
    - Patient has recurrent or progressive low-grade glioma with prior fractionated external beam radiation therapy (EBRT); **OR**
    - Patient has recurrent anaplastic glioma or glioblastoma; **OR**
- Used for brain metastases in patients with BRAF V600E mutation-positive melanoma; **AND**
  - Used in combination with trametinib; **AND**
    - Used as primary treatment in patients with small asymptomatic brain metastases; **OR**
    - Patient has recurrent limited brain metastases; **OR**
    - Used for relapsed limited brain metastases with stable systemic disease or reasonable systemic treatment options; **OR**
    - Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Hepatobiliary Cancers (Gallbladder Cancer, Intra-/Extra-Hepatic Cholangiocarcinoma)**

- Patient is at least 18 years or older; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib) unless otherwise specified; **AND**
- LVEF is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole; if therapy is unavoidable, patient will be closely monitored for adverse reactions and/or dose modifications will be implemented
  - Strong CYP2C8 inhibitors (e.g., gemfibrozil, clopidogrel); if therapy is unavoidable, patient will be closely monitored for adverse reactions and/or dose modifications will be implemented; **AND**

- Used in combination with trametinib; **AND**
- Used as subsequent therapy for progression on or after systemic treatment for unresectable or metastatic BRAF-V600E mutation positive disease

Diagnosis of **Histiocytic Neoplasms**

- Patient is at least 18 years or older; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib) unless otherwise specified; **AND**
- LVEF is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole). If therapy is unavoidable, patient will be closely monitored for adverse reactions and/or dose modifications will be implemented; **AND**
  - Strong CYP2C8 inhibitors (e.g., gemfibrozil, clopidogrel). If therapy is unavoidable, patient will be closely monitored for adverse reactions and/or dose modifications will be implemented; **AND**

- Used as single agent therapy; **AND**
- Patient has BRAF V600E mutation-positive disease; **AND**
- Patient has one of the following:
  - Patient relapsed/refractory or symptomatic Erdheim-Chester disease **OR**
  - Langerhans Cell Histiocytosis (LCH) **AND**
    - Patient has multisystem disease with symptomatic or impending organ dysfunction; **OR**
    - Patient has pulmonary disease; **OR**
    - Patient has multifocal single system bone disease not responsive to treatment with a bisphosphonate and > 2 lesions; **OR**
    - Patient has CNS lesions; **OR**
    - Patient has relapsed or refractory disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- LVEF has not had an **absolute** decrease of > 20% from baseline and is not below the lower limit of normal (LLN) **(LVEF results must be within the previous 3 months); AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include major hemorrhagic events, cardiomyopathy, uveitis, severe febrile reactions, serious dermatological reactions (e.g., Stevens-Johnson syndrome [SJS] and drug reaction with eosinophilia and systemic symptoms [DRESS]), hyperglycemia, new primary malignancies, hemolytic anemia in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency, etc.

Adjuvant treatment of Melanoma

- Treatment has not exceeded 1 year of therapy

Cutaneous Melanoma (re-induction therapy

- Refer to initial criteria – used as re-induction therapy

TAGRISSO® (OSIMERTINIB)

Length of Authorization:	6 months, may be renewed Adjuvant treatment of NSCLC can be authorized up to a maximum of 3 years of therapy
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC):**

- Patient is at least 18 years; **AND**
- Must be used as a single agent; **AND**
- Patient's tumor is epidermal growth factor receptor (EGFR) mutation-positive, confirmed by an FDA-approved or CLIA-compliant test; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with drugs known to prolong the QTc interval with known risk of Torsades de pointes (e.g. amiodarone, citalopram, fluconazole, clarithromycin, etc.); **AND**
- Used for recurrent, advanced or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **OR**
  - Used as continuation of therapy following disease progression on osimertinib for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions; **OR**
  - Used as subsequent therapy for T790M mutation-positive disease after progression on or after EGFR tyrosine kinase inhibitor therapy (e.g., erlotinib, gefitinib, afatinib, dacomitinib); **OR**
  - Used for the treatment of progressive CNS disease or leptomeningeal disease following progression on EGFR tyrosine kinase inhibitor therapy (e.g., erlotinib, gefitinib, afatinib, dacomitinib)
- Used in adjuvant therapy after tumor resection

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Central Nervous System Cancers – Brain Metastases:**

- Patient is at least 18 years or older; **AND**
- Must be used as a single agent; **AND**
- Patient's tumor is epidermal growth factor receptor (EGFR) mutation-positive, confirmed by an FDA-approved or CLIA-compliant test; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with drugs known to prolong the QTc interval with known risk of Torsades de pointes (e.g. amiodarone, citalopram, fluconazole, clarithromycin, etc.); **AND**
- Patient has brain metastases from T790M mutation-positive non-small cell lung cancer; **AND**
  - Used as initial treatment in patients with small asymptomatic limited or extensive brain metastases; **OR**
  - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
- Patient has leptomeningeal metastases from EGFR mutation-positive non-small cell lung cancer; **AND**
  - Used as primary treatment for patients with good risk status (e.g., KPS ≥60, no major neurologic deficits, minimal systemic disease, and reasonable systemic treatment options if needed); **OR**
  - Used as maintenance treatment in patients with negative CSF cytology or in clinically stable patients with persistently positive CSF cytology; **OR**
  - Used in patients with positive CSF cytology that have disease progression after prior treatment

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: interstitial lung disease (ILD)/pneumonitis, QTc interval prolongation, cardiomyopathy (cardiac failure, congestive heart failure, pulmonary edema, or decreased ejection fraction), keratitis, erythema multiforme/ Stevens-Johnson syndrome, cutaneous vasculitis, etc.

TALZENNA® (TALAZOPARIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**:

- Patient is at least 18 years or older; **AND**
- Used as single-agent therapy; **AND**
- Patient has not received previous treatment with a PARP-inhibitor (e.g., niraparib, rucaparib, olaparib) prior to initiating therapy; **AND**
- Patient does not have untreated central nervous system (CNS) metastases (i.e., patient has completed definitive local therapy and have stable CNS lesions on repeat brain imaging); **AND**
- Patient has deleterious or suspected-deleterious germline BRCA-mutated (gBRCAm) disease as detected by a CLIA-compliant or FDA-approved test; **AND**
- Patient has HER2-negative locally advanced, recurrent unresectable, or metastatic disease; **AND**
  - If hormone receptor positive, patient must have visceral crisis or be refractory to endocrine therapy; **OR**
- Patient has HER2-positive recurrent unresectable or metastatic disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include myelodysplastic syndrome/acute myeloid leukemia (MDS/AML), bone marrow suppression (e.g., anemia, leukopenia, neutropenia, and/or thrombocytopenia), etc.

TARCEVA® (ERLOTINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Pancreatic Cancer**

- Patient is at least 18 years old; **AND**
- Patient will avoid concomitant therapy with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented:
  - Coadministration with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); **AND**
  - Coadministration with combined CYP3A4 and CYP1A2 inhibitors (e.g., ciprofloxacin); **AND**
  - Coadministration with CYP3A4 inducers (e.g., carbamazepine, phenytoin, rifampin); **AND**
  - Coadministration with cigarette smoking and CYP1A2 inducers (e.g., teriflunomide, rifampin, phenytoin); **AND**
  - Coadministration with acid-reducing agents (e.g., proton pump inhibitors, H2-recepotor antagonists, antacids); **AND**
- Used in combination with gemcitabine

Diagnosis of **Non–Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years old; **AND**
- Patient will avoid concomitant therapy with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented:
  - Coadministration with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); **AND**
  - Coadministration with combined CYP3A4 and CYP1A2 inhibitors (e.g., ciprofloxacin); **AND**
  - Coadministration with CYP3A4 inducers (e.g., carbamazepine, phenytoin, rifampin); **AND**
  - Coadministration with cigarette smoking and CYP1A2 inducers (e.g., teriflunomide, rifampin, phenytoin); **AND**
  - Coadministration with acid-reducing agents (e.g., proton pump inhibitors, H2-recepotor antagonists, antacids); **AND**
- Patient's disease has a known sensitizing EGFR mutation (i.e., exon 19 deletions or exon 21 [L858R] substitution mutations) as detected by an FDA-approved or CLIA-compliant test ; **AND**
  - Used as single agent therapy; **OR**
  - Used in combination with bevacizumab for non-squamous cell histology in patients with no history of hemoptysis; **OR**
  - Used in combination with ramucirumab

In addition to the above criteria:

- ***In patients with metastatic NSCLC and EGFR exon 19 deletions or exon 21 substitution mutations, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic erlotinib***

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Central Nervous System (CNS) Cancer (Limited or Extensive Brain Metastases)**

- Patient is at least 18 years old; **AND**
- Patient will avoid concomitant therapy with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented:
  - Coadministration with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); **AND**
  - Coadministration with combined CYP3A4 and CYP1A2 inhibitors (e.g., ciprofloxacin); **AND**
  - Coadministration with CYP3A4 inducers (e.g., carbamazepine, phenytoin, rifampin); **AND**
  - Coadministration with cigarette smoking and CYP1A2 inducers (e.g., teriflunomide, rifampin, phenytoin); **AND**
  - Coadministration with acid-reducing agents (e.g., proton pump inhibitors, H2-recepotor antagonists, antacids); **AND**
- Used as single-agent therapy; **AND**
- Patient has EGFR sensitizing mutation-positive non-small cell lung cancer as detected by an FDA-approved or CLIA-compliant test

Diagnosis of **Bone Cancer – Chordoma**

- Patient is at least 18 years of age; **AND**
- Patient will avoid concomitant therapy with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented:
  - Coadministration with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); **AND**
  - Coadministration with combined CYP3A4 and CYP1A2 inhibitors (e.g., ciprofloxacin); **AND**
  - Coadministration with CYP3A4 inducers (e.g., carbamazepine, phenytoin, rifampin); **AND**
  - Coadministration with cigarette smoking and CYP1A2 inducers (e.g., teriflunomide, rifampin, phenytoin); **AND**
  - Coadministration with acid-reducing agents (e.g., proton pump inhibitors, H2-recepotor antagonists, antacids); **AND**
- Patient has recurrent disease with conventional or chondroid histology; **AND**
- Used as single-agent therapy

Diagnosis of **Renal Cell Carcinoma**

- Patient is at least 18 years old; **AND**
- Patient will avoid concomitant therapy with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented:
  - Coadministration with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); **AND**
  - Coadministration with combined CYP3A4 and CYP1A2 inhibitors (e.g., ciprofloxacin); **AND**
  - Coadministration with CYP3A4 inducers (e.g., carbamazepine, phenytoin, rifampin); **AND**
  - Coadministration with cigarette smoking and CYP1A2 inducers (e.g., teriflunomide, rifampin, phenytoin); **AND**
  - Coadministration with acid-reducing agents (e.g., proton pump inhibitors, H2-recepotor antagonists, antacids); **AND**
- Patient has relapsed or metastatic (i.e., stage IV) disease with non-clear cell histology; **AND**
  - Used as a single-agent therapy; **OR**
  - Used in combination with bevacizumab to treat advanced papillary renal cell carcinoma (includes hereditary leiomyomatosis and renal cell cancer [HLRCC])

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., interstitial lung disease [ILD], acute renal failure, hepatotoxicity [severe changes in liver function], gastrointestinal perforations, bullous, blistering, and exfoliative skin disorders [e.g., Stevens-Johnson syndrome/toxic epidermal necrolysis], cerebrovascular accident, microangiopathic hemolytic anemia with thrombocytopenia, ocular disorders [e.g., decreased tear production, abnormal eyelash growth, keratoconjunctivitis sicca, or keratitis], hemorrhage in patients taking warfarin)

TARGRETIN® (BEXAROTENE) ORAL FORMULATION

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cutaneous T-cell lymphoma (CTCL)**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant use with gemfibrozil **(Note: This only applies to the oral formulation)**; **AND**
- Females of reproductive potential must have a negative pregnancy test and use effective contraception one month prior to initiating treatment and monthly while on therapy; **AND**
- Patient has a diagnosis of cutaneous manifestations of cutaneous T-cell lymphoma (e.g., mycosis fungoides/Sezary syndrome); **AND**
  - Used as primary therapy for stage IB or more advanced disease; **OR**
  - Patient is refractory to, or has progressed on, prior therapy; **OR**
  - Patient has relapsed or persistent disease

Diagnosis of **Cutaneous T-cell lymphoproliferative Disorders**

- Patient is 18 years of age or older; **AND**
- Patient will avoid concomitant use with gemfibrozil **(Note: This only applies to the oral formulation)**; **AND**
- Females of reproductive potential must have a negative pregnancy test and use effective contraception, one month prior to initiating treatment and monthly while on therapy; **AND**
- Patient is CD30-positive; **AND**
- Patient has cutaneous manifestation of disease; **AND**
- Used as a single agent; **AND**
- Used as primary therapy or for relapsed or refractory disease; **AND**
  - Patient has a diagnosis of primary cutaneous anaplastic large cell lymphoma (ALCL); **AND**
    - Patient has multifocal lesions; **OR**
  - Patient has a diagnosis of lymphomatoid papulosis (LyP); **AND**
    - Patient has extensive lesions

Note: For topical Targretin please see the DERMATOLOGICS: TOPICAL ANTINEOPLASTICS section

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hyperlipidemia, pancreatitis, hepatotoxicity (greater than three times the upper limit of normal values for SGOT/AST, SGPT/ALT, or bilirubin), cholestasis, hepatic failure, hematologic toxicities (e.g., leukopenia, neutropenia), hypothyroidism, hypoglycemia, cataracts, photosensitivity, etc.

TASIGNA® (NILOTINIB)

Length of Authorization:	6 months, may renewed Patients with Ph+ CML-CP who have achieved a sustained molecular response should be evaluated for discontinuation after taking nilotinib for a minimum of 3 years
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myelogenous Leukemia (CML)**

- *For Standard and Precision* ***for CML, for new starts only: patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic imatinib OR Bosulif®**** *(***following the NCCN guidelines surrounding genetic mutations)*

- Patient is at least 18 years old; **AND**
- Patient has a baseline QTc interval of ≤ 480 ms **and** does not have a history of long QT-syndrome; **AND**
- Patient does not have hypokalemia or hypomagnesemia; **AND**
- Patient will avoid concomitant use of all the following:
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with proton pump inhibitors (PPIs), or if acid-reduction therapy is required, use of H2-receptor antagonists or antacids may be used at staggered administration times; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan); **AND**
- Patient's disease is confirmed by either Philadelphia chromosome-positive (Ph+) or BCR-ABL1 positive laboratory test result; **AND**
- Patient does not have any of the following *BCR-ABL1* mutations: T315I, Y253H, E255K/V or F359V/C/I (****Note:** This does **not** apply to patients receiving first-line or continued therapy); **AND**
  - Patient is resistant, intolerant, or had an inadequate response to prior therapy consisting of a 3-month trial or longer with a tyrosine kinase inhibitor (e.g., imatinib, bosutinib, dasatinib)
    - Patient is at least 1 year of age; **AND**
    - Used as a single agent for chronic phase or accelerated phase disease; **OR**
  - Used as primary treatment; **AND**
    - Used as single agent for newly diagnosed chronic phase disease in patients at least 1 year of age; **OR**
    - Used as a single agent for accelerated or myeloid blast phase disease; **OR**
    - Used in combination with corticosteroids for lymphoid blast phase disease; **OR**
    - Used in combination with induction chemotherapy for disease in lymphoid blast phase or myeloid blast phase; **OR**
  - Used as switch therapy; **AND**
    - Patient received primary therapy with one of the following: imatinib, bosutinib, or dasatinib; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient has *BCR-ALB1* transcript levels:
  - > 0.1% to 1% at 12 months (if treatment goal is treatment-free remission); **OR**
  - > 1% to 10% at 12 months; **OR**
  - > 10% at any response milestone; **OR**

– Used as continued therapy; **AND**
- Patient has *BCR-ALB1* transcript levels:
  - ≤ 10% at any response milestone; **OR**
  - > 10% at 3 months; **OR**

– Used post-allogeneic hematopoietic stem cell transplant (HCT); **AND**
- Used for at least one year in patients with prior complete cytogenetic response (CCyR) for accelerated or blast phase disease; **OR**
- Used as follow-up therapy in patients with molecular relapse (BCR-ABL1 transcript positive) following CCyR; **OR**
- Used as follow-up therapy in patients with relapse or those who are not in CCyR; **OR**

– Re-initiation of treatment; **AND**
- Patient lost molecular response (MMR or MR4.0) after discontinuation of therapy with nilotinib

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 18 years old unless otherwise specified; **AND**
- Patient has a baseline QTc interval of ≤ 480 ms **and** does not have a history of long QT-syndrome; **AND**
- Patient will avoid concomitant use of all the following:
  – Coadministration with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  – Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  – Coadministration with proton pump inhibitors (PPIs), or if acid-reduction therapy is required, use of H2-receptor antagonists or antacids may be used at staggered administration times; **AND**
  – Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan); **AND**
- Patient does not have hypokalemia or hypomagnesemia; **AND**
- Patient's disease is Philadelphia chromosome positive (Ph+) disease; **AND**
- Patient does not have any of the following BCR-ABL1 mutations: T315I, Y253H, E255K/V, F359V/C/I or G250E; **AND**
  – Used for relapsed or refractory disease; **AND**
    - Used as a single agent; **OR**
    - Used in combination with an induction therapy not previously used; **OR**
    - Used in combination with blinatumomab; **OR**
  – Used as maintenance therapy; **AND**
    - Used in combination with vincristine and prednisone with or without methotrexate and mercaptopurine; **OR**
    - Used post-hematopoietic stem cell transplant; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient is at least 15 years of age and < 65 years of age; **AND**
  - Used in a multiagent chemotherapy regimen for induction or consolidation therapy; **OR**
  - Used in combination with a corticosteroid for induction or consolidation therapy; **OR**
  - Used in combination with vincristine and dexamethasone for induction therapy; **OR**
  - Used in combination with blinatumomab as consolidation therapy for persistent/rising minimal residual disease following a complete response (CR) to induction therapy; **OR**
- Patient is ≥ 65 years of age or with substantial comorbidities; **AND**
  - Used as induction therapy as part of one of the following regimens:
    - As a single agent or in combination with a corticosteroid; **OR**
    - In combination with vincristine and dexamethasone; **OR**
    - In combination with a multiagent chemotherapy regimen
  - Used as consolidation therapy; **AND**
    - Patient has persistent/rising minimal residual disease following a complete response to induction therapy; **AND**
    - Used in combination with blinatumomab

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is at least 18 years old; **AND**
- Patient has a baseline QTc interval of ≤ 480 ms **and** does not have a history of long QT-syndrome; **AND**
- Patient does not have hypokalemia or hypomagnesemia; **AND**
- Patient will avoid concomitant use of all the following:
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with proton pump inhibitors (PPIs), or if acid-reduction therapy is required, use of H2-receptor antagonists or antacids may be used at staggered administration times; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan); **AND**
- Patient had unresectable, recurrent, or metastatic disease; **AND**
- Used as a single agent; **AND**
- Used after failure on approved therapies including each of the following: imatinib, regorafenib, ripretinib, and sunitinib

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**

- Patient is at least 18 years old; **AND**
- Patient has a baseline QTc interval of ≤ 480 ms **and** does not have a history of long QT-syndrome; **AND**
- Patient does not have hypokalemia or hypomagnesemia; **AND**
- Patient will avoid concomitant use of all the following:
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with proton pump inhibitors (PPIs), or if acid-reduction therapy is required, use of H2-receptor antagonists or antacids may be used at staggered administration times; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan); **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient has eosinophilia and ABL1 rearrangement; **AND**
  - Patient chronic phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

CLINICAL CRITERIA FOR RENEWAL

- Patient adherent to therapy; **AND**
  - Absence of unacceptable toxicity from the drug (e.g., electrolyte abnormalities [hypophosphatemia, hypokalemia, hyperkalemia, hypocalcemia, hyponatremia], myelosuppression [neutropenia, thrombocytopenia, anemia], QT prolongation, cardiac and arterial vascular occlusive events, pancreatitis and elevated serum lipase, hepatotoxicity [severe changes in liver function tests], tumor lysis syndrome, hemorrhage, fluid retention, growth retardation in pediatric patients); **AND**
- **Acute lymphoblastic leukemia (ALL) Only:**
  - Treatment response or stabilization of disease as indicated by complete blood count (CBC), bone marrow cytogenic analysis, real-time quantitative polymerase chain reaction (QPCR), or Fluorescence in situ hybridization (FISH)
- **Chronic myelogenous leukemia (CML) only:**
  - Re-initiation of treatment:
    - Patient lost molecular response (MMR or MR4.0) after discontinuation of therapy with nilotinib; **OR**
  - Treatment response as indicated by one of the following *BCR-ABL1* (IS) transcript levels:
    - > 0.1% to 10% at 3 months or 6 months; **OR**
    - > 0.1% to 1% at 12 months and beyond (if treatment goal is long-term survival); **OR**
    - ≤ 0.1% at 12 months and beyond (if treatment goal is treatment-free remission)

    Note: cytogenetic assessment of response may be used if quantitative PT-PCR (QPCR) using international scale (IS) for *BCR-ABL1* is not available

    Note: For patients who are within the first year of treatment with Tasigna® and are not meeting the levels under the renewal criteria for CML, the levels under initial sections "Continued Therapy" may be utilized. If the patient has been on therapy for longer than a year, they must meet the levels mentioned in the renewal criteria.
- **Gastrointestinal stromal tumors (GIST) only:**
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread
- **Myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes only:**
  - Disease response as evidenced by at least one of the following:
    - Decrease in spleen size or improvements in other myelofibrosis symptoms (e.g., fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding)
    - Stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic, or molecular complete response CR), complete hematologic response, or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

Consider discontinuation of treatment in patients with Ph+ CML-CP	
Newly diagnosed Ph+ CML-CP who have: – been treated with Tasigna® for at least 3 years – maintained a molecular response of at least MR4.0 (corresponding to = BCR-ABL/ABL ≤ 0.01% IS) for one year prior to discontinuation of therapy – achieved an MR4.5 for the last assessment taken immediately prior to discontinuation of therapy – been confirmed to express the typical BCR-ABL transcripts (e13a2/b2a2 or e14a2/b3a2) – no history of accelerated phase or blast crisis – no history of prior attempts of treatment-free remission discontinuation that resulted in relapse.	Ph+ CML-CP that are resistant or intolerant to treatment with imatinib who have achieved a sustained molecular response (MR4.5) on Tasigna® who have: – been treated with Tasigna® for a minimum of 3 years – been treated with imatinib only prior to treatment with Tasigna® – achieved a molecular response of MR.4.5 (corresponding to = BCR-ABL/ABL ≤ 0.0032% IS) – sustained an MR4.5 for a minimum of one year immediately prior to discontinuation of therapy – been confirmed to express the typical BCR-ABL transcripts (e13a2/b2a2 or e14a2/b3a2) – no history of accelerated phase or blast crisis – no history of prior attempts of treatment-free remission discontinuation that resulted in relapse.

ENHANCED FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myelogenous Leukemia (CML)**

- *For Enhanced Formulary **for CML, for new starts only: patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic imatinib OR Bosulif® OR Sprycel**** (***following the NCCN guidelines surrounding genetic mutations)*

- Patient is at least 18 years old; **AND**
- Patient has a baseline QTc interval of ≤ 480 ms **and** does not have a history of long QT-syndrome; **AND**
- Patient does not have hypokalemia or hypomagnesemia; **AND**
- Patient will avoid concomitant use of all the following:
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with proton pump inhibitors (PPIs), or if acid-reduction therapy is required, use of H2-receptor antagonists or antacids may be used at staggered administration times; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan); **AND**
- Patient's disease is confirmed by either Philadelphia chromosome-positive (Ph+) or BCR-ABL1 positive laboratory test result; **AND**

- Patient does not have any of the following *BCR-ABL1* mutations: T315I, Y253H, E255K/V, or F359V/C/I (****Note:** This does **NOT** apply to patients receiving first-line or continued therapy); **AND**
  - Patient is resistant, intolerant, or had an inadequate response to prior therapy consisting of a 3-month trial or longer with a tyrosine kinase inhibitor (e.g., imatinib, bosutinib, dasatinib)
    - Patient is at least 1 year of age; **AND**
    - Used as a single agent for chronic phase or accelerated phase disease; **OR**
  - Used as primary treatment; **AND**
    - Used as single agent for newly diagnosed chronic phase disease in patients at least 1 year of age; **OR**
    - Used as a single agent for accelerated or myeloid blast phase disease; **OR**
    - Used in combination with corticosteroids for lymphoid blast phase disease; **OR**
    - Used in combination with induction chemotherapy for disease in lymphoid blast phase or myeloid blast phase; **OR**
  - Used as switch therapy; **AND**
    - Patient received primary therapy with one of the following: imatinib, bosutinib, or dasatinib; **AND**
    - Patient has *BCR-ALB1* transcript levels:
      - > 0.1% to 1% at 12 months (if treatment goal is treatment-free remission); **OR**
      - > 1% to 10% at 12 months; **OR**
      - > 10% at any response milestone; **OR**
  - Used as continued therapy; **AND**
    - Patient has *BCR-ALB1* transcript levels:
      - ≤ 10% at any response milestone; **OR**
      - > 10% at 3 months; **OR**
  - Used post-allogeneic hematopoietic stem cell transplant (HCT); **AND**
    - Used for at least one year in patients with prior complete cytogenetic response (CCyR) for accelerated or blast phase disease; **OR**
    - Used as follow-up therapy in patients with molecular relapse (BCR-ABL1 transcript positive) following CCyR; **OR**
    - Used as follow-up therapy in patients with relapse or those who are not in CCyR; **OR**
  - Re-initiation of treatment; **AND**
    - Patient lost molecular response (MMR or MR4.0) after discontinuation of therapy with nilotinib

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 18 years old unless otherwise specified; **AND**
- Patient has a baseline QTc interval of ≤ 480 ms **and** does not have a history of long QT-syndrome; **AND**
- Patient will avoid concomitant use of all the following:
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with proton pump inhibitors (PPIs), or if acid-reduction therapy is required, use of H2-receptor antagonists or antacids may be used at staggered administration times; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan); **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient does not have hypokalemia or hypomagnesemia; **AND**
- Patient's disease is Philadelphia chromosome positive (Ph+) disease; **AND**
- Patient does not have any of the following BCR-ABL1 mutations: T315I, Y253H, E255K/V, F359V/C/I or G250E; **AND**
  - Used for relapsed or refractory disease; **AND**
    - Used as a single agent; **OR**
    - Used in combination with an induction therapy not previously used; **OR**
    - Used in combination with blinatumomab; **OR**
  - Used as maintenance therapy; **AND**
    - Used in combination with vincristine and prednisone with or without methotrexate and mercaptopurine; **OR**
    - Used post-hematopoietic stem cell transplant; **OR**
  - Patient is at least 15 years of age and < 65 years of age; **AND**
    - Used in a multiagent chemotherapy regimen for induction or consolidation therapy; **OR**
    - Used in combination with a corticosteroid for induction or consolidation therapy; **OR**
    - Used in combination with vincristine and dexamethasone for induction therapy; **OR**
    - Used in combination with blinatumomab as consolidation therapy for persistent/rising minimal residual disease following a complete response (CR) to induction therapy; **OR**
  - Patient is ≥ 65 years of age or with substantial comorbidities; **AND**
    - Used as induction therapy as part of one of the following regimens:
      - As a single agent or in combination with a corticosteroid; **OR**
      - In combination with vincristine and dexamethasone; **OR**
      - In combination with a multiagent chemotherapy regimen
    - Used as consolidation therapy; **AND**
      - Patient has persistent/rising minimal residual disease following a complete response to induction therapy; **AND**
      - Used in combination with blinatumomab

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is at least 18 years old; **AND**
- Patient has a baseline QTc interval of ≤ 480 ms **and** does not have a history of long QT-syndrome; **AND**
- Patient does not have hypokalemia or hypomagnesemia; **AND**
- Patient will avoid concomitant use of all the following:
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with proton pump inhibitors (PPIs), or if acid-reduction therapy is required, use of H2-receptor antagonists or antacids may be used at staggered administration times; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan); **AND**
- Patient had unresectable, recurrent, or metastatic disease; **AND**
- Used as a single agent; **AND**
- Used after failure on approved therapies including each of the following: imatinib, regorafenib, ripretinib, and sunitinib

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**

- Patient is at least 18 years old; **AND**
- Patient has a baseline QTc interval of ≤ 480 ms **and** does not have a history of long QT-syndrome; **AND**
- Patient does not have hypokalemia or hypomagnesemia; **AND**
- Patient will avoid concomitant use of all the following:
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with proton pump inhibitors (PPIs), or if acid-reduction therapy is required, use of H2-receptor antagonists or antacids may be used at staggered administration times; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan); **AND**
- Patient has eosinophilia and ABL1 rearrangement; **AND**
  - Patient chronic phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

CLINICAL CRITERIA FOR RENEWAL

- Patient adherent to therapy; **AND**
  - Absence of unacceptable toxicity from the drug (e.g., electrolyte abnormalities [hypophosphatemia, hypokalemia, hyperkalemia, hypocalcemia, hyponatremia], myelosuppression [neutropenia, thrombocytopenia, anemia], QT prolongation, cardiac and arterial vascular occlusive events, pancreatitis and elevated serum lipase, hepatotoxicity [severe changes in liver function tests], tumor lysis syndrome, hemorrhage, fluid retention, growth retardation in pediatric patients); **AND**
- **Acute lymphoblastic leukemia (ALL) only:**
  - Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH
- **Chronic myelogenous leukemia (CML) only:**
  - Re-initiation of treatment:
    - Patient lost molecular response (MMR or MR4.0) after discontinuation of therapy with nilotinib; **OR**
  - Treatment response as indicated by one of the following *BCR-ABL1* (IS) transcript levels:
    - > 0.1% to 10% at 3 months or 6 months; **OR**
    - > 0.1% to 1% at 12 months and beyond (if treatment goal is long-term survival); **OR**
    - ≤ 0.1% at 12 months and beyond (if treatment goal is treatment-free remission)

    Note: cytogenetic assessment of response may be used if quantitative PT-PCR (QPCR) using international scale (IS) for *BCR-ABL1* is not available

    Note: For patients who are within the first year of treatment with Tasigna® and are not meeting the levels under the renewal criteria for CML, the levels under initial sections "Continued Therapy" may be utilized. If the patient has been on therapy for longer than a year, they must meet the levels mentioned in the renewal criteria.

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

- **Gastrointestinal Stromal Tumors (GIST) only:**
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes only:**
  - Disease response as evidenced by at least one of the following:
    - Decrease in spleen size or improvements in other myelofibrosis symptoms (e.g., fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding)
    - Stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic, or molecular complete response CR), complete hematologic response, or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

Consider discontinuation of treatment in patients with Ph+ CML-CP	
Newly diagnosed Ph+ CML-CP who have: – been treated with Tasigna® for at least 3 years – maintained a molecular response of at least MR4.0 (corresponding to = BCR-ABL/ABL ≤ 0.01% IS) for one year prior to discontinuation of therapy – achieved an MR4.5 for the last assessment taken immediately prior to discontinuation of therapy – been confirmed to express the typical BCR-ABL transcripts (e13a2/b2a2 or e14a2/b3a2) – no history of accelerated phase or blast crisis – no history of prior attempts of treatment-free remission discontinuation that resulted in relapse.	Ph+ CML-CP that are resistant or intolerant to treatment with imatinib who have achieved a sustained molecular response (MR4.5) on Tasigna® who have: – been treated with Tasigna® for a minimum of 3 years – been treated with imatinib only prior to treatment with Tasigna® – achieved a molecular response of MR.4.5 (corresponding to = BCR-ABL/ABL ≤ 0.0032% IS) – sustained an MR4.5 for a minimum of one year immediately prior to discontinuation of therapy – been confirmed to express the typical BCR-ABL transcripts (e13a2/b2a2 or e14a2/b3a2) – no history of accelerated phase or blast crisis – no history of prior attempts of treatment-free remission discontinuation that resulted in relapse.

CORE FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Myelogenous Leukemia (CML)**

- ***For Core Formulary for CML, for new starts only: patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of generic imatinib**** *(***following the NCCN guidelines surrounding genetic mutations)*

- Patient is at least 18 years old; **AND**
- Patient has a baseline QTc interval of ≤ 480 ms **and** does not have a history of long QT-syndrome; **AND**
- Patient does not have hypokalemia or hypomagnesemia; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient will avoid concomitant use of all the following:
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with proton pump inhibitors (PPIs), or if acid-reduction therapy is required, use of H2-receptor antagonists or antacids may be used at staggered administration times; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan); **AND**
- Patient's disease is confirmed by either Philadelphia chromosome-positive (Ph+) or BCR-ABL1 positive laboratory test result; **AND**
- Patient does not have any of the following *BCR-ABL1* mutations: T315I, Y253H, E255K/V, or F359V/C/I (****Note:** This does **NOT** apply to patients receiving first-line or continued therapy); **AND**
  - Patient is resistant, intolerant, or had an inadequate response to prior therapy consisting of a 3-month trial or longer with a tyrosine kinase inhibitor (e.g., imatinib, bosutinib, dasatinib)
    - Patient is at least 1 year of age; **AND**
    - Used as a single agent for chronic phase or accelerated phase disease; **OR**
  - Used as primary treatment; **AND**
    - Used as single agent for newly diagnosed chronic phase disease in patients at least 1 year of age; **OR**
    - Used as a single agent for accelerated or myeloid blast phase disease; **OR**
    - Used in combination with corticosteroids for lymphoid blast phase disease; **OR**
    - Used in combination with induction chemotherapy for disease in lymphoid blast phase or myeloid blast phase; **OR**
  - Used as switch therapy; **AND**
    - Patient received primary therapy with one of the following: imatinib, bosutinib, or dasatinib; **AND**
    - Patient has *BCR-ALB1* transcript levels:
      - > 0.1% to 1% at 12 months (if treatment goal is treatment-free remission); **OR**
      - > 1% to 10% at 12 months; **OR**
      - > 10% at any response milestone; **OR**
  - Used as continued therapy; **AND**
    - Patient has *BCR-ALB1* transcript levels:
      - ≤ 10% at any response milestone; **OR**
      - > 10% at 3 months; **OR**
  - Used post-allogeneic hematopoietic stem cell transplant (HCT); **AND**
    - Used for at least one year in patients with prior complete cytogenetic response (CCyR) for accelerated or blast phase disease; **OR**
    - Used as follow-up therapy in patients with molecular relapse (BCR-ABL1 transcript positive) following CCyR; **OR**
    - Used as follow-up therapy in patients with relapse or those who are not in CCyR; **OR**
    - Re-initiation of treatment; **AND**
    - Patient lost molecular response (MMR or MR4.0) after discontinuation of therapy with nilotinib

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Acute Lymphoblastic Leukemia (ALL)**

- Patient is at least 18 years old unless otherwise specified; **AND**
- Patient has a baseline QTc interval of ≤ 480 ms **and** does not have a history of long QT-syndrome; **AND**
- Patient will avoid concomitant use of all the following:
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with proton pump inhibitors (PPIs), or if acid-reduction therapy is required, use of H2-receptor antagonists or antacids may be used at staggered administration times; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan); **AND**
- Patient does not have hypokalemia or hypomagnesemia; **AND**
- Patient's disease is Philadelphia chromosome positive (Ph+) disease; **AND**
- Patient does not have any of the following BCR-ABL1 mutations: T315I, Y253H, E255K/V, F359V/C/I or G250E; **AND**
  - Used for relapsed or refractory disease; **AND**
    - Used as a single agent; **OR**
    - Used in combination with an induction therapy not previously used; **OR**
    - Used in combination with blinatumomab; **OR**
  - Used as maintenance therapy; **AND**
    - Used in combination with vincristine and prednisone with or without methotrexate and mercaptopurine; **OR**
    - Used post-hematopoietic stem cell transplant; **OR**
  - Patient is at least 15 years of age and < 65 years of age; **AND**
    - Used in a multiagent chemotherapy regimen for induction or consolidation therapy; **OR**
    - Used in combination with a corticosteroid for induction or consolidation therapy; **OR**
    - Used in combination with vincristine and dexamethasone for induction therapy; **OR**
    - Used in combination with blinatumomab as consolidation therapy for persistent/rising minimal residual disease following a complete response (CR) to induction therapy; **OR**
  - Patient is ≥ 65 years of age or with substantial comorbidities; **AND**
    - Used as induction therapy as part of one of the following regimens:
      - As a single agent or in combination with a corticosteroid; **OR**
      - In combination with vincristine and dexamethasone; **OR**
      - In combination with a multiagent chemotherapy regimen
    - Used as consolidation therapy; **AND**
      - Patient has persistent/rising minimal residual disease following a complete response to induction therapy; **AND**
      - Used in combination with blinatumomab

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is at least 18 years old; **AND**
- Patient has a baseline QTc interval of ≤ 480 ms **and** does not have a history of long QT-syndrome; **AND**
- Patient does not have hypokalemia or hypomagnesemia; **AND**
- Patient will avoid concomitant use of all the following:
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with proton pump inhibitors (PPIs), or if acid-reduction therapy is required, use of H2-receptor antagonists or antacids may be used at staggered administration times; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan); **AND**
- Patient had unresectable, recurrent, or metastatic disease; **AND**
- Used as a single agent; **AND**
- Used after failure on approved therapies including each of the following: imatinib, regorafenib, ripretinib, and sunitinib

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**

- Patient is at least 18 years old; **AND**
- Patient has a baseline QTc interval of ≤ 480 ms **and** does not have a history of long QT-syndrome; **AND**
- Patient does not have hypokalemia or hypomagnesemia; **AND**
- Patient will avoid concomitant use of all the following:
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with proton pump inhibitors (PPIs), or if acid-reduction therapy is required, use of H2-receptor antagonists or antacids may be used at staggered administration times; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan); **AND**
- Patient has eosinophilia and ABL1 rearrangement; **AND**
  - Patient chronic phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)
- Patient adherent to therapy; **AND**
  - Absence of unacceptable toxicity from the drug (e.g., electrolyte abnormalities [hypophosphatemia, hypokalemia, hyperkalemia, hypocalcemia, hyponatremia], myelosuppression [neutropenia, thrombocytopenia, anemia], QT prolongation, cardiac and arterial vascular occlusive events, pancreatitis and elevated serum lipase, hepatotoxicity [severe changes in liver function tests], tumor lysis syndrome, hemorrhage, fluid retention, growth retardation in pediatric patients); **AND**

CLINICAL CRITERIA FOR RENEWAL

- **Acute lymphoblastic leukemia (ALL) only:**
  - Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH
- **Chronic myelogenous leukemia (CML) only:**
  - Re-initiation of treatment:
    - Patient lost molecular response (MMR or MR4.0) after discontinuation of therapy with nilotinib; **OR**
  - Treatment response as indicated by one of the following *BCR-ABL1* (IS) transcript levels:
    - > 0.1% to 10% at 3 months or 6 months; **OR**
    - > 0.1% to 1% at 12 months and beyond (if treatment goal is long-term survival); **OR**
    - ≤ 0.1% at 12 months and beyond (if treatment goal is treatment-free remission)

    Note: Cytogenetic assessment of response may be used if quantitative PT-PCR (QPCR) using international scale (IS) for *BCR-ABL1* is not available

    Note: For patients who are within the first year of treatment with Tasigna® and are not meeting the levels under the renewal criteria for CML, the levels under initial sections "Continued Therapy" may be utilized. If the patient has been on therapy for longer than a year, they must meet the levels mentioned in the renewal criteria.
- **Gastrointestinal Stromal Tumors (GIST) only:**
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes only:**
  - Disease response as evidenced by at least one of the following:
    - Decrease in spleen size or improvements in other myelofibrosis symptoms (e.g., fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding)
    - Stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic, or molecular complete response CR), complete hematologic response, or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

Consider discontinuation of treatment in patients with Ph+ CML-CP	
Newly diagnosed Ph+ CML-CP who have: – been treated with Tasigna® for at least 3 years – maintained a molecular response of at least MR4.0 (corresponding to = BCR-ABL/ABL ≤ 0.01% IS) for one year prior to discontinuation of therapy – achieved an MR4.5 for the last assessment taken immediately prior to discontinuation of therapy – been confirmed to express the typical BCR-ABL transcripts (e13a2/b2a2 or e14a2/b3a2) – no history of accelerated phase or blast crisis – no history of prior attempts of treatment-free remission discontinuation that resulted in relapse.	Ph+ CML-CP that are resistant or intolerant to treatment with imatinib who have achieved a sustained molecular response (MR4.5) on Tasigna® who have: – been treated with Tasigna® for a minimum of 3 years – been treated with imatinib only prior to treatment with Tasigna® – achieved a molecular response of MR.4.5 (corresponding to = BCR-ABL/ABL ≤ 0.0032% IS) – sustained an MR4.5 for a minimum of one year immediately prior to discontinuation of therapy – been confirmed to express the typical BCR-ABL transcripts (e13a2/b2a2 or e14a2/b3a2) – no history of accelerated phase or blast crisis – no history of prior attempts of treatment-free remission discontinuation that resulted in relapse.

TAVALISSE™ (FOSTAMATINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Blood Modifiers (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic immune (idiopathic) thrombocytopenia (ITP)**

- Patient age is 18 years or older; **AND**
- Patient is not receiving a thrombopoietin receptor agonist or mimetic (e.g., romiplostim, eltrombopag, lusutrombopag, avatrombopag); **AND**
- Laboratory values are current (i.e., drawn within the previous 28 days); **AND**
- Fostamatinib is not being used to attempt to normalize platelet count; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, ketoconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient has had persistent/chronic ITP for at least 3 months; **AND**
- Patient has previously failed any of the following treatments for ITP:
  - Patient has failed previous therapy with corticosteroids (i.e., patient had no response to at least a 3-month trial or is corticosteroid-dependent); **OR**
  - Patient has failed previous therapy with immunoglobulins; **OR**
  - Patient has had a splenectomy; **OR**
  - Patient has failed previous therapy with a thrombopoietin receptor agonist; **AND**
- The patient is at increased risk for bleeding as indicated by platelet count of less than 30×10^9/L (30,000/mm³)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hepatotoxicity (abnormal liver enzymes), hypertension, severe diarrhea, severe neutropenia, etc.; **AND**
- Disease response indicated by the achievement and maintenance of a platelet count of at least 50×10^9/L as necessary to reduce the risk of bleeding and/or the patient has demonstrated a documented decrease in requiring rescue treatment with platelet transfusions.

TAXOL® (PACLITAXEL)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Coverage is provided in the following conditions:

- Ovarian Cancer
- Breast Cancer
- Non-Small Cell Lung Cancer (NSCLC)
- AIDS-related Kaposi Sarcoma
- Anal Squamous Cell Carcinoma
- Bladder Cancer
- Cervical Cancer
- Esophageal Cancer and Esophagogastric Junction Cancer
- Gastric Adenocarcinoma
- Gestational Trophoblastic Neoplasia
- Head and Neck Cancers
- Kidney Cancer (Non-Clear Cell)
- Occult Primary
- Penile Cancer
- Small Bowel Adenocarcinoma
- Small Cell Lung Cancer
- Soft Tissue Sarcoma (Angiosarcoma)
- Uterine Neoplasms (Endometrial Carcinoma)
- Thymomas and Thymic Carcinomas
- Cutaneous Melanoma
- Testicular Cancer
- Thyroid Cancer (Anaplastic Carcinoma)
- Uveal Melanoma
- Vulvar Squamous Cell Carcinoma

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, severe bone marrow suppression, severe cardiac conduction abnormalities)

TAXOTERE® (DOCETAXEL)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Coverage is provided in the following conditions:

- Breast Cancer
- Gastric Adenocarcinoma
- Head and Neck Cancer
- Non-Small Cell Lung Cancer
- Prostate Cancer
- Bladder Cancer (Urothelial Carcinoma)
- Bone Cancer
  - Used for Ewing Sarcoma or Osteosarcoma
- Esophageal Cancer and Esophagogastric Junction Cancers
- Occult Primary
- Ovarian Cancer
- Small Bowel Adenocarcinoma
- Small Cell Lung Cancer
- Soft Tissue Sarcoma
- Thyroid Carcinoma (Anaplastic Carcinoma)
- Uterine Neoplasms (Endometrial Carcinoma/ Uterine Sarcoma)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: enterocolitis/neutropenic colitis, severe fluid retention, severe skin toxicities, delayed myelodysplasia or myeloid reactions, severe neurosensory symptoms, cystoid macular edema, severe asthenia, tumor lysis syndrome, etc.

TAZVERIK™ (TAZEMETOSTAT)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of Epithelioid Sarcoma

- Patient is 16 years or older; **AND**
- Patient will avoid concomitant therapy with all the following:
  - Coadministration with moderate or strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), **AND**
  - Coadministration with moderate or strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have a history of T-cell lymphoblastic leukemia or T-cell acute lymphoblastic leukemia; **AND**
- Must be used as a single agent; **AND**
- Patient has locally advanced or metastatic disease; **AND**
- Patient is not eligible for complete resection; **AND**
- Patient's tumor does **not** express INI1 (i.e., INI1 loss)

Diagnosis of **Follicular Lymphoma**

- Patient is 18 years or older; **AND**
- Patient will avoid concomitant therapy with all the following:
  - Coadministration with moderate or strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), **AND**
  - Coadministration with moderate or strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have a history of T-cell lymphoblastic leukemia or T-cell acute lymphoblastic leukemia; **AND**
- Must be used as a single agent; **AND**
- Patient has relapsed or refractory disease; **AND**
  - Patient has an Enhancer of Zeste Homolog 2 (EZH2) mutation as determined by an FDA-approved or CLIA compliant test; **AND**
    - Patient has received at least two prior systemic therapies; **OR**
  - Patient has no satisfactory alternative treatment options

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: secondary malignancies (i.e., T-cell lymphoblastic lymphoma, myelodysplastic syndrome, acute myeloid leukemia), neutropenia, thrombocytopenia, anemia, etc

TECARTUS® (BREXUCABTAGENE AUTOLEUCEL)

Length of Authorization:	Coverage will be provided for one treatment course (1 dose of Tecartus®) and may not be renewed.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Submission of medical records related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation via direct upload through the PA web portal or by fax.

Diagnosis of **Mantle Cell Lymphoma**

- Patient is 18 years of age or older; **AND**
- Healthcare facility has enrolled in the Yescarta® and Tecartus® Risk Evaluation and Mitigation Strategies (REMS) and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
- Patient does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
- Prophylaxis for infection will be followed according to local guidelines; **AND**
- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during brexucabtagene autoleucel treatment, and until immune recovery following treatment; **AND**
- Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); **AND**
- Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0–1; **AND**
- Patient has not received prior CAR-T therapy; **AND**
- Patient has relapsed or refractory disease; **AND**
- Patient has at least one measurable lesion; **AND**
- Patient did not receive prior allogeneic hematopoietic stem cell transplantation (HSCT); **AND**
- Patient does not have central nervous system lymphoma, detectable cerebrospinal fluid malignant cells or brain metastases; **AND**
- Patient must have received previous systemic therapy which included at least one agent from each of the following categories:
  - Bruton tyrosine kinase (BTK) inhibitor (e.g., ibrutinib, acalabrutinib, zanubrutinib)
  - Anti-CD20 monoclonal antibody (e.g., rituximab)
  - Anthracycline- **or** bendamustine-containing chemotherapy

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)**

- Patient is 18 years of age or older; **AND**
- Healthcare facility has enrolled in the Yescarta® and Tecartus® REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
- Patient does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
- Prophylaxis for infection will be followed according to local guidelines; **AND**
- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during brexucabtagene autoleucel treatment, and until immune recovery following treatment; **AND**
- Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); **AND**
- Patient has an ECOG performance status of 0-1; **AND**
- Patient has not received prior CAR-T therapy; **AND**
- Patient has relapsed or refractory disease; **AND**
- Patient has not received prior anti-CD19 therapy, (e.g., blinatumomab) or patient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**
- Patient does not have CNS-3 disease or CNS-2 disease with neurological changes; **AND**
  - Patient has Philadelphia chromosome (Ph)-positive disease; **AND**
    - Disease is tyrosine kinase inhibitor (TKI) intolerant OR refractory to at least two (2) different TKIs; **OR**
  - Patient has Philadelphia chromosome (Ph)-negative disease

CLINICAL CRITERIA FOR RENEWAL

- Coverage cannot be renewed

TECENTRIQ® (ATEZOLIZUMAB)

Length of Authorization:	6 months, may be renewed Adjuvant therapy in NSCLC can be authorized up to a maximum of twelve (12) months of therapy
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Urothelial Carcinoma (Bladder Cancer)**

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, durvalumab, avelumab, cemiplimab, dostarlimab); **AND**
- Patient has one of the following diagnoses:
  - Locally advanced or metastatic urothelial carcinoma; **OR**
  - Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder; **OR**
  - Metastatic or local bladder cancer recurrence post-cystectomy; **OR**
  - Primary carcinoma of the urethra; **AND**
    - Used for recurrent (excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes) or metastatic disease; **OR**
    - Used for stage T3-4, cN1-2 disease, or cN1-2 palpable inguinal lymph nodes (first-line therapy only); **OR**
  - Metastatic upper genitourinary tract tumors; **OR**
  - Metastatic urothelial carcinoma of the prostate; **AND**
- Used as first-line therapy in cisplatin-ineligible patients; **AND**
  - Patient is carboplatin-ineligible; **OR**
  - Patient has a PD-L1 expression of ≥ 5% (PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 5% of the tumor area) as determined by a Food and Drug Administration (FDA)-approved or Clinical Laboratory Improvement Amendments (CLIA)-compliant test

*** Note:**

- *Cisplatin-ineligible comorbidities may include the following: CrCl < 60 mL/min, PS ≥ 2, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, grade ≥ 2 peripheral neuropathy, or NYHA class ≥ 3. Carboplatin may be substituted for cisplatin particularly in those patients with a CrCl <60 mL/min or a PS of 2.*
- *Carboplatin-ineligible comorbidities may include the following: CrCl < 30 mL/min, PS > 3, grade > 3 peripheral neuropathy, or NYHA class > 3, etc*.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, durvalumab, avelumab, cemiplimab, dostarlimab) **AND**
- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **AND**
    - Used for tumors that are negative for actionable molecular markers* and PD-L1 ≥ 50% (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by an FDA-approved test or CLIA-compliant test; **AND**
      - Used as a single agent; **OR**
    - Used for non-squamous disease in one of the following:
      - Patients with PS 0-1 who have tumors that are negative for actionable molecular markers* and PD-L1 < 1%
      - Patients with tumors that are negative for actionable molecular markers* and PD-L1 ≥ 1%
      - Patients with PS 0-1 who are positive for one of the following molecular markers: BRAF V600E-mutation, NTRK1/2/3 gene fusion, or MET exon-14 skipping mutation; **AND**
    - Used in combination with carboplatin, paclitaxel, and bevacizumab; **OR**
    - Used in combination with carboplatin and albumin-bound paclitaxel; **OR**
  - Used as subsequent therapy; **AND**
    - Used as a single agent; **OR**
      - Used for non-squamous disease as one of the following:
        - Used in patients with PS 0-1 for BRAF V600E-mutation, NTRK1/2/3 gene fusion, or MET exon-14 skipping mutation
        - Used in patients with PS 0-1 and ROS1 positive tumors after prior targeted therapy; **AND**
    - Used in combination with carboplatin, paclitaxel, and bevacizumab; **OR**
    - Used in combination with carboplatin and albumin-bound paclitaxel; **OR**
  - Used as continuation maintenance therapy in patients who have achieved a tumor response or stable disease following initial therapy; **AND**
    - Used in combination with bevacizumab following a first-line regimen with atezolizumab, carboplatin, paclitaxel, and bevacizumab for non-squamous histology; **OR**
    - Used as a single agent following a first-line regimen with atezolizumab, carboplatin, and albumin-bound paclitaxel for non-squamous histology; **OR**
    - Used as a single agent following a first-line regimen with single agent atezolizumab
- Patient has stage II to IIIA disease; **AND**
  - Used as a single agent; **AND**
  - Used as adjuvant treatment following resection and platinum-based chemotherapy; **AND**
  - Tumor expresses PD-L1 ≥ 1% as determined by an FDA-approved test or CLIA-compliant test

** Note: Actionable molecular genomic biomarkers include EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, and RET rearrangement. If there is insufficient issue to allow testing for all of EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET, and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Small Cell Lung Cancer (SCLC)**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, durvalumab, avelumab, cemiplimab, dostarlimab); **AND**
- Patient has extensive stage disease (ES-SCLC); **AND**
  - Used as first-line therapy in combination with etoposide and carboplatin; **OR**
  - Used as single-agent maintenance therapy after initial therapy with etoposide and carboplatin

Diagnosis of **Hepatocellular Carcinoma (HCC)**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, durvalumab, avelumab, cemiplimab, dostarlimab); **AND**
- Used as first-line therapy in combination with bevacizumab; **AND**
- Patient has Child-Pugh Class A disease; **AND**
- Patient has unresectable or metastatic disease, inoperable (e.g., performance status, comorbidity or with minimal or uncertain extrahepatic-disease) liver-confined disease, or extensive liver tumor burden

Diagnosis of **Cutaneous Melanoma**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, durvalumab, avelumab, cemiplimab, dostarlimab); **AND**
- Patient has BRAF V600 mutation-positive disease; **AND**
- Patient has unresectable or metastatic disease; **AND**
- Used as first-line therapy in combination with cobimetinib and vemurafenib

  *** Note: Metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease.**

Genomic Aberration/Mutational Driver Targeted Therapies (Note: *not all inclusive, refer to guidelines for appropriate use*) §				
Sensitizing *EGFR* mutation-positive tumors	*ALK* rearrangement-positive tumors	*ROS1* rearrangement-positive tumors	*BRAF* V600E-mutation positive tumors	*NTRK* Gene Fusion positive tumors
– Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab *(exon-20 insertion)*	– Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib	– Ceritinib – Crizotinib – Entrectinib	– Dabrafenib ± Trametinib – Vemurafenib	– Larotrectinib – Entrectinib
PD-1/PD-L1 expression-positive tumors (≥1%)	*MET* Exon-14 skipping mutations	*RET* rearrangement-positive tumors	KRAS G12C mutations	
– Pembrolizumab – Atezolizumab – Nivolumab ± ipilimumab	– Capmatinib – Crizotinib – Tepotinib	– Selpercatinib – Cabozantinib – Vandetanib – Pralsetinib	– Sotorasib	

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis/renal dysfunction, rash/dermatitis), severe infusion-related reactions, etc.
- **Continuation Maintenance Therapy for NSCLC or SCLC**
  - Refer to initial criteria
- **NSCLC (adjuvant treatment)**
  - Patient has not exceeded a maximum of twelve (12) months of therapy

TEGSEDI® (INOTERSEN)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Polyneuropathy Due to Hereditary Transthyretin-Mediated (hATTR) Amyloidosis /Familial Amyloidotic Polyneuropathy (FAP)**

- Patient must be at least 18 years of age; **AND**
- Patient has a platelet count of ≥ 100 X 10^9/L; **AND**
- Patient has a baseline urine protein to creatinine ratio (UPCR) of < 1,000 mg/g and UPCR will be monitored every 2 weeks during treatment; **AND**
- Both the patient **and** prescriber are enrolled in and meet the conditions of the Tegsedi® Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
- Patient is receiving supplementation with vitamin A at the recommended daily allowance; **AND**
- Must not be used in combination with other transthyretin (TTR) reducing agents (e.g., patisiran, tafamidis); **AND**
- Patient has a definitive diagnosis of hATTR amyloidosis/FAP as documented by amyloid deposition on tissue biopsy and identification of a pathogenic *TTR* variant using molecular genetic testing; **AND**
- Used for the treatment of polyneuropathy as demonstrated by at least **two** of the following criteria:
  - Subjective patient symptoms are suggestive of neuropathy
  - Abnormal nerve conduction studies are consistent with polyneuropathy
  - Abnormal neurological examination is suggestive of neuropathy; **AND**
- Patient's peripheral neuropathy is attributed to hATTR/FAP and other causes of neuropathy have been excluded; **AND**
- Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., Medical Research Council [MRC] muscle strength, etc.); **AND**
- Patient has not been the recipient of an orthotopic liver transplant (OLT)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include stroke and cervicocephalic arterial dissection, ocular symptoms related to hypovitaminosis A, severe thrombocytopenia, glomerulonephritis and renal toxicity, hepatotoxicity, serious inflammatory and immune reactions, hypersensitivity reactions/antibody formation, etc.; **AND**
- Disease response compared to pre-treatment baseline as evidenced by stabilization or improvement in one or more of the following:
  - Signs and symptoms of neuropathy
  - MRC muscle strength

TEMODAR® (TEMOZOLOMIDE): IV FORMULATION

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Bone Cancer**

- Patient has a documented diagnosis of Ewing sarcoma; **AND**
- Used as second-line therapy in combination with irinotecan; **AND**
  - Used for progressive disease following primary treatment; **OR**
  - Used for relapsed or metastatic disease

Diagnosis of **Central Nervous System (CNS) Cancer – Glioblastoma Multiforme (GBM)**

- Used concomitantly with radiation therapy and then as a single agent as maintenance treatment for newly diagnosed disease; **OR**
- Used as adjuvant treatment as a single agent; **AND**
  - Used concurrently or following radiation therapy; **OR**
  - Used as chemotherapy for patients with O6-methylguanine-DNA methyltransferase (MGMT) promoter methylated tumors; **OR**
- Patient has recurrent disease and used as a single agent or in combination with bevacizumab

Diagnosis of **Central Nervous System (CNS) Cancer – Astrocytoma/Oligodendroglioma- WHO Grade II**

- Used as adjuvant treatment as a single agent either concurrently or following radiation therapy; **AND**
  - Patient has high risk features (e.g., > 40 years of age, subtotal resection or biopsy, tumor size, neurologic deficits, presence of sequencing verified IDH wild type); **OR**
- Used for recurrent or progressive disease as a single agent either concurrently or following radiation therapy

Diagnosis of **Central Nervous System (CNS) Cancer – Adult Intracranial and Spinal Ependymoma**

- Used as single agent for progressive disease; **AND**
- Patient is refractory to surgery or prior radiation therapy; **AND**
- Patient does **not** have subependymoma

Diagnosis of **Central Nervous System (CNS) Cancer – Adult medulloblastoma**

- Used as a single agent for disease recurrence in patients who have received prior chemotherapy

Diagnosis of **Central Nervous System (CNS) Cancer – Anaplastic Gliomas (Anaplastic Astrocytoma, Anaplastic Oligoastrocytoma, Anaplastic oligodendroglioma–1p19p codeleted)**

- Patient has recurrent disease and used as a single agent or in combination with bevacizumab; **OR**
- Used as adjuvant treatment for patients with KPS ≥ 60 (i.e., ECOG 0-2) as a single agent either concurrently or following standard radiation therapy; **OR**
- Patient has refractory Anaplastic Astrocytoma and used as a single agent for disease progression on a nitrosourea and procarbazine-containing regimen

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Central Nervous System (CNS) Cancer – CNS metastases**

- Used as single agent therapy; **AND**
  - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
  - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

Diagnosis of **Primary Central Nervous System (CNS) Lymphoma**

- Used as induction therapy; **AND**
  - Used in combination with rituximab and high-dose methotrexate; **OR**
  - Used in combination with rituximab **or** as a single agent if patient is unsuitable for or intolerant to high-dose methotrexate; **OR**
- Used as consolidation therapy in patients who have had a complete response or complete response unconfirmed (CRu) to induction therapy; **AND**
  - Used in combination with rituximab and high-dose methotrexate; **OR**
- Used as a single agent or in combination with rituximab for patients with relapsed or refractory disease

Diagnosis of **Cutaneous Melanoma**

- Used as single agent therapy; **AND**
- Patient has unresectable or metastatic disease; **AND**
- Used as subsequent therapy in patients who have had disease progression (or maximum clinical benefit achieved) from BRAF targeted therapies (e.g., dabrafenib, trametinib, vemurafenib)

Diagnosis of **Neuroendocrine Tumors (NET)**

- Patient has documented pancreatic neuroendocrine tumors; **AND**
  - Used in combination with capecitabine; **AND**
  - Patient has locally advanced or metastatic disease; **AND**
  - Patient has symptomatic or bulky (i.e., clinically significant tumor burden) or progressive disease; **OR**
- Patient has documented pheochromocytoma/paraganglioma; **AND**
  - Used as a single agent for primary treatment of distant metastases in combination with octreotide or lanreotide; **OR**
- Patient has disease in the lung/thymus with carcinoid syndrome that is poorly controlled; **AND**
  - Used as a single agent or in combination with capecitabine; **AND**
  - Used in combination with octreotide LAR, lanreotide or telotristat for persistent symptoms (e.g., diarrhea); **OR**
- Patient has bronchopulmonary or thymic disease; **AND**
  - Will **not** be used for adjuvant therapy; **AND**
  - Used as a single agent or in combination with capecitabine; **AND**
    - Patient has distant metastatic disease; **AND**
      - Patient has clinically significant tumor burden and low grade (typical) histology, evidence of progression, intermediate grade (atypical) histology, or symptomatic disease; **OR**
    - Patient has locally advanced unresectable disease; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Neuroendocrine Tumors (NET)** ***(Continued)***

- Patient has poorly differentiated (i.e., high-grade) neuroendocrine carcinoma or large or small cell carcinoma (other than lung); **AND**
  - Used as a single agent or in combination with capecitabine; **AND**
    - Used for locally advanced, unresectable or metastatic disease; **OR**
    - Used as neoadjuvant or adjuvant therapy or as chemotherapy alone for resectable disease; **OR**
- Patient has well differentiated (grade 3) neuroendocrine carcinoma; **AND**
  - Used as a single agent or in combination with capecitabine; **AND**
    - Patient has distant metastatic disease; **AND**
      - Used as neoadjuvant treatment for resectable, locally advanced disease; **OR**
      - Used for unresectable, locally advanced, metastatic disease that has clinically significant tumor burden or evidence of progression

Diagnosis of **Mycosis Fungoides/Sézary Syndrome**

- Patient has CNS involvement; **AND**
- Used as a single agent as subsequent treatment for relapsed or refractory disease

Diagnosis of **Small Cell Lung Cancer**

- Used as subsequent therapy as a single agent; **AND**
  - Patient has relapsed disease following complete or partial response or stable disease with primary treatment; **OR**
  - Patient has primary progressive disease

Diagnosis of **Soft Tissue Sarcoma**

- Used as palliative therapy as a single agent; **AND**
  - Patient has angiosarcoma; **OR**
  - Patient has retroperitoneal or intra-abdominal disease; **AND**
    - Used as subsequent therapy for recurrent unresectable or stage IV disease; **OR**
  - Patient has pleomorphic rhabdomyosarcoma; **AND**
    - Used as subsequent therapy for advanced or metastatic disease; **OR**
  - Patient has sarcoma of the extremity/body wall or head/neck; **AND**
    - Used as subsequent therapy for advanced or metastatic disease; **OR**
  - Patient has solitary fibrous tumor; **OR**
  - Patient has undifferentiated pleomorphic sarcoma (UPS); **OR**
- Used in combination with vincristine and irinotecan for non-pleomorphic rhabdomyosarcoma; **OR**
- Used in combination with bevacizumab for solitary fibrous tumor**s**

Diagnosis of **Uterine Sarcoma**

- Used as a single agent for recurrent or metastatic disease which has progressed following prior cytotoxic chemotherapy

Diagnosis of **Uveal Melanoma**

- Used as a single agent for distant metastatic disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include myelosuppression (pancytopenia, leukopenia, anemia), myelodysplastic syndrome or secondary malignancy, pneumocystis pneumonia (PCP), severe hepatotoxicity, etc.

TEMODAR® (TEMOZOLOMIDE): ORAL FORMULATION

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Coverage is provided in the following conditions:

- **Bone cancer – Ewing's sarcoma**
- **Central nervous system (CNS)** cancer
  - Glioblastoma multiforme (GBM)
  - Astrocytoma/oligodendroglioma (WHO grade II)
  - Adult intracranial and spinal ependymoma (excluding subependymoma)
  - Adult medulloblastoma
  - Anaplastic gliomas (anaplastic astrocytoma †, anaplastic oligodendroglioma–1p19p codeleted)
  - CNS metastases (when active against the primary tumor)
- **Primary CNS lymphoma**
- **Cutaneous melanoma**
- **Uveal melanoma**
- **Neuroendocrine tumors (NET)**
  - Lung and thymus neuroendocrine tumors
  - Carcinoid syndrome
  - Pancreatic neuroendocrine tumors
  - Pheochromocytoma/Paraganglioma
  - Poorly differentiated (high-grade) neuroendocrine carcinoma or large or small cell carcinoma (other than lung)
  - Well-differentiated (grade 3) neuroendocrine carcinoma
- **Mycosis fungoides/Sézary syndrome**
- **Small cell lung cancer**
- **Soft tissue sarcoma**
  - Angiosarcoma
  - Retroperitoneal or intra-abdominal disease
  - Rhabdomyosarcoma
  - Extremity/body wall or head/neck
  - Solitary fibrous tumor
- **Uterine sarcoma (stage II-IV disease)**

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include myelosuppression (pancytopenia, leukopenia, and anemia), myelodysplastic syndrome or secondary malignancy, pneumocystis pneumonia (PCP), severe hepatotoxicity, etc.

TEPEZZA® (TEPROTUMUMAB-TRBW)

Length of Authorization:	Coverage is provided for 6 months (max total of 8 infusions) and may not be renewed
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR APPROVAL

Diagnosis of **Thyroid Eye Disease (TED)**

- Patient is 18 years or older; **AND**
- Must be prescribed by, or in consultation with, a specialist in ophthalmology, endocrinology, oculoplastic surgery, or neuro-ophthalmology; **AND**
- Patient has not had a decrease in best corrected visual acuity (BVCA) due to optic neuropathy within the previous six months (i.e., decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement); **AND**
- Patient is euthyroid (**Note:** mild hypo- or hyperthyroidism is permitted which is defined as free thyroxine [FT4] and free triiodothyronine [FT3] levels less than 50% above or below the normal limits [every effort should be made to correct the mild hypo- or hyperthyroidism promptly]); **AND**
- Patient does not have corneal decompensation that is unresponsive to medical management; **AND**
- Patient does not have poorly controlled diabetes; **AND**
- Must be used as single agent therapy**; AND**
- Patient has a baseline clinical activity score (CAS) of at least 4 §; **AND**
- Patient has a clinical diagnosis of TED that is related to Graves' Disease (i.e., Graves' orbitopathy); **AND**
- Patient has active phase TED that is non-sight threatening but has a significant impact on daily living (e.g., lid retraction ≥ 2 mm, moderate or severe soft tissue involvement, exophthalmos ≥ 3 mm above normal for race and gender, and/or inconstant or constant diplopia); **AND**
- Patient must have active disease (e.g., onset of TED symptoms within the previous 9 months); **AND**
- Patient had an inadequate response, or there is a contraindication or intolerance, to high-dose intravenous glucocorticoids

§ Assessment of Thyroid Eye Disease (TED): Clinical Activity Score (CAS) Elements [5]
– Painful feeling behind the globe over last four weeks – Pain with eye movement during last four weeks – Redness of the eyelids – Redness of the conjunctiva – Swelling of the eyelids – Chemosis (edema of the conjunctiva) – Swollen caruncle (flesh body at medial angle of eye)1 – Increase in proptosis ≥ 2 mm* – Decreased eye movements ≥ 5° any direction* – Decreased visual acuity ≥ 1 line on Snellen chart*
Note: Each element is assigned a score of one. Elements denoted with a * can be used when a previous assessment is available. A seven-point scale is used when prior assessment is not available.

CLINICAL CRITERIA FOR RENEWAL

Cannot be renewed

TEPMETKO™ (TEPOTINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years old; **AND**
- Must be used as a single agent; **AND**
- Patient will avoid coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid coadministration with dual strong CYP3A inhibitors and P-gp inhibitors (e.g., boceprevir, indinavir, itraconazole, ketoconazole, lopinavir and ritonavir, ritonavir, saquinavir, telaprevir); **AND**
- Therapy will not be used concomitantly with, or after prior treatment failure with, other tyrosine-protein kinase mesenchymal-epithelial transition [cMET] or hepatocyte growth factor receptor [HGFR]-inhibitors (e.g., crizotinib, capmatinib); **AND**
- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Patient has mesenchymal-epithelial transition (MET) exon 14 (METex14) skipping mutation positive disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: interstitial lung disease (ILD), pneumonitis, severe hepatotoxicity, etc.

TERIPARATIDE (FORTEO®, BONSITY™)

Length of Authorization:	• Coverage will be provided for 12 months and may be renewed once up to a total length of therapy of 2 years, unless otherwise specified • Forteo ONLY: Patient has received ≥ 2 years of treatment AND remains at or has returned to having a high risk for fracture.
Initiative:	SPC: Osteoporosis Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

*Bonsity™ was approved by the FDA as a 505(b) (2) NDA of the innovator product, Forteo® (teriparatide) and thus should **not** be considered therapeutically interchangeable (i.e., not suitable for substitution) for other non-approved indications

Diagnosis of **Osteoporosis in Women**

- Patient is at least 18 years or older; **AND**
- Patient must be post-menopausal; **AND**
- Confirmation patient is receiving calcium and vitamin D supplementation if dietary intake is inadequate; **AND**
- Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
  - Hip DXA (femoral neck or total hip) or lumbar spine T-score ≤ -2.5 and/or forearm DXA 33% (one-third) radius; **OR**
  - T-score ≤ -1 or low bone mass and a history of fragility fracture to the hip or spine; **OR**
  - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; **AND**
- Patient is at high risk for fractures (see table below); **AND**
- Patient is not at increased risk for osteosarcoma (e.g., Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton, hereditary disorders predisposing to osteosarcoma); **AND**
- Patient does not have bone metastases or a history of skeletal malignancies; **AND**
- Patient does not have metabolic bone disease other than osteoporosis; **AND**
- Patient does not have hypercalcemia or an underlying hypercalcemic disorder (e.g., primary hyperparathyroidism); **AND**
- Patient has not received therapy with parathyroid hormone analogs (e.g., abaloparatide, teriparatide) in excess of 2 years in total; **OR**
  - Patient has received ≥ 2 years of treatment with Forteo AND remains at or has returned to having a high risk for fracture; **AND**
- **§**Documented treatment failure, contraindication, or ineffective response to a minimum 12-month trial on previous therapy with oral bisphosphonates (e.g., alendronate, risedronate, ibandronate); (**Note:** Ineffective response to therapy and contraindications to oral bisphosphonate therapy are included in table below); **OR**
  - Patient has a documented contraindication***** or intolerance to oral bisphosphonates such as alendronate, risedronate, or ibandronate; **AND**
- **§**Documented treatment failure or ineffective response**±** to a minimum 12-month trial on previous therapy with injectable bisphosphonates (e.g., ibandronate, zoledronic acid); **OR**
  - Patient has a documented contraindication***** or intolerance to injectable bisphosphonates (e.g., ibandronate, zoledronic acid); **AND**
- **§**Documented treatment failure or ineffective response**±** to a minimum 12-month trial on previous therapy with *RANKL*-blocking agents such as denosumab, etc.; **OR**
  - Patient has a documented contraindication***** or intolerance to *RANKL*-blocking agents (e.g., denosumab); **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Documented treatment failure or ineffective response± to a minimum 12-month trial of an injectable sclerostin-inhibitor (e.g., romosozumab); **OR**
  - Patient has a documented contraindication* or intolerance to an injectable sclerostin inhibitor such as romosozumab; **AND**
- Documented treatment failure or ineffective response± to a minimum 12-month trial of an injectable PTHrP (1-34) analog (e.g., abaloparatide)

Diagnosis of **Primary or Hypogonadal Osteoporosis in Men**

- Patient is at least 18 years or older; **AND**
- Confirmation patient is receiving calcium and Vitamin D supplementation if dietary intake is inadequate; **AND**
- Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
  - Hip DXA (femoral neck or total hip) or lumbar spine T-score ≤ -2.5 and/or forearm DXA 33% (one-third) radius; **OR**
  - T-score ≤ -1 or low bone mass **and** a history of fragility fracture to the hip or spine; **OR**
  - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; **AND**
- Patient is at high risk for fractures (see table below); **AND**
- Patient is not at increased risk for osteosarcoma (e.g., Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton, hereditary disorders predisposing to osteosarcoma); **AND**
- Patient does not have bone metastases or a history of skeletal malignancies; **AND**
- Patient does not have metabolic bone disease other than osteoporosis; **AND**
- Patient does not have hypercalcemia or an underlying hypercalcemic disorder (e.g., primary hyperparathyroidism); **AND**
- Patient has not received therapy with parathyroid hormone analogs (e.g., abaloparatide, teriparatide) in excess of 2 years in total; **OR**
  - Patient has received ≥ 2 years of treatment with Forteo AND remains at or has returned to having a high risk for fracture; **AND**
- **§**Documented treatment failure, contraindication, or ineffective response to a minimum 12-month trial on previous therapy with oral bisphosphonates (e.g., alendronate, risedronate, ibandronate); (**Note:** Ineffective response to therapy and contraindications to oral bisphosphonate therapy are included in table below); **OR**
- Patient has a documented contraindication* or intolerance to oral bisphosphonates (e.g., alendronate, risedronate, ibandronate)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Systemic Glucocorticoid-Induced Osteoporosis**

- Patient is at least 18 years or older; **AND**
- Patient is being treated with sustained long-term glucocorticoid therapy (i.e., a mean daily dose of 5 mg or more of prednisone or its equivalent for 3 or more consecutive months); **AND**
- Confirmation patient is receiving calcium and vitamin D supplementation if dietary intake is inadequate; **AND**
- Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
  - Hip DXA (femoral neck or total hip) or lumbar spine T-score ≤ -2.5 and/or forearm DXA 33% (one-third) radius; **OR**
  - T-score ≤ -1 or low bone mass **and** a history of fragility fracture to the hip or spine; **OR**
  - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; **AND**
- Patient is at high risk for fractures (see table below); **AND**
- Patient is not at increased risk for osteosarcoma (e.g., Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton, hereditary disorders predisposing to osteosarcoma); **AND**
- Patient does not have bone metastases or a history of skeletal malignancies; **AND**
- Patient does not have metabolic bone disease other than osteoporosis; **AND**
- Patient does not have hypercalcemia or an underlying hypercalcemic disorder (e.g., primary hyperparathyroidism); **AND**
- Patient has not received therapy with parathyroid hormone analogs (e.g., abaloparatide, teriparatide) in excess of 2 years in total; **OR**
  - Patient has received ≥ 2 years of treatment with Forteo **AND** remains at or has returned to having a high risk for fracture; **AND**
- **§**Documented treatment failure, contraindication or ineffective response to a minimum 12-month trial on previous therapy with oral bisphosphonates (e.g., alendronate, risedronate, ibandronate) (**Note:** Ineffective response to therapy and contraindications to oral bisphosphonate therapy are included in table below); **OR**
- Patient has a documented contraindication***** or intolerance to oral bisphosphonates (e.g., alendronate, risedronate, ibandronate)

Note: § Patients with extremely low BMD (T < -3.5) or a T < -2.5 with a history of fragility fractures are not subject to prior trial and failure requirements with bisphosphonates and/or denosumab

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

± Ineffective response is defined as one or more of the following:

- Decrease in T-score in comparison with baseline T-score from DXA scan
- Patient has a new fracture while on bisphosphonate therapy

‡ High risk for fractures include, but are not limited to, one or more of the following:

- History of an osteoporotic fracture as an adult
- Parental history of hip fracture
- Low BMI
- Rheumatoid arthritis
- Alcohol intake (3 or more drinks per day)
- Current smoking
- History of oral glucocorticoids ≥ 5 mg per day of prednisone for > 3 months (ever)

*** Examples of contraindications to oral bisphosphonate therapy include the following:**

- Documented inability to sit or stand upright for at least 30 minutes
- Documented pre-existing gastrointestinal disorder such as inability to swallow, Barrett's esophagus, esophageal stricture, dysmotility, or achalasia

Examples of contraindications to injectable bisphosphonate therapy include the following:

- Documented pre-existing hypocalcemia and disturbances of mineral metabolism
- Documented pre-existing renal insufficiency defined as creatinine clearance < 35 mL/min

Examples of contraindications to *RANKL*-blocking therapy include the following:

- Documented pre-existing hypocalcemia and disturbances of mineral metabolism
- Documented hypersensitivity to the active ingredient or its excipients

Examples of contraindications to sclerostin inhibitor therapy include the following:

- Documented pre-existing hypocalcemia and disturbances of mineral metabolism
- Documented pre-existing severe cardiovascular disease that precludes use
- Documented hypersensitivity to the active ingredient or its excipients

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of severe allergic reactions, osteosarcoma, hypercalcemia, calciphylaxis and worsening of previously stable cutaneous calcification, urolithiasis, hypercalciuria, orthostatic hypotension, etc.; **AND**
- Disease response as indicated by one or more of the following:
  - Absence of fractures
  - Increase in bone mineral density compared to pretreatment baseline
  - Increase in bone formation markers (i.e., procollagen type 1 N-propeptide [P1NP])

TESTOPEL® (TESTOSTERONE PELLETS) (SUBCUTANEOUS IMPLANT)

Length of Authorization:	Primary or secondary hypogonadism in males: 6 months initially and may be renewed annually thereafter Delayed puberty: 6 months and may be renewed once
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Primary or Secondary (Hypogonadotropic) Hypogonadism in Males**

- Patient does not have carcinoma of the breast or known or suspected carcinoma of the prostate; **AND**
- Prescribed by, or in consultation with, an endocrinologist or urologist; **AND**
- The patient will be receiving only one androgen or anabolic agent; **AND**
- Patient hemoglobin, hematocrit, and lipid concentrations are measured at baseline and monitored periodically, during treatment; **AND**
- Patient does not have "age-related" hypogonadism; **AND**
- Patient does not have a prostate specific antigen (PSA) level of > 4.0 ng/mL, at baseline; **AND**
- Pre-treatment morning total testosterone of less than 300 ng/dL (or below lower limit of normal by the testing laboratory); **AND**
- Patient has signs and symptoms consistent with hypogonadism (e.g., low libido, decreased morning erections, loss of body hair, low bone mineral density, gynecomastia, small testes); **AND**
- Diagnosis is confirmed by one of the following:
  - Repeat morning total testosterone test (as above); **OR**
  - Pre-treatment free testosterone of less than 50 pg/mL (or below lower limit of normal by the testing laboratory); **AND**
- Patient has had an inadequate response (or contraindication or intolerance) to a 3 or more-month trial with a topical agent such as testosterone gel, testosterone patch, bio-adhesive buccal testosterone, testosterone nasal gel, testosterone topical solution, etc.; **AND**
- Patient has had an inadequate response (or contraindication or intolerance) to a 3 or more-month trial with intramuscular testosterone such as testosterone cypionate or testosterone enanthate

Primary hypogonadism	Secondary (hypogonadotropic) hypogonadism
• Testicular failure due to cryptorchidism • Bilateral torsion • Orchitis • Vanishing testes syndrome • Orchiectomy • Klinefelter's syndrome • Chemotherapy • Toxic damage from alcohol or heavy metals	• Gonadotropic LHRH deficiency • Pituitary hypothalamic injury due to trauma, radiation, or tumor

Diagnosis of **Delayed Puberty in males**

- Patient is at least 14 years of age; **AND**
- Patient does not have carcinoma of the breast or known or suspected carcinoma of the prostate; **AND**
- Prescribed by, or in consultation with, an endocrinologist or urologist; **AND**
- The patient will be receiving only one androgen or anabolic agent; **AND**
- Patient hemoglobin, hematocrit, and lipid concentrations are measured at baseline and monitored periodically, during treatment; **AND**
- Patient did not respond to psychological support for delayed puberty; **AND**
- Effect on bone maturation has been discussed with the patient and parent(s); **AND**
- Secondary causes of delayed puberty (e.g., hypothyroidism, hyperprolactinemia) have been addressed or ruled out; **AND**
- Bone maturation must be monitored by assessing bone age of the wrist and hand via x-ray examinations every 6 months to determine the rate of bone maturation and the effects of androgen therapy on the epiphyseal centers; **AND**
- Patient has had an inadequate response, contraindication, or intolerance to at least a 3-month trial with intramuscular testosterone such as testosterone cypionate, testosterone enanthate, etc.

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

Primary or Secondary Hypogonadism

- Absence of unacceptable toxicity from the drug (e.g., hepatotoxicity, hepatitis, hepatic carcinoma, stroke, myocardial infarction, fluid/electrolyte disturbances, prostatic hypertrophy/carcinoma, polycythemia, venous thromboembolism, implant site infection and/or pellet extrusion); **AND**
- Patient's testosterone levels (within the preceding 28 days) do not exceed the upper limit of the normal range for the testing laboratory (generally mid-range is targeted); **AND**
- Patient has an improvement in signs and symptoms; **AND**
- Patient has not had a PSA increase of > 1.4 ng/mL above baseline or an absolute level > 4.0 ng/mL

Delayed Puberty

- Absence of unacceptable toxicity from the drug (e.g., hepatotoxicity, hepatitis, hepatic carcinoma, stroke, myocardial infarction, fluid/electrolyte disturbances, prostatic hypertrophy/carcinoma, polycythemia, venous thromboembolism, implant site infection, and/or pellet extrusion); **AND**
- Patient's testosterone levels (within the preceding 28 days) do not exceed the upper limit of the normal range for the testing laboratory (generally mid-range is targeted).
- Patient is continuing to be monitored for bone maturation (refer to initial criteria); **AND**
- Patient continues to require testosterone supplementation in order to complete development of secondary sexual characteristics (i.e., patient has not progressed spontaneously through puberty which may occur in patients with constitutional delay of puberty); **AND**
- Testopel® therapy has not exceeded a total of 12 months in duration

THALOMID®

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma (MM)**

- Prescriber and patient must be enrolled in Thalomid REMS program; **AND**
- Women of child-bearing age must be using two forms of contraception; **AND**
- Patient is 18 years of age or older; **AND**
- Used as primary chemotherapy for active (symptomatic) disease; **AND**
  - Used in combination with dexamethasone; **OR**
  - Used in combination with dexamethasone and bortezomib, with or without daratumumab, in transplant candidates; **OR**
  - Used as part of a VTD-PACE (bortezomib, dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen in transplant candidates; **OR**
- Used for disease relapse that occurred after 6 months following primary therapy with the same regimen; **AND**
  - Used as part of VTD-PACE regimen in transplant candidates; **OR**
- Used for previously treated disease that is progressive or relapsed; **AND**
  - Used as part of DT-PACE (dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen; **OR**
  - Used as part of VTD-PACE regimen; **OR**
  - Used in combination with carfilzomib, cyclophosphamide and dexamethasone.

Diagnosis of **Erythema Nodosum Leprosum (ENL)**

- Prescriber and patient must be enrolled in Thalomid REMS program; **AND**
- Women of child-bearing age must be using two forms of contraception; **AND**
- Patient is 18 years of age or older; **AND**
- Used as acute treatment of cutaneous manifestations of ENL in patient with moderate to severe disease; **AND**
  - Will not be used as monotherapy for patients with moderate to severe neuritis; **OR**
- Used as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence

Diagnosis of **Multicentric Castleman's Disease (CD)**

- Prescriber and patient must be enrolled in Thalomid REMS program; **AND**
- Women of child-bearing age must be using two forms of contraception; **AND**
- Patient is 18 years of age or older; **AND**
- Used as subsequent therapy, with or without rituximab, for disease that has progressed following treatment of relapsed/refractory or progressive disease; **OR**
- Used in combination with cyclophosphamide and prednisone for hyaline vascular histology in patients negative for HIV and HH8

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Myelofibrosis**

- Prescriber and patient must be enrolled in Thalomid REMS program; **AND**
- Women of child-bearing age must be using two forms of contraception; **AND**
- Patient is 18 years of age or older; **AND**
- Must be used as a single agent or in combination with prednisone for management of myelofibrosis-associated anemia; **AND**
  - With serum EPO ≥ 500 mU/mL; **OR**
  - With serum EPO < 500 mU/mL and no response or loss of response to erythropoietic stimulating agents.

Diagnosis of **AIDS-Related Kaposi Sarcoma**

- Prescriber and patient must be enrolled in Thalomid REMS program; **AND**
- Women of child-bearing age must be using two forms of contraception; **AND**
- Patient is 18 years of age or older; **AND**
- Used in combination with antiretroviral therapy (ART); **AND**
- Used as subsequent systemic therapy for relapsed or refractory advanced disease that has progressed or not responded to first-line and alternate first-line systemic therapy for one of the following disease types:
  - Cutaneous disease
  - Oral disease
  - Visceral disease
  - Nodal disease

CLINICAL CRITERIA FOR RENEWAL:

Authorizations can be renewed based on the following criteria:

- Absence of unacceptable toxicity from the drug (e.g., hematologic toxicity [neutropenia, thrombocytopenia], ischemic heart disease [including myocardial infarction and stroke], pulmonary embolism, deep vein thrombosis, peripheral neuropathy, severe bradycardia/syncope, severe cutaneous reactions, seizures, tumor lysis syndrome, bradycardia); **AND**
- Oncology Indications:
  - Disease response with treatment as defined as stabilization or disease or decrease in size of tumor or tumor spread
- Erythema nodosum leprosum:
  - Disease response as evidenced by a decrease/reduction in the total steroid dosage and/or a decrease in disease relapse

THIOLA (TIOPRONIN)

Length of Authorization:	Thiola Immediate release: Initial and Renewal: 6 months Thiola EC: Initial 6 months, renewal 1 year
Initiative:	MNC: Miscellaneous PA required

CLINICAL CRITERIA FOR INITIAL APPROVAL

THIOLA IMMEDIATE RELEASE

- Patient must weigh at least 20 kg; **AND**
- Patient has a diagnosis of severe homozygous cystinuria; **AND**
- Diagnosis is confirmed by nephrolithiasis and 1 of the following: family history of cystinuria, stone analysis confirming cystine stones, elevated urine cystine output; **AND**
- Urine cystine is ≥ 500 mg/day; **AND**
- Patient has had a trial and failure (ongoing documented signs and/or symptoms of cystine stones) of conservative and/or nonpharmacologic treatments (e.g., patient's ongoing attempt to minimize dietary intake of methionine [unless not clinically appropriate, such as growing child or pregnant], protein and sodium restriction, increased fluid intake; urinary alkalization); **AND**
- If patient is of childbearing potential, patient is not pregnant or nursing, or prescriber affirms that a full discussion of the risk versus benefits in child-bearing women have been discussed with patient; **AND**
- Patient has had no prior history of agranulocytosis, aplastic anemia, or thrombocytopenia associated with tiopronin; **AND**
- Prescriber attests planned monitoring will follow manufacturer recommended schedule (e.g., urine cystine [more frequently during first 6 months to establish dose], peripheral blood counts, direct platelet count, hemoglobin, serum albumin, liver function tests, 24-hour urinary protein and routine urinalysis at 3 to 6 month intervals during treatment; abdominal X-ray annually); **OR**
- Patient is continuing therapy, documented by prescriber as effective based on laboratory analysis (e.g., urine cystine) or lack of stone formation.

THIOLA EC (DELAYED RELEASE)

- Patient must weigh at least 20 kg; **AND**
- Patient has a diagnosis of cystinuria; **AND**
- Diagnosis is confirmed by nephrolithiasis and 1 of the following: family history of cystinuria, stone analysis confirming cystine stone, or elevated cystine output; **AND**
- Patient continues to minimize dietary intake of cystine and methionine [unless not clinically appropriate], restrict protein and sodium, and maintain adequate fluid intake while taking tiopronin delayed-release; **AND**
- Patient is also prescribed alkali therapy (e.g., potassium citrate, sodium bicarbonate); **AND**
- Patient has had a trial and failure of nonpharmacologic treatments used alone (e.g., dietary intake restriction of cystine and methionine [unless not clinically appropriate], protein and sodium restriction, increased fluid intake, urinary alkalization)

CLINICAL CRITERIA FOR RENEWAL

THIOLA IMMEDIATE RELEASE

- Patient continues to meet above criteria; **AND**
- Patients symptoms are clinically improving, as documented by laboratory analysis (e.g., urine cystine) and incidence of stone formation/lack of stone formation; **AND**
- Prescriber affirms ongoing patient compliance; **AND**
- Patient has no treatment-limiting adverse effects (e.g., reduction in white blood cell count < 3,500 mm^3, platelets < 100,000 mm^3, or persistent decrease in WBC or platelets [3 successive determinations]; proteinuria or hematuria, particularly in RA patients [risk versus benefit consideration in Wilson's disease or cystinuria]; signs or symptoms of Goodpasture's syndrome [e.g., hemoptysis, pulmonary infiltrates]; pulmonary symptoms consistent with obliterative bronchiolitis [e.g., exertional dyspnea, unexplained cough or wheezing]; new neurological symptoms [e.g., Myasthenic syndrome]; pemphigus [e.g., pemphigus vulgaris, pemphigus foliaceus]; persistent drug fever or rash; hypersensitivity reaction or drug eruption; or persistent stomatitis); **AND**
- Documentation of appropriate monitoring as described above.

THIOLA EC (DELAYED RELEASE)

- Patient continues to meet criteria identified above; **AND**
- Patient has an improvement in cystinuria, documented by prescriber based on laboratory analysis (e.g., urine cystine) or lack of stone formation; **AND**
- Prescriber affirms ongoing patient compliance to dietary restrictions and tiopronin therapy; **AND**
- Patient has not experienced any treatment-restricting adverse effects (e.g., hypersensitivity, proteinuria); **AND**
- Prescriber monitors cystine levels every 3 months to maintain a urinary cystine concentration < 250 mg/L; **AND**
- Prescriber assesses for proteinuria every 3 to 6 months during treatment

THYROGEN® (THYROTROPIN ALFA)

Length of Authorization:	2 doses, cannot be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Thyroid Carcinoma**

- Patient is 18 years or older; **AND**
- Patient has a diagnosis of well-differentiated thyroid cancer; **AND**
  - Used as an adjunctive diagnostic test; **AND**
    - Patient has had previous thyroidectomy; **OR**
  - Used as an adjunctive treatment for radioiodine ablation; **AND**
    - Patient has undergone total/near-total thyroidectomy; **AND**
    - Patient does not have distant metastases

CLINICAL CRITERIA FOR RENEWAL:

- Cannot be renewed

TIBSOVO® (IVOSIDENIB)

Length of Authorization:	6 months; may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of Acute Myeloid Leukemia (AML)

- Patient is at least 18 years of age; AND
- Patient will avoid concomitant use with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid concomitant use with strong or moderate CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, erythromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with QTc prolonging drugs (e.g., amiodarone, haloperidol, tizanidine); **AND**
- Patient has an isocitrate dehydrogenase-1 (IDH1) mutation, as detected by any FDA-approved of CLIA-compliant test; **AND**
- Used as single agent therapy; **AND**
  - Patient has relapsed or refractory disease; **OR**
  - Used as induction therapy in patients ≥ 60 years of age who are not candidates for or decline intensive therapy; **OR**
  - Used as post-remission therapy following response to a previous lower intensity therapy with the same regimen in patients ≥ 60 years of age**; OR**
- Used as a component of repeating the initial successful induction regimen for relapsed or refractory disease in patients experiencing a late relapse (≥ 12 months after induction regimen); **AND**
  - Treatment has not been administered continuously; **AND**
  - Treatment was not previously stopped due to development of clinical resistance

Diagnosis of **Cholangiocarcinoma (including both intrahepatic and extrahepatic disease)**

- Patient is at least 18 years of age; AND
- Patient will avoid concomitant use with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid concomitant use with strong or moderate CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, erythromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with QTc prolonging drugs (e.g., amiodarone, haloperidol, tizanidine); **AND**
- Patient has an isocitrate dehydrogenase-1 (IDH1) mutation, as detected by any FDA-approved of CLIA-compliant test; **AND**
- Used as a single agent; **AND**
- Used as subsequent treatment for disease progression on or after systemic treatment for unresectable, locally advanced, or metastatic disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Bone Cancer (Chondrosarcoma)**

- Patient is at least 18 years of age; AND
- Patient will avoid concomitant use with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
- Patient will avoid concomitant use with strong or moderate CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, erythromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient will avoid concomitant use with QTc prolonging drugs (e.g., amiodarone, haloperidol, tizanidine); **AND**
- Patient has an isocitrate dehydrogenase-1 (IDH1) mutation, as detected by any FDA-approved of CLIA-compliant test; **AND**
- Used as a single agent; **AND**
- Patient has conventional (stages 1–3) or dedifferentiated (osteosarcoma) disease

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., symptoms of differentiation syndrome [e.g., fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, hypotension, and hepatic, renal, or multi-organ dysfunction], QTc interval prolongation, Guillain-Barre Syndrome); **AND**

AML

- Disease stabilization or improvement as evidenced by a complete response (CR) (i.e., morphologic, cytogenetic, or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

Cholangiocarcinoma and Bone Cancer

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

EXSERVAN™ (RILUZOLE FILM) AND TIGLUTIK® (RILUZOLE SUSPENSION)

Length of Authorization:	1 year, may be renewed
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INTIAL APPROVAL

- Patient is 18 years of age or older; **AND**
- Patient has a diagnosis of amyotrophic lateral sclerosis (ALS); **AND**
- Patient has difficulty swallowing or cannot swallow tablets (available as generic).

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient has had a disease response; **AND**
- Patient is free of unacceptable toxicity from the drug.

TOBRAMYCIN NEBULIZER

Length of Authorization:	1 YEAR
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cystic Fibrosis (CF)**

- Patient is 6 years or older; **AND**
- Patient has a baseline percent predicted forced expiratory volume in 1 second (FEV_1). *Reported measurements may be used on renewal*; **AND**
- Patient is colonized with *Pseudomonas aeruginosa* per positive sputum culture; **AND**
- Patient is **not** colonized with *Burkholderia cepacia* per sputum culture*;* **AND**
- Patient is not receiving concurrent treatment with other inhaled antibiotics and/or anti-infective agents, including alternating treatment schedules; **AND**

Requesting Kitabis® solution:

- All items above; **AND**
- Patient has a documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum of 3-month trial on previous therapy with tobramycin inhalation solution (generic TOBI®); **AND**
- Prescriber **must** provide clinical justification for prescribing Kitabis solution instead of tobramycin inhalation solution including clinical information specific to the patient and statement of medical necessity.

Requesting TOBI® Podhaler®:

- All items above; **AND**
- Patient has a documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial on previous therapy with tobramycin inhalation solution (generic TOBI®); **AND**
- Prescriber must provide clinical justification for prescribing TOBI® Podhaler® instead of tobramycin inhalation solution including clinical information specific to the patient and statement of medically necessity.

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

- Disease response as indicated by one of the following:
  - Improvement or stabilization of lung function as measured by percent predicted FEV_1 within the previous 30 days compared to pre-treatment baseline
  - Decrease in decline of lung function as measured by percent predicted FEV_1 within the previous 30 days compared to pre-treatment baseline
  - Decrease in respiratory-related hospitalizations
  - Decrease in use of intravenous antipseudomonal antibiotics
  - Reduced sputum bacterial density (i.e., reduced number of *P. aeruginosa* colony forming units [CFUs]); **AND**
- Confirmation the patient is not receiving treatment with other inhaled antibiotics and/or anti-infective agents, including alternating treatment schedules; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include nephrotoxicity, bronchospasm, ototoxicity (e.g., hearing loss, dizziness/vertigo, tinnitus), aggravated muscle weakness in patients with muscle disorders (e.g., myasthenia gravis, Parkinson's disease), etc.

TORISEL® (TEMSIROLIMUS)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Renal Cell Carcinoma**

- Patient is at least 18 years of age; **AND**
- Therapy will not be administered concurrently with live vaccines and close contact with individuals who have received live vaccines will be avoided; **AND**
- Confirmation that patient does not have bilirubin > 1.5 times the upper limit of normal (ULN); **AND**
- Used as single agent therapy; **AND**
- Patient has advanced disease

Diagnosis of **Soft Tissue Sarcoma (PEComa/Recurrent angiomyolipoma/lymphangioleiomyomatosis)**

- Patient is at least 18 years of age; **AND**
- Therapy will not be administered concurrently with live vaccines and close contact with individuals who have received live vaccines will be avoided; **AND**
- Confirmation that patient does not have bilirubin > 1.5 times the upper limit of normal (ULN); **AND**
- Used as single agent therapy

Diagnosis of **Uterine Neoplasm-Endometrial Carcinoma**

- Patient is at least 18 years of age; **AND**
- Therapy will not be administered concurrently with live vaccines and close contact with individuals who have received live vaccines will be avoided; **AND**
- Confirmation that patient does not have bilirubin > 1.5 times the upper limit of normal (ULN); **AND**
- Used as single agent therapy

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity/infusion reactions, hepatic impairment, hyperglycemia/glucose intolerance, infections, interstitial lung disease, hyperlipidemia, bowel perforation, renal failure, wound healing complications, intracerebral hemorrhage, proteinuria/nephrotic syndrome, etc.

TRIKAFTA® (ELEXACAFTOR/TEZACAFTOR/IVACAFTOR)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Respiratory Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cystic Fibrosis**

- Patient is at least 6 years of age; **AND**
- Patient has a baseline percent predicted forced expiratory volume in 1 second (FEV1) – reported measurements may be used on renewal; **AND**
- Patient is not receiving concurrent treatment with any other cystic fibrosis transmembrane conductance regulator (CFTR)-targeted therapy containing one or more of the following: ivacaftor, lumacaftor, tezacaftor, elexacaftor; **AND**
- Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND**
- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, St. John's Wort); **AND**
- Patient will avoid concomitant use with strong or moderate CYP3A inhibitors (e.g., ketoconazole, fluconazole, itraconazole, grapefruit juice), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has a baseline ophthalmological test obtained prior to initiation of therapy and will continue to have follow-up ophthalmological examinations periodically thereafter (pediatric patients only); **AND**
- Patient has a documented diagnosis of cystic fibrosis; **AND**
- Patient has at least one F508del mutation, as confirmed by an FDA-cleared, or CLIA-compliant, CF mutation test; **OR**
- Patient has a mutation in the *CFTR* gene, as confirmed by an FDA-cleared or CLIA-compliant CF mutation test, that is responsive to elexacaftor/ tezacaftor/ivacaftor based on in vitro assay data

***CFTR* Gene Mutations that produce CFTR Protein and are responsive to elexacaftor/tezacaftor/ivacaftor:**
3141del9; E822K; G1069R; L967S; R117L; S912L; 546insCTA; F191V; G1244E; L997F; R117P; S945L; A46D; F311del; G1249R; L1077P; R170H; S977F; A120T; F311L; G1349D; L1324P; R258G; S1159F; A234D; F508C; H139R; L1335P; R334L; S1159P; A349V; F508C;S1251N†; H199Y; L1480P; R334Q; S1251N; A455E; F508del; H939R; M152V; R347H; S1255P; A554E; F575Y; H1054D; M265R; R347L; T338I; A1006E; F1016S; H1085P; M952I; R347P; T1036N; A1067T; F1052V; H1085R; M952T; R352Q; T1053I; D110E; F1074L; H1375P; M1101K; R352W; V201M; D110H; F1099L; I148T; P5L; R553Q; V232D; D192G; G27R; I175V; P67L; R668C; V456A; D443Y; G85E; I336K; P205S; R751L; V456F; D443Y; G576A; R668C†; G126D; I502T; P574H; R792G; V562I; D579G; G178E; I601F; Q98R; R933G; V754M; D614G; G178R; I618T; Q237E; R1066H; V1153E; D836Y; G194R; I807M; Q237H; R1070Q; V1240G; D924N; G194V; I980K; Q359R; R1070W; V1293G; D979V; G314E; I1027T; Q1291R; R1162L; W361R; D1152H; G463V; I1139V; R31L; R1283M; W1098C; D1270N; G480C; I1269N; R74Q; R1283S; W1282R; E56K; G551D; I1366N; R74W; S13F; Y109N; E60K; G551S; K1060T; R74W; D1270N†; S341P; Y161D; E92K; G576A; L15P; R74W; V201M†; S364P; Y161S; E116K; G576A; R668C†; L165S; R74W; V201M; D1270N†; S492F; Y563N; E193K; G622D; L206W; R75Q; S549N; Y1014C; E403D; G628R; L320V; R117C; S549R; Y1032C; E474K; G970D; L346P; R117G; S589N; E588V; G1061R; L453S; R117H; S737F*
** F508del is a responsive CFTR mutation based on both clinical and in vitro data.*

Table may not be all-inclusive; verify gene mutations responsive to elexacaftor/tezacaftor/ivacaftor in the current prescribing information

CLINICAL CRITERIA FOR RENEWAL

Authorizations can be renewed based on the following criteria:

- Disease response as indicated by one or more of the following:
  - Decreased pulmonary exacerbations compared to pre-treatment baseline
  - Decrease in decline of lung function as measured by percent predicted FEV1 within the previous 30 days compared to pre-treatment baseline
  - Improvement or stabilization of lung function as measured by percent predicted FEV1 within the previous 30 days compared to pre-treatment baseline
  - Improvement in quality of life (e.g., Cystic Fibrosis Questionnaire-Revised [CFQ-R] score), weight gain, or growth; **AND**
- Patient has not received a lung transplant; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include elevated liver function tests (ALT, AST, or bilirubin), development of non-congenital cataracts or lens opacities, etc.

TRODELVY® (SACITUZUMAB GOVITECAN-HZIY)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**

- Patient at least 18 years of age; **AND**
- Therapy will **not** be substituted for or used in combination with irinotecan; **AND**
- Patients that are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)* 28 allele will be closely monitored for adverse reactions; **AND**
- Therapy will not be used in combination with UGT1A1 inhibitors (e.g., nilotinib, regorafenib) or inducers (e.g., phenytoin, carbamazepine); **AND**
- Used as single agent therapy; **AND**
- Patient has recurrent unresectable, locally advanced, or metastatic disease; **AND**
- Patient has unequivocal triple-negative disease [mTNBC] (i.e., estrogen, progesterone, and HER2-negative)*; **AND**
- Patient was previously treated with at least two systemic therapies, at least one of them for metastatic disease

Diagnosis of **Urothelial Cancer**

- Patient at least 18 years of age; **AND**
- Therapy will **not** be substituted for or used in combination with irinotecan; **AND**
- Patients that are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)* 28 allele will be closely monitored for adverse reactions; **AND**
- Therapy will not be used in combination with UGT1A1 inhibitors (e.g., nilotinib, regorafenib) or inducers (e.g., phenytoin, carbamazepine); **AND**
- Used as single agent therapy; **AND**
- Patient has locally advanced or metastatic disease; **AND**
- Patient was previously treated with platinum-containing chemotherapy and programmed death (PD-1 or PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab)

***HER2-negative expression criteria:**

- Immunohistochemistry (IHC) assay is 0 or 1+; **OR**
- Dual-probe in situ hybridization (ISH) assay indicating (Group 5) HER2/CEP17 ratio < 2.0 **and** average HER2 copy number < 4.0 signals/cell; **OR**
- Concurrent dual-probe ISH and IHC assay results indicating one of the following:
  - (Group 2) HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number < 4.0 signals/cell and concurrent IHC 0-1+ or 2+; **OR**
  - (Group 3) HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 6.0 signals/cell and concurrent IHC 0-1+; **OR**
  - (Group 4) HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 4.0 and < 6.0 signals/cell and concurrent IHC 0-1+ or 2+

***ER/PR-negative expression criteria:**

- Immunohistochemistry (IHC) assay: Sample is considered ER/PR negative if the percentage of cancer cells staining on evaluation is < 1% **or** 0% of tumor cell nuclei are immunoreactive

Note: A sample may be deemed uninterpretable for ER or PR if the sample is inadequate (insufficient cancer or severe artifacts present, as determined at the discretion of the pathologist), if external and internal controls (if present) do not stain appropriately, or if pre-analytic variables have interfered with the assay's accuracy.

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hypersensitivity, severe nausea/vomiting, severe neutropenia/febrile neutropenia, severe diarrhea, etc.

TRUSELTIQ™ (INFIGRATINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Miscellaneous: Pa Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cholangiocarcinoma**

- Patient is at least 18 years old; **AND**
- Patient has received a comprehensive ophthalmic examination, including optical coherence tomography at baseline and repeated periodically (months 1, 3, and every 3 months thereafter) throughout therapy; **AND**
- Patient serum phosphate level is measured at baseline and periodically throughout therapy; **AND**
- Therapy will not be used concomitantly with other selective FGFR-inhibitors (e.g., erdafitinib, pemigatinib, etc.); **AND**
- Patient will not be on concomitant therapy with any of the following:
  - Acid-reducing agents (if therapy with H2-antagonists or locally acting antacids is unavoidable, stagger the administration); **AND**
  - Strong or moderate CYP3A-Inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Strong or moderate CYP3A inhibitors (e.g., fluconazole, itraconazole, etc.); if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Must be used as a single agent; **AND**
- Patient has unresectable locally advanced or metastatic disease; **AND**
- Patient has a susceptible gene mutation rearrangement or fusion in the fibroblast growth factor receptor 2 (FGFR2) gene, as determined by an FDA-approved or CLIA-compliant test **§**; **AND**
- Used as subsequent therapy; **AND**
- Patient received at least one line of prior therapy which contained gemcitabine

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include retinal pigment epithelial detachment (RPED), severe hyperphosphatemia, etc.; **AND**
- Patient serum phosphate level is ≤ 7.5 mg/dL

TRUXIMA® (RITUXIMAB-ABBS)

Length of Authorization:	6 months (see below for RA), may be renewed • Maintenance therapy for oncology indications (excluding Hairy Cell Leukemia and mantle cell lymphoma) may be renewed for up to a maximum of 2 years. – Mantle cell lymphoma may be renewed until disease progression or intolerable toxicity • Hairy Cell Leukemia may not be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)**

For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Ruxience®.

- Patient age is 18 years or older; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive; **AND**
- Used in combination with fludarabine and cyclophosphamide (FC); **OR**
- Patient has disease that is ***without*** del(17p)/TP53 mutation; **AND**
  - Used as first-line therapy in **ONE** of the following settings or in combination with:
    - Bendamustine (patients ≥ 65 years, or younger patients with or without significant comorbidities; *excluding use in frail patients [i.e., not able to tolerate purine analogs])*
    - Fludarabine (patient is without del(11q) and is < 65 years without significant comorbidities); **OR**
  - Used as subsequent therapy in combination with **ONE** of the following:
    - Alemtuzumab
    - Bendamustine (patients < 65 years without significant comorbidities)
    - Chlorambucil (patients ≥ 65 years or younger patients with significant comorbidities)
    - High-dose Methylprednisolone
    - Idelalisib
    - Lenalidomide
    - Venetoclax
    - PCR (pentostatin, cyclophosphamide, and rituximab); **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient has disease ***with*** del(17p)/TP53 mutation; **AND**
  - Used as first-line therapy in one of the following settings or in combination with:
    - Alemtuzumab
    - High-dose Methylprednisolone; **OR**
  - Used as subsequent therapy in one of the following settings or in combination with:
    - Alemtuzumab
    - High-dose Methylprednisolone
    - Idelalisib
    - Lenalidomide
    - Venetoclax; **OR**
- Used as first line therapy for histologic (Richter's) transformation to diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, and vincristine-based regimens or as a component of OFAR (oxaliplatin, fludarabine, cytarabine, and rituximab).

Diagnosis of **Non-Hodgkin lymphomas (NHL) including, but not limited to, the following:**

For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Ruxience®.

- Patient age is 18 years or older; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive; **AND**
- AIDS-related B-Cell Lymphoma
  - Disease is related to Burkitt Lymphoma or diffuse large B-cell lymphoma *(including HHV-8 DLBCL, not otherwise specified)*
- Burkitt Lymphoma
  - Used in combination with other chemotherapy
- Castleman Disease
  - Patient has multicentric disease; **OR**
  - Patient has unicentric disease; **AND**
    - Used as second-line therapy for relapsed or refractory disease; **OR**
    - Used for patients with symptoms after resection
- Diffuse large B-cell lymphoma
- Low-grade or follicular lymphoma
- Gastric and non-gastric MALT lymphoma
- High-grade B-cell lymphoma
- Mantle cell lymphoma
- Nodal and splenic marginal zone lymphoma

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Histologic transformation of follicular or nodal marginal zone lymphoma to diffuse large B-cell lymphoma
- Post-transplant lymphoproliferative disorder (PTLD) (B-cell type)
  - Patient has had solid organ transplant or allogeneic hematopoietic stem cell transplantation
- Pediatric aggressive mature B-cell lymphomas
  - Patient age is 18 years and under*; **AND**
  - Used in combination with chemotherapy

  **Pediatric aggressive mature B-cell lymphoma may be applicable to adolescent and young adult (AYA) patients older than 18 years of age and less than 39 years of age, who are treated in the pediatric oncology setting*
- Primary cutaneous B-cell lymphomas

Diagnosis of **Hairy Cell Leukemia**

- Patient age is 18 years old or older; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive; **AND**
- Used in combination with cladribine as initial therapy; **OR**
  - Used for relapsed or refractory disease or in patients with a less than complete response (CR) to initial therapy.

Diagnosis of **Granulomatosis with Polyangiitis (GPA) (Wegener's granulomatosis) and Microscopic Polyangiitis (MPA)**

For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Ruxience®.

- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient is at least 2 years of age; **AND**
- Used in combination with glucocorticoids (e.g., prednisone, methylprednisolone).

Diagnosis of **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma**

- Patient age is 18 years or older; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient CD20 antigen expression is positive.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infusion-related reactions; tumor lysis syndrome (TLS); severe mucocutaneous reactions; progressive multifocal leukoencephalopathy (PML); hepatitis B virus reactivation; serious bacterial, fungal, or viral infections; cardiovascular adverse reactions (e.g., ventricular fibrillation, myocardial infarction, cardiogenic shock, cardiac arrhythmias); renal toxicity; bowel obstruction or perforation, etc.; **AND**

Oncology Indications

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **OR**

Granulomatosis with Polyangiitis (GPA) (Wegener's granulomatosis) and Microscopic Polyangiitis (MPA)

- Disease response as indicated by disease control and improvement in signs and symptoms of condition compared to baseline; **AND**
- A decrease frequency in the occurrence of major relapses (defined by the reappearance of clinical and/or laboratory signs of vasculitis activity that could lead to organ failure or damage or could be life threatening).

Drug Name:	Truxima® (rituximab-abbs)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	1 month
Therapy Stage:	Initial Authorization

Criteria:

- Diagnosis of **moderately- to severely-active rheumatoid arthritis**; **AND**
- **ONE** of the following:
  - Patient is concurrently on methotrexate [A]; **OR**
  - History of contraindication or intolerance to methotrexate**; AND**
- **ONE** of the following:
  - **BOTH** of the following:
    - Trial and failure, contraindication, or intolerance to **TWO** of the following, or attestation demonstrating a trial may be inappropriate*
      - Cimzia® (certolizumab)
      - Humira® (adalimumab)
      - Rinvoq™ (upadacitinib)
      - Simponi® (golimumab)
      - Xeljanz® (tofacitinib) or Xeljanz XR (tofacitinib ER); **AND**
    - Trial and failure, contraindication, or intolerance to **BOTH** of the following:
      - Actemra® (tocilizumab)
      - Orencia® (abatacept); **OR**
  - Continuation of prior therapy for Standard and Precision only. No grandfathering allowed for Precision Plus; **AND**
- Prescribed by or in consultation with a rheumatologist

Notes: **Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.*

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

Drug Name:	Truxima® (rituximab-abbs)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	1 month
Therapy Stage:	Reauthorization

Criteria:

- Documentation of positive clinical response to therapy

Drug Name:	Truxima® (rituximab-abbs)
Diagnosis:	Rheumatoid Arthritis (RA)
Approval Length:	1 month
Therapy Stage:	Non Formulary

Criteria:

- Diagnosis of **moderately- to severely-active rheumatoid arthritis**; **AND**
- Paid claims or submission of medical records (e.g., chart notes) confirming **ONE** of the following:
  - Patient is concurrently on methotrexate [A]; **OR**
  - History of contraindication or intolerance to methotrexate**; AND**
- **ONE** of the following:
  - **BOTH** of the following:
    - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **TWO** of the following, or attestation demonstrating that a trial may be inappropriate*
      - Cimzia® (certolizumab)
      - Humira® (adalimumab)
      - Rinvoq™ (upadacitinib)
      - Simpon®i (golimumab)
      - Xeljanz® (tofacitinib) or Xeljanz XR (tofacitinib ER); **AND**
    - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **BOTH** of the following:
      - Actemra® (tocilizumab)
      - Orencia® (abatacept); **OR**
  - Continuation of prior therapy, defined as no more than a 45-day gap in therapy, for Standard and Precision only. No grandfathering allowed for Precision Plus; **AND**
- Prescribed by or in consultation with a rheumatologist

Notes: **Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.*

TUKYSA® (TUCATINIB)

Length of Authorization:	6 months and may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has human epidermal growth factor receptor positive (HER2+) disease; **AND**
- Patient will avoid all the following potential drug-drug interactions:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort)
  - Coadministration with moderate CYP2C8 inducers (e.g., rifampin)
  - Coadministration with strong or moderate CYP2C8 inhibitors (e.g., gemfibrozil, clopidogrel, deferasirox, teriflunomide) or, if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented**; AND**
- Patient has recurrent, advanced unresectable, or metastatic disease; **AND**
- Used as subsequent therapy in combination with trastuzumab and capecitabine; **AND**
- Patient has been previously treated with one or more lines of HER2-targeted therapy in the metastatic setting (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine)

Diagnosis of **Central Nervous System (CNS) Cancer (Brain Metastases from Breast Cancer)**

- Patient is at least 18 years of age; **AND**
- Patient has human epidermal growth factor receptor positive (HER2+) disease; **AND**
- Patient will avoid all the following potential drug-drug interactions:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort)
  - Coadministration with moderate CYP2C8 inducers (e.g., rifampin)
  - Coadministration with strong or moderate CYP2C8 inhibitors (e.g., gemfibrozil, clopidogrel, deferasirox, teriflunomide) or, if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has brain metastases related to breast cancer previously treated with one or more lines of HER2-targeted therapy (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine); **AND**
- Patient does not have leptomeningeal disease; **AND**
- Used in combination with trastuzumab and capecitabine; **AND**
  - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
  - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

*HER2 overexpression must be confirmed as follows:
• Immunohistochemistry (IHC) assay 3+; **OR** • Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number ≥ 4.0 signals/cell; **OR** • Dual-probe in situ hybridization (ISH) assay **and** concurrent IHC indicating one of the following: – HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number < 4.0 signals/cell **and** concurrent IHC 3+; **OR** – HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 6.0 signals/cell **and** concurrent IHC 2+ or 3+; **OR** – HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 4.0 and < 6.0 signals/cell **and** concurrent IHC 3+

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hepatotoxicity [severe changes in liver function tests], severe diarrhea)

TURALIO™ (PEXIDARTINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Tenosynovial Giant Cell Tumor (TGCT)**

- Patient is at least 18 years old; **AND**
- Patient does not have any pre-existing active liver or biliary tract disease; **AND**
- Patient and provider are enrolled in the Turalio Risk Evaluation and Mitigation Strategy (REMS) Program; **AND**
- Patient will avoid concomitant use with the following drugs:
  - Strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Moderate or strong CYP3A inhibitors (e.g., fluconazole, itraconazole, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - UGT inhibitors (e.g., probenecid, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Acid reducing agents (e.g., proton-pump inhibitors, etc.); **AND**
- Patient has a histologically confirmed diagnosis of TGCT [also referred to as giant cell tumor of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS)]; **AND**
- Will be used as single-agent therapy

Diagnosis of **Histiocytic Neoplasms**

- Patient is at least 18 years old; **AND**
- Patient does not have any pre-existing active liver or biliary tract disease; **AND**
- Patient and provider are enrolled in the Turalio Risk Evaluation and Mitigation Strategy (REMS) Program; **AND**
- Patient will avoid concomitant use with the following drugs:
  - Strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Moderate or strong CYP3A inhibitors (e.g., fluconazole, itraconazole, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - UGT inhibitors (e.g., probenecid, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Acid reducing agents (e.g., proton-pump inhibitors, etc.); **AND**
- Used for disease with colony stimulating factor 1 receptor (CSF 1R) mutation target; **AND**
- Will be used as single-agent therapy; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient has one of the following sub-types of disease:
  - Langerhans Cell Histiocytosis (LCH); **AND**
    - Used for multisystem disease with symptomatic or impending organ dysfunction; **OR**
    - Used for pulmonary LCH; **OR**
    - Patient has multifocal single system bone disease not responsive to treatment with a bisphosphonate and more than 2 lesions; **OR**
    - Patient has CNS lesions; **OR**
    - Used for relapsed/refractory disease; **OR**
  - Erdheim-Chester Disease; **AND**
    - Patient has symptomatic disease; **OR**
    - Used for relapsed or refractory disease; **OR**
  - Rosai-Dorfman Disease; **AND**
    - Patient has symptomatic disease that is multifocal or unresectable unifocal; **OR**
    - Used for relapsed or refractory disease

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe hepatotoxicity); **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread or improvement in patient symptoms and/or functional status; **AND**
- Patient does not have any of the following signs of hepatotoxicity:
  - Increased ALT and/or AST > 3 times the upper limit of normal; **OR**
  - Increase in both alkaline phosphatase and GGT > 2 times the upper limit of normal; **OR**
  - Increased total bilirubin above the upper limit of normal

TYKERB® (LAPATINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**

- Patient is at least 18 years old; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient's disease is human epidermal growth factor receptor positive (HER2+)*; **AND**
- Patient will avoid concomitant use with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will implemented:
  - Strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, cobicistat)
  - Strong CYP3A4 inducers (e.g., carbamazepine, phenobarbital, rifampin); **AND**
- Patient has advanced, metastatic, or recurrent unresectable disease; **AND**
  - Used as subsequent therapy in combination with trastuzumab or capecitabine; **AND**
    - Patient's disease is hormone receptor negative; **OR**
    - Patient's disease is hormone receptor positive and used with or without endocrine therapy; **OR**
  - Used in combination with an aromatase inhibitor (e.g., letrozole); **AND**
    - Patient's disease is hormone receptor-positive; **AND**
      - Patient is a male receiving concomitant suppression of testicular steroidogenesis; **OR**
      - Patient is a postmenopausal female; **OR**
      - Patient is a premenopausal female treated with ovarian ablation/suppression

Bone Cancer – Chordoma

- Patient is at least 18 years old; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid concomitant use with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will implemented:
  - Strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, cobicistat)
  - Strong CYP3A4 inducers (e.g., carbamazepine, phenobarbital, rifampin); **AND**
- Patient has EGFR-positive recurrent conventional or chondroid chordoma; **AND**
- Used as a single agent therapy

Diagnosis of **Central Nervous System Cancers – Brain Metastases**

- Patient is at least 18 years old; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient's disease is human epidermal growth factor receptor positive (HER2+)*; **AND**
- Patient will avoid concomitant use with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will implemented:
  - Strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, cobicistat)
  - Strong CYP3A4 inducers (e.g., carbamazepine, phenobarbital, rifampin); **AND**

- Patient has brain metastases from HER2-positive breast cancer; **AND**
- Used in combination with capecitabine; **AND**
  - Used as initial treatment of with small, asymptomatic brain lesions; **OR**
  - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

Colorectal Adenocarcinoma

- Patient is at least 18 years old; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient's disease is human epidermal growth factor receptor positive (HER2+)*; **AND**
- Patient will avoid concomitant use with any of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will implemented:
  - Strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, cobicistat)
  - Strong CYP3A4 inducers (e.g., carbamazepine, phenobarbital, rifampin); **AND**
- Used in combination with trastuzumab; **AND**
- Patient has RAS and BRAF wild-type (WT) disease; **AND**
  - Patient has not previously received HER2-targeted therapy; **AND**
    - Used as subsequent therapy for progression of advanced or metastatic disease after at least one prior line of treatment in the advanced or metastatic disease setting; **OR**
    - Patient is not appropriate for intensive therapy; **AND**
      - Used as initial systemic therapy for locally unresectable (or medically inoperable) or metastatic disease;
      - Used for unresectable metastases that remain unresectable after primary treatment; **OR**
      - Used for metastatic disease in patients who have received adjuvant FOLFOX or CapeOX more than 12 months ago OR who have received previous fluorouracil/leucovorin (5-FU/LV) or capecitabine therapy

***HER2 overexpression must be confirmed as follows: [4]**

- Immunohistochemistry (IHC) assay 3+; **OR**
- Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number ≥ 4.0 signals/cell; **OR**
- Dual-probe in situ hybridization (ISH) assay **and** concurrent IHC indicating one of the following:
  - HER2/CEP17 ratio ≥ 2.0 **and** average HER2 copy number < 4.0 signals/cell **and** concurrent IHC 3+; **OR**
  - HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 6.0 signals/cell **and** concurrent IHC 2+ or 3+; **OR**
  - HER2/CEP17 ratio < 2.0 **and** average HER2 copy number ≥ 4.0 and < 6.0 signals/cell **and** concurrent IHC 3+

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Left ventricular ejection fraction (LVEF) has not had an absolute decrease of >20% from pre-treatment baseline and is within normal limits; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hepatotoxicity [severe changes in liver function tests]; cardiac toxicity [QT prolongation, decreased LVEF], interstitial lung disease/pneumonitis, severe cutaneous reactions, severe diarrhea)

TYMLOS® (ABALOPARATIDE)

Length of Authorization:	1 year with one renewal of 6 months (total length of therapy may not exceed 18 months)
Initiative:	SPC: Osteoporosis Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Osteoporosis in Women**

- Patient is 18 years or older; **AND**
- Confirmation patient is receiving calcium and Vitamin D supplementation if dietary intake is inadequate; **AND**
- Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
  - Hip/femur DXA (femoral neck or total hip) or lumbar spine T-score ≤ -2.5 and/or forearm DXA 33% (one-third) of the radius; **OR**
  - T-score ≤ -1 or low bone mass **and** a history of fragility fracture to the hip or spine; **OR**
  - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; **AND**
- Patient is at a high risk for fractures‡; **AND**
- Patient is not at increased risk for osteosarcoma (e.g., Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton); **AND**
- Patient has not received therapy with parathyroid hormone analogs (e.g., abaloparatide, teriparatide) in excess of 2 years in total; **AND**
- Patient does not have hypercalcemia or an underlying hypercalcemic disorder (e.g., primary hyperparathyroidism); **AND**
- Patient must be at a high risk for fracture**; **AND**
- Patient must be post-menopausal; **AND**
- **§**Documented treatment failure or ineffective response± to a minimum (12) month trial on previous therapy with oral bisphosphonates such as alendronate, risedronate, ibandronate, etc.; **OR**
  - Patient has a documented contraindication* or intolerance to oral bisphosphonates such as alendronate, risedronate, or ibandronate; **AND**
- **§**Documented treatment failure or ineffective response± to a minimum (12) month trial on previous therapy with injectable bisphosphonates such as ibandronate, zoledronic acid, etc.; **OR**
  - Patient has a documented contraindication* or intolerance to injectable bisphosphonates such as ibandronate, zoledronic acid, etc.; **AND**
- **§**Documented treatment failure or ineffective response± to a minimum (12) month trial on previous therapy with *RANKL*-blocking agents such as denosumab, etc.; **OR**
  - Patient has a documented contraindication* or intolerance to *RANKL*-blocking agents such as denosumab, etc.; **AND**
- Documented treatment failure or ineffective response± to a minimum (12) month trial of an injectable sclerostin-inhibitor such as romosozumab, etc.; **OR**
  - Patient has a documented contraindication* or intolerance to an injectable sclerostin inhibitor such as romosozumab, etc.
- § Patients with extremely low BMD (T < -3.5) or a T < -2.5 with a history of fragility fractures are not subject to prior trial and failure requirements with bisphosphonates and/or denosumab

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

± Ineffective response is defined as one or more of the following:

- Decrease in T-score in comparison with baseline T-score from DXA scan
- Patient has a new fracture while on therapy to treat osteoporosis

‡ High risk for fractures include, but are not limited to, one or more of the following:

- History of an osteoporotic fracture as an adult
- Parental history of hip fracture
- Low BMI
- Rheumatoid arthritis
- Alcohol intake (3 or more drinks per day)
- Current smoking
- History of oral glucocorticoids ≥ 5 mg per day of prednisone for > 3 months (ever)

***Examples of contraindications to oral bisphosphonate therapy include the following:**

- Documented inability to sit or stand upright for at least 30 minutes
- Documented pre-existing gastrointestinal disorder such as inability to swallow, Barrett's esophagus, esophageal stricture, dysmotility, or achalasia

Examples of contraindications to injectable bisphosphonate therapy include the following:

- Documented pre-existing hypocalcemia and disturbances of mineral metabolism
- Documented pre-existing renal insufficiency defined as creatinine clearance < 35 mL/min

Examples of contraindications to *RANKL*-blocking therapy include the following:

- Documented pre-existing hypocalcemia and disturbances of mineral metabolism
- Documented hypersensitivity to the active ingredient or its excipients

Examples of contraindications to sclerostin inhibitor therapy include the following:

- Documented pre-existing hypocalcemia and disturbances of mineral metabolism
- Documented pre-existing severe cardiovascular disease that precludes use
- Documented hypersensitivity to the active ingredient or its excipients

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., osteosarcoma, orthostatic hypotension, hypercalcemia, hypercalciuria and urolithiasis); **AND**
- Total length of therapy has not exceeded 18 months for abaloparatide and/or 2 years for parathyroid hormone analogs (e.g., abaloparatide, teriparatide); **AND**
- Disease response as indicated by one or more of the following:
  - Absence of fractures
  - Increase in bone mineral density compared to pretreatment baseline
  - Increase in bone formation markers (i.e., procollagen type 1 N-propeptide [P1NP])

UKONIQ® (UMBRALISIB)

Length of Authorization:	6 months, eligible for renewal
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **B-Cell Lymphomas**

- Patient is at least 18 years of age; **AND**
- Will not be used in combination with other PI3K-inhibitors (e.g., idelalisib, duvelisib, copanlisib, alpelisib); **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will receive prophylactic therapy for *Pneumocystis jirovecii* (PJP) while on treatment with umbralisib; **AND**
- Patient has relapsed or refractory disease; **AND**
  - Used as subsequent therapy after at least one prior anti-CD20-based regimen; **AND**
    - Patient has one of the following diagnoses:
      - Marginal zone lymphoma; **OR**
      - Gastric MALT lymphoma**; OR**
      - Non-Gastric MALT lymphoma (noncutaneous); **OR**
  - Patient has a diagnosis of Follicular Lymphoma (grade 1–2); **AND**
    - Used as subsequent therapy after at least three prior lines of systemic therapy, including an anti-CD20 monoclonal antibody and an alkylating agent

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include active/severe infections, neutropenia with ANC < 0.5 x 10^9/L, thrombocytopenia with platelets < 25 x 10^9/L, severe diarrhea or colitis, hepatoxicity, severe cutaneous reactions, serious allergic reactions, etc.

ULCERATIVE COLITIS THERAPY

STANDARD FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

Length of Authorization:	1 year (for Uceris extended-release tablet and its generic only: 8 weeks, initial and renewal)
Initiative:	MNC: Miscellaneous: PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL (NO GRANDFATHERING)

ASACOL HD, LIALDA, MESALAMINE DR, OR DELZICOL

- Patient has failed a trial of Apriso

DIPENTUM

- The patient must step through any one generic in class (e.g., balsalazide, budesonide DR, mesalamine, sulfasalazine) **AND** Apriso.

UCERIS ER 9MG AND GENERIC BUDESONIDE ER 9MG TABLET

- For the extended-release tablet:
  - Prescribed by or in consultation with a gastroenterologist or colorectal surgeon; **AND**
  - Patient is at least 18 years of age; **AND**
  - Patient has active, mild to moderate ulcerative colitis; **AND**
  - Medication is being used to induce remission; **AND**
  - Patient has an inadequate response or clinically significant adverse effects to an adequate trial of aminosalicylates (e.g., sulfasalazine, mesalamine) (as per ACG 2019 guidelines).

CLINICAL CRITERIA FOR RENEWAL

UCERIS ER AND GENERIC BUDESONIDE ER 9MG TABLET

- Patient continues to meet criteria above; **AND**
- Patient is free of unacceptable toxicity from the drug.

PRECISION/PLUS FORMULARY CRITERIA

CORE FORMULARY CRITERIA

For Precision/Plus and Core exclusions, follow the Precision/Plus and Core Exception process.

GENERIC BUDESONIDE ER 9 MG TABLET

- For the extended-release tablet:
  - Prescribed by or in consultation with a gastroenterologist or colorectal surgeon; **AND**
  - Patient is at least 18 years of age; **AND**
  - Patient has active, mild to moderate ulcerative colitis; **AND**
  - Medication is being used to induce remission; **AND**
  - Patient has an inadequate response or clinically significant adverse effects to an adequate trial of aminosalicylates (e.g., sulfasalazine, mesalamine) (as per ACG 2019 guidelines).

CLINICAL CRITERIA FOR RENEWAL

GENERIC BUDESONIDE ER 9MG TABLET

- Patient continues to meet criteria above; **AND**
- Patient is free of unacceptable toxicity from the drug.

ULTOMIRIS® (RAVULIZUMAB-CWVZ)

Length of Authorization:	1 year, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Paroxysmal Nocturnal Hemoglobinuria (PNH)**

- Patient is at least 1 month of age; **AND**
- Prescriber is enrolled in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
- Patients must be administered a meningococcal vaccine at least two weeks prior to initiation of therapy and will continue to be revaccinated according to current medical guidelines for vaccine use (If urgent Ultomiris® therapy is indicated in an unvaccinated patient, administer meningococcal vaccine(s) as soon as possible and provide patients with two weeks of antibacterial drug prophylaxis.); **AND**
- Will not be used in combination with other complement-inhibitor therapy (e.g., eculizumab, pegcetacoplan); **AND**
- Used as switch therapy; **AND**
  - Patient is currently receiving treatment with Soliris® and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy; **OR**
- Patient is complement inhibitor treatment-naïve; **AND**
  - Diagnosis must be accompanied by detection of PNH clones of at least 5% by flow cytometry diagnostic testing; **AND**
    - Demonstrate the presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59) within at least 2 different cell lines (e.g., granulocytes, monocytes, erythrocytes); **AND**
    - Patient has laboratory evidence of significant intravascular hemolysis (i.e., lactate dehydrogenase [LDH] ≥ 1.5 x upper limit of normal [ULN]) and at least one other indication for therapy from the following:
      - Presence of a thrombotic event
      - Presence of organ damage secondary to chronic hemolysis (i.e., renal insufficiency, pulmonary insufficiency, or hypertension)
      - Patient is pregnant and potential benefit outweighs potential fetal risk
      - Patient has symptomatic anemia (regardless of transfusion dependence)
      - Patient has disabling fatigue
      - Patient has abdominal pain requiring admission or opioid analgesia; **AND**
    - Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH), hemoglobin level, packed red blood cell (RBC) transfusion requirement, and history of thrombotic events

Diagnosis of **Atypical Hemolytic Uremic Syndrome (aHUS)**

- Patient is at least 1 month of age; **AND**
- Prescriber is enrolled in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
- Patients must be administered a meningococcal vaccine at least two weeks prior to initiation of therapy and will continue to be revaccinated according to current medical guidelines for vaccine use (If urgent Ultomiris therapy is indicated in an unvaccinated patient, administer meningococcal vaccine(s) as soon as possible and provide patients with two weeks of antibacterial drug prophylaxis.); **AND**
- Will not be used in combination with other complement-inhibitor therapy (e.g., eculizumab, pegcetacoplan); **AND**
- Used as switch therapy; **AND**
  - Patient is currently receiving treatment with Soliris and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy; **OR**
- Patient is complement inhibitor treatment-naïve; **AND**
  - Patient shows signs of thrombotic microangiopathy (TMA) (e.g., changes in mental status, seizures, angina, dyspnea, thrombosis, increasing blood pressure, decreased platelet count, increased serum creatinine, increased LDH); **AND**
    - Thrombotic thrombocytopenic purpura (TTP) has been ruled out by evaluating ADAMTS-13 level (ADAMTS-13 activity level ≥ 10%); **AND**
    - Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS) has been ruled out; **AND**
    - Other causes have been ruled out such as coexisting diseases or conditions (e.g., bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug-induced) or known genetic defect in cobalamin C metabolism; **AND**
    - Documented baseline values for one or more of the following (necessary for renewal): serum LDH, serum creatinine/estimated glomerular filtration rate (eGFR), platelet count, and dialysis requirement

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include serious meningococcal infections (i.e., septicemia and/or meningitis), infusion-related reactions, other serious infections (i.e., *Streptococcus pneumoniae, Haemophilus influenzae*, *Neisseria gonorrhoeae)*, thrombotic microangiopathy (TMA) complications, etc.; **AND**
- Disease response indicated by one or more of the following:
  - **For PNH:**
    - Decrease in serum LDH from pretreatment baseline
    - Stabilization/improvement in hemoglobin level from pretreatment baseline
    - Decrease in packed RBC transfusion requirement from pretreatment baseline
    - Reduction in thromboembolic events
  - **For aHUS:**
    - Decrease in serum LDH from pretreatment baseline
    - Stabilization/improvement in serum creatinine/eGFR from pretreatment baseline
    - Increase in platelet count from pretreatment baseline
    - Patient no longer requires dialysis treatments

Switch therapy from Soliris® to Ultomiris®

- Refer to initial criteria

UNITUXIN® (DINUTUXIMAB)

Length of Authorization:	Coverage is provided for six months (total therapy is 5 cycles) and may not be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **High-Risk Neuroblastoma**

- Patient's age is less than 18 years; **AND**
- Will not be used in combination with other GD2-binding monoclonal antibodies (e.g., naxitamab); **AND**
- Used in combination with granulocyte-macrophage colony-stimulating factor [GM-CSF] (e.g., sargramostim); **AND**
- Used in combination with interleukin-2 [Il-2] (e.g., aldesleukin); **AND**
- Used in combination with 13-cis-retinoic acid (e.g., isotretinoin); **AND**
- Patient had at least partial response to first-line multiagent, multimodality therapy

CLINICAL CRITERIA FOR RENEWAL

Coverage may **not** be renewed

UPLIZNA™ (INEBILIZUMAB-CDON)

Length of Authorization:	6 months initially, may be renewed annually thereafter
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Neuromyelitis Optica Spectrum Disorder (NMOSD)**

- Patient is 18 years of age or older; **AND**
- Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment and confirmed negative for active HBV; **AND**
- Patient serum immunoglobulin baseline measured prior to the start of therapy; **AND**
- Patient has not received intravenous immunoglobulin (IVIG) within 1 month prior to the start of therapy**; AND**
- Patient does not have an underlying immunodeficiency disorder (e.g., acquired/congenital primary immunodeficiency, human immunodeficiency virus [HIV]); **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Live or live-attenuated vaccinations will not be administered within the 4-weeks prior to the start of therapy and will not be administered concurrently while on therapy**; AND**
- Patient has not previously received, and will not concomitantly receive, therapy with any of the following:
  - Other drugs which can result in prolonged additive immunosuppression (e.g., alemtuzumab, natalizumab, cyclosporin, methotrexate, mitoxantrone, cyclophosphamide, tocilizumab, maintenance corticosteroids **[not including pre-medications or rescue therapy)**]); **AND**
  - Other immunosuppressant procedures (e.g., total lymphoid irradiation, bone marrow transplant, T-cell vaccination therapy); **AND**
- Patient will not concomitantly receive therapy with any of the following:
  - Complement-inhibitor (e.g., eculizumab, ravulizumab); **AND**
  - Anti-CD20-directed antibody (e.g., rituximab); **AND**
  - IL-6 inhibitor (e.g., satralizumab, tocilizimab, sarilumab) therapies; **AND**
- Patient has a confirmed diagnosis based on the following:
  - Patient was found to be seropositive for aquaporin-4 (AQP4) IgG antibodies; **AND**
  - Patient has at least one core clinical characteristic §**; AND**
  - Alternative diagnoses have been excluded (e.g., multiple sclerosis, sarcoidosis, cancer, chronic infection); **AND**
- Patient has a history of one or more relapses that required rescue therapy within the prior year **or** two or more relapses that required rescue therapy within the prior 2 years; **AND**
- Patient has an Expanded Disability Status Score (EDSS) of ≤ 7.5 (i.e., inability to take more than a few steps; restricted to wheelchair and may need aid in transferring; can wheel self but cannot carry on in standard wheelchair for a full day and may require a motorized wheelchair)

§ Core Clinical Characteristics of NMOSD
• Optic neuritis • Acute myelitis • Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting • Acute brainstem syndrome • Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic lesions seen in magnetic resonance imaging (MRI) • Symptomatic cerebral syndrome with NMOSD-typical brain lesions

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include serious or life-threatening infusion related reactions, serious infections including progressive multifocal leukoencephalopathy (PML), hypogammaglobulinemia necessitating IVIG treatment or leading to recurrent infections, etc.; **AND**
- Disease response as indicated by stabilization/improvement in one or more of the following:
  - Neurologic symptoms as evidenced by a decrease in acute relapses, stability, or improvement in EDSS
  - Reduced hospitalizations
  - Reduction in plasma exchange treatments

UPNEEQ® (OXYMETAZOLINE)

Length of Authorization:	1 year
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is 18 years of age or older; **AND**
- Prescribed by or in consultation with an ophthalmologist or optometrist; **AND**
- Patient has a diagnosis of acquired blepharoptosis (non-congenital); **AND**
- Blepharoptosis hinders vision.

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet criteria above; **AND**
- Patient is considered to have clinically meaningful response to treatment; **AND**
- Patient is not experiencing any treatment-limiting adverse reactions of the medication; **AND**
- Patient has not had surgical correction

URINARY TRACT ANTISPASMODICS

Length of Authorization:	1 year
Initiative:	MNC: Antispasmodics: Urinary tract (IE 2462 / NCPDP 75)

STEP CRITERIA (NO GRANDFATHERING)

OXYTROL, GELNIQUE, GEMTESA

- Must try a trial of TWO of the following:
  - Myrbetriq®
  - generic darifenacin ER
  - generic oxybutynin IR/ER
  - generic solifenacin
  - generic tolterodine IR/ER
  - generic trospium IR/ER

VACCINES

Length of Authorization:	6 months
Initiative:	MNC: Miscellaneous: PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL (IF BENEFIT BUILDER HAS PA REQUIRED)

- COVID-19 vaccine mRNA (Comirnaty®):
  - As of 08/23/2021, patient is 16 years of age or older; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Haemophilus B conjugate vaccine (ActHIB®):
  - Patient is 2 months through 5 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur; **AND**
  - Patient is not on immunosuppressive therapy**; AND**
  - Immunosuppressive agents should not be administered during post-exposure therapy unless essential for the treatment of other conditions
- Haemophilus B conjugate vaccine (Hiberix®):
  - Patient is 6 weeks through 4 years of age (prior to 5th birthday); **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Haemophilus B conjugate vaccine (PedvaxHIB®):
  - Patient is 2 months to 71 months of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Diphtheria, pertussis, and tetanus vaccine (Adacel®):
  - Patient is 10 years of age through 64 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur; **AND**
  - Patient is not on immunosuppressive therapy; **AND**
  - Immunosuppressive agents should not be administered during post-exposure therapy unless essential for the treatment of other conditions
- Diphtheria, pertussis (acellular), and tetanus (Boostrix®):
  - Patient is 10 years of age or older; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Diphtheria and tetanus toxoid adsorbed
  - Patient is 6 weeks through 6 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Tetanus and diphtheria toxoid adsorbed (TdVax™)
  - Patient is 7 years of age or older; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Tetanus and diphtheria toxoids adsorbed (Tenivac®)
  - Patient is 7 years of age or older; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Diphtheria, pertussis, tetanus pediatric vaccine/PF (Daptacel®):
  - Patient is 6 weeks through 6 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur

CLINICAL CRITERIA FOR INITIAL APPROVAL (IF BENEFIT BUILDER HAS PA REQUIRED) *(CONTINUED)*

- Diphtheria, pertussis (acellular), and tetanus pediatric vaccine, PF (Infanrix® DTaP):
  - Patient is 6 weeks through 6 years (prior to 7th birthday); **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Diphtheria, pertussis, tetanus, and polio vaccine (Kinrix®):
  - Patient is 4 years through 6 years of age; **AND**
  - Patient does not have a severe allergy to neomycin and polymyxin; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Diphtheria, pertussis, tetanus, and polio vaccine (Quadracel® DTaP):
  - Patient is 4 years through 6 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Diphtheria and tetanus toxoids and acellular pertussis, inactivated poliovirus, haemophilus b conjugate and hepatitis B vaccine (Vaxelis™):
  - Patient is 6 weeks through 4 years of age; **AND**
  - Patient does not have a history of encephalopathy within 7 days of a previous dose of a pertussis-containing vaccine that is not attributable to another identifiable cause; **AND**
  - Patient does not have a history of progressive neurologic disorder until a treatment regimen has been established and the condition stabilized; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Diphtheria, pertussis, tetanus, and polio vaccine (Pentacel®):
  - Patient is 6 weeks through 4 years of age (prior to 5th birthday); **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Adenovirus vaccine live Type-4 and adenovirus vaccine live Type-7:
  - Patient is in the military; **AND**
  - Patient is 17 years through 50 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Influenza virus vaccine **quadrivalent** (Afluria®):
  - Patient is 6 months of age or older; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Influenza virus vaccine **quadrivalent** (Fluzone®):
  - Patient is 6 months or older; **AND**
  - Patient does not have a severe egg protein allergy; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Influenza virus vaccine **quadrivalent** (Fluzone® quadrivalent PF):
  - Patient is 6 months or older; **AND**
  - Patient does not have a severe egg protein allergy; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Influenza virus vaccine quadrivalent split (Fluzone® high-dose quadrivalent):
  - Patient is 65 years of age or older; **AND**
  - Patient does not have a severe egg protein allergy; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur

CLINICAL CRITERIA FOR INITIAL APPROVAL (IF BENEFIT BUILDER HAS PA REQUIRED) *(CONTINUED)*

- Influenza virus vaccine (FLUAD® QUADRIVALENT):
  - Patient is 65 years of age or older; **AND**
  - Patient does not have a severe egg protein allergy; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur

CLINICAL CRITERIA FOR INITIAL APPROVAL (IF BENEFIT BUILDER HAS PA REQUIRED) *(CONTINUED)*

- Influenza virus vaccine quadrivalent split (Fluarix® quadrivalent):
  - Patient is 6 months of age or older; **AND**
  - Patient does not have a severe egg protein allergy; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Influenza virus vaccine quadrivalent (Flublok®):
  - Patient is 18 years of age or older; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Influenza virus vaccine quadrivalent (Flulaval® quadrivalent):
  - Patient is 6 months of age or older**; AND**
  - Patient does not have a severe egg protein allergy; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Influenza virus vaccine quadrivalent live (FluMist®):
  - Patient is 2 years through 49 years of age; **AND**
  - Patient does not have a severe egg protein allergy; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Flu vaccine QS (Flucelvax® quadrivalent):
  - Patient is 4 years of age or older; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Pneumococcal 23-valent polysaccharide vaccine (Pneumovax® 23):
  - Patient is 50 years of age or older; **OR**
  - Patient must be at increased risk for pneumococcal disease and be over 2 years of age**; AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Pneumococcal 13-valent conjugate vaccine (Prevnar 13®):
  - Patient is at least 6 weeks of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Pneumococcal 15-valent conjugate vaccine (Vaxneuvance™):
  - Patient is at least 18 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Pneumococcal 20-valent conjugate vaccine (Prevnar 20™):
  - Patient is at least 18 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- BCG Vaccine, Live/PF (TICE strain):
  - BCG vaccine administration should not be attempted in individuals with severe immune deficiency disease; **AND**
  - BCG vaccine should be administered with caution to persons in groups at high risk of HIV infection; **AND**
  - Patient is not on immunosuppressive therapy; **AND**
  - Immunosuppressive agents should not be administered during postexposure therapy unless essential for the treatment of other conditions; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur

CLINICAL CRITERIA FOR INITIAL APPROVAL (IF BENEFIT BUILDER HAS PA REQUIRED) *(CONTINUED)*

- Meningococcal group B vaccine, 4-component/PF (Bexsero®):
  - Patient is 10 years through 25 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Meningococcal vaccine, A, C, Y and W-135 (Menactra®):
  - Patient is between 9 months and 55 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Meningococcal vaccine, A, C, Y, and W (MenQuadfi™):
  - Patient is at least 2 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Meningococcal vaccine A, C, Y, W-135, diphtheria toxoid con (Menveo®):
  - Patient is 2 months through55 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Anthrax vaccine (Biothrax®):
  - Patient is 18 through 65 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Human papillomavirus vaccine (Gardasil® 9):
  - Patient is 9 through 45 years of age; **AND**
  - Patient does not have any severe yeast allergic reactions; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Hepatitis B virus vaccine recombinant/PF adult (Engerix-B®):
  - Patient is 20 years of age or older; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Hepatitis B virus vaccine recombinant/PF pediatric (Engerix-B®):
  - Patient is 19 years of age or younger; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur; **AND**
  - Must not be administered in infants with a birth weight less than 2,000 grams born to HBsAg-negative mothers
- Hepatitis B virus vaccine recombinant, adjuvanted (HEPLISAV-B®):
  - Patient is 18 years of age or older; **AND**
  - Patient does not have any severe yeast allergic reactions
- Hepatitis B virus vaccine recombinant/PF (Recombivax HB®):
  - Patient must not have a severe reaction to yeast; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Hepatitis B virus, RCMB/diphtheria, pertussis, tetanus, and polio vaccine (Pediarix®):
  - Patient is 6 weeks through 6 years of age (prior to the 7th birthday); **AND**
  - Patient must be born to a hepatitis B surface antigen (HBsAg) negative mother; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Hepatitis A virus vaccine (Havrix®):
  - Patient is 1 year of age or older; **AND**
  - Patient does not have an allergy to neomycin; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur

CLINICAL CRITERIA FOR INITIAL APPROVAL (IF BENEFIT BUILDER HAS PA REQUIRED) *(CONTINUED)*

- Hepatitis A virus vaccine (Vaqta®):
  - Patient is 12 months of age or older; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Hepatitis A virus and hepatitis B virus vaccine (Twinrix®):
  - Patient is 18 years of age or older; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Rabies vaccine, Human Diploid cell/PF (Imovax):
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Rabies vaccine, purified chicken embryo cell (RabAvert®):
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur; **AND**
  - Immunosuppressive agents should not be administered during postexposure therapy unless essential for the treatment of other conditions
- Poliomyelitis vaccine, killed (Ipol®):
  - Patient is 6 weeks of age or older; **AND**
  - Patient does not have an allergy to neomycin, streptomycin, and polymyxin; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Japanese encephalitis vaccine (Ixiaro®):
  - Patient is 2 months of age or older; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Measles, mumps, rubella vaccine (M-M-R II):
  - Patient is 12 months of age or older; **AND**
  - Patient must not have a severe egg protein allergy; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Measles, mumps, rubella, and varicella vaccine (ProQuad®):
  - Patient is 12 months through 12 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Rotavirus vaccine (Rotarix®):
  - Patient is 6 weeks and up to 24 weeks of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Rotavirus vaccine (RotaTeq®):
  - Patient is 6 weeks to 32 weeks of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Neisseria meningitidis group B (Trumenba®):
  - Patient is 10 years through 25 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Typhoid vaccine (Typhim Vi®):
  - Patient is 2 years of age or older; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur

CLINICAL CRITERIA FOR INITIAL APPROVAL (IF BENEFIT BUILDER HAS PA REQUIRED) *(CONTINUED)*

- Typhoid vaccine (Vivotif® and Vivotif® Berna):
  - Patient is 6 years of age or older; **AND**
  - Patient does not have acute febrile illness; **AND**
  - The patient is not taking sulfonamides and antibiotics; **AND**
  - Must be used in one of the following groups:
    - Travelers to areas in which there is a recognized risk of exposure to *S. typhi*; **OR**
    - Persons with intimate exposure (i.e., household contact) to a *S. typhi* carrier; **OR**
    - Microbiology laboratorians who work frequently with *S. typhi*; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Varicella virus vaccine (Varivax®):
  - Patient is 12 months of age or older; **AND**
  - The patient must not have primary or acquired immunodeficiency state; **AND**
  - The patient must not have febrile illness or active infection including untreated tuberculosis (TB); **AND**
  - The patient must not be pregnant; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Cholera vaccine (Vaxchora®):
  - Patient is 2 years through 64 years of age; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Yellow fever vaccine (YF-Vax® and Stamaril®):
  - Patient is 9 months of age or older; **AND**
  - Patient must not have a severe allergy to egg protein; **AND**
  - The patient must meet one of the following:
    - Patient is living in or traveling to endemic areas; **OR**
    - Patient is traveling internationally through countries with yellow fever; **OR**
    - Laboratory personnel; **AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur
- Zoster vaccine recombinant, adjuvanted (Shingrix®):
  - Patient is 18 years of age or older**; AND**
  - Epinephrine and other appropriate agents are available should an acute anaphylactic reaction occur

VECTIBIX® (PANITUMUMAB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Colorectal Cancer:**

- Patient is at least 18 years of age; **AND**
- Patient is both KRAS and NRAS mutation negative (wild-type) as determined by a Food and Drug Administration (FDA)- or Clinical Laboratory Improvement Amendments (CLIA)-compliant test*; **AND**
- Patient has not been previously treated with cetuximab or panitumumab; **AND**
- Will not be used as part of an adjuvant treatment regimen; **AND**
- Patient has metastatic, unresectable (or medically inoperable), or advanced disease that is BRAF mutation negative (wild-type); **AND**
  - Used as primary therapy; **AND**
    - Used in combination with FOLFOX; **OR**
    - Used in combination with FOLFIRI (Note: Colon cancer patients must have left-sided tumors); **OR**
    - Used in combination with an irinotecan-based regimen after previous adjuvant FOLFOX or CapeOX within the past 12 months; **OR**
  - Used as subsequent therapy; **AND**
    - Used as a single agent for oxaliplatin– and/or irinotecan-refractory disease **or** irinotecan-intolerant disease; **OR**
    - Used in combination with irinotecan for oxaliplatin- and/or irinotecan-refractory disease; **OR**
    - Used in combination with FOLFIRI for oxaliplatin-refractory disease; **OR**
    - Used in combination with FOLFOX for irinotecan-refractory disease; **OR**
- Patient has BRAF V600E mutation positive disease; **AND**
  - Used in combination with encorafenib; **AND**
    - Used as subsequent therapy for disease progression after at least one prior line of treatment in the advanced or metastatic disease setting; **OR**
    - Used as primary treatment for unresectable metastatic disease after previous adjuvant FOLFOX or CapeOX within the past 12 months

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by a stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include dermatologic/soft-tissue toxicity, electrolyte depletion, severe infusion-related reactions, acute renal failure, pulmonary fibrosis/interstitial lung disease (ILD), photosensitivity, keratitis, etc.

VELCADE® (BORTEZOMIB) AND BORTEZOMIB IV

Length of Authorization:	6 months, may be renewed unless otherwise specified. • **Initial treatment for Multiple Myeloma**: Coverage will be provided for a total of 9 cycles (42 days per cycle) • **Re-treatment of Multiple Myeloma, initial treatment of Mantle Cell Lymphoma, and Adult T-Cell Leukemia/Lymphoma**: Coverage will be provided for a total of 8 cycles (21 days per cycle). • **Systemic Light Chain Amyloidosis as a single agent or in combination with cyclophosphamide and/or dexamethasone**: Coverage will be provided for a total of 8 cycles (35 days per cycle as a single agent; 21 or 28 days per cycle in combination with cyclophosphamide and/or dexamethasone). • **Systemic Light Chain Amyloidosis in combination with melphalan and dexamethasone**: Coverage will be provided for a total of 9 cycles (21 days per cycle) • **Systemic Light Chain Amyloidosis in combination with lenalidomide and dexamethasone:** Coverage will be provided for a total of 8 cycles (28-days per cycle). • **Systemic Light Chain Amyloidosis in combination with daratumumab and hyaluronidase-fihj, cyclophosphamide, and dexamethasone:** Coverage will be provided for a total of 2 years. • **Waldenström's Macroglobulinemia in combination with rituximab and/or dexamethasone**: Coverage will be provided for a total of 6 cycles (28 days per cycle) or 8 cycles (21 days per cycle). • **Pediatric Hodgkin Lymphoma:** Coverage will be provided for a total of 4 cycles (21-days per cycle).
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma**

- Patient is at least 18 years of age; **AND**
- Will not be administered intrathecally; **AND**
- Used in combination with a corticosteroid containing regimen as primary therapy for symptomatic disease or for relapse (re-treatment) after 6 months following primary induction therapy with the same regimen; **OR**
- Used as maintenance therapy as a single agent or in combination with lenalidomide; **OR**
- Used for relapsed or progressive disease in combination with a dexamethasone containing regimen; **OR**
- Used in combination with dexamethasone in patients with a confirmed diagnosis of POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Mantle Cell Lymphoma – B-Cell Lymphoma**

- Patient is at least 18 years of age; **AND**
- Will not be administered intrathecally; **AND**
- Used as induction or additional therapy; **AND**
  - Used as a component of VR-CAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, and prednisone); **OR**
- Used as subsequent therapy; **AND**
  - Used as a single agent; **OR**
  - Used in combination with rituximab; **OR**

Diagnosis of **Systemic Light Chain Amyloidosis**

- Patient is at least 18 years of age; **AND**
- Will not be administered intrathecally; **AND**
- Patient has newly diagnosed disease OR used as repeat initial therapy if relapse-free for several years ; **AND**
  - Used in combination with cyclophosphamide and dexamethasone; **OR**
  - Used as a single agent; **OR**
  - Used in combination with dexamethasone with or without melphalan or lenalidomide; **OR**
  - Used in combination with daratumumab and hyaluronidase-fihj, cyclophosphamide, and dexamethasone; **OR**
- Patient has relapsed or refractory disease; **AND**
  - Used as a single agent; **OR**
  - Used in combination with dexamethasone with or without melphalan

Diagnosis of **Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma**

- Patient is at least 18 years of age; **AND**
- Will not be administered intrathecally; **AND**
- Used in combination with dexamethasone and rituximab; **OR**
- Used as a single agent; **OR**
- Used in combination with rituximab; **OR**
- Used in combination with dexamethasone

Diagnosis of **Multicentric Castleman's Disease – B-Cell Lymphoma**

- Patient is at least 18 years of age; **AND**
- Will not be administered intrathecally; **AND**
- Used as subsequent therapy; **AND**
- Patient has progressed following treatment for relapsed/refractory or progressive disease; **AND**
- Used as a single agent or in combination with rituximab

Diagnosis of **Adult T-Cell Leukemia/Lymphoma**

- Patient is at least 18 years of age; **AND**
- Will not be administered intrathecally; **AND**
- Used as a single agent; **AND**
- Used as subsequent therapy for non-responders to first-line therapy for acute disease or lymphoma subtypes

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Pediatric Acute Lymphoblastic Leukemia**

- Will not be administered intrathecally; **AND**
- Patient is at least 1 year of age*: **AND**
  - Patient has relapsed or refractory B-cell disease (B-ALL); **AND**
    - Used as a component of the COG AALL07P1 regimen (bortezomib, vincristine, doxorubicin, pegaspargase, prednisone); **AND**
      - Patient has Philadelphia (Ph) chromosome negative disease; **OR**
      - Used in combination with dasatinib or imatinib for Philadelphia (Ph) chromosome positive disease; **OR**
  - Patient has relapsed or refractory T-cell disease (T-ALL); **AND**
    - Used in combination with a corticosteroid (e.g., prednisone or dexamethasone), vincristine, doxorubicin, and pegaspargase.

***** *Pediatric ALL patients may include certain adolescent and young adult (AYA) patients up to 30 years of age*

Diagnosis of **Kaposi Sarcoma**

- Patient is at least 18 years of age; **AND**
- Will not be administered intrathecally; **AND**
- Used as subsequent therapy for relapsed or refractory disease; **AND**
- Patient has advanced cutaneous, oral, visceral, or nodal disease; **AND**
- Patient has progressed on or not responded to first-line therapy; **AND**
- Patient has progressed on alternate first-line therapy; **AND**
  - Used as a single-agent in patients without human immunodeficiency virus (HIV); **OR**
  - Used in combination with antiretroviral therapy (ART) for patients with HIV

Diagnosis of **Pediatric Hodgkin Lymphoma**

- Will not be administered intrathecally; **AND**
- Patient age is 18 years and under***** **AND**
- Used for relapsed or refractory disease in combination with ifosfamide and vinorelbine

***** *Pediatric Hodgkin Lymphoma patients may include certain adolescent and young adult (AYA) patients up to 39 years of age.*

*NOTE: Bortezomib was approved by the FDA as a 505(b)(2) NDA of the innovator product, Velcade® (bortezomib) for injection, for intravenous use only and thus should **not** be considered therapeutically interchangeable (i.e., not suitable for substitution) for other non-approved indications.*

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., peripheral neuropathy, hypotension, cardiac toxicity, pulmonary toxicity, posterior reversible encephalopathy syndrome [PRES], gastrointestinal toxicity, thrombocytopenia, neutropenia, tumor lysis syndrome, hepatic toxicity, thrombotic microangiopathy)

VENCLEXTA® (VENETOCLAX)

Length of Authorization:	6 months, may be renewed When used for CLL/SLL in combination with rituximab, coverage may be renewed up to a total of 24 months of therapy (from day 1 of cycle 1 of rituximab) When used for CLL/SLL in combination with obinutuzumab, coverage may be renewed up until the end of 12 cycles of obinutuzumab therapy (Venetoclax therapy begins on day 22 of cycle 1 of obinutuzumab)
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**

- Patient is 18 years of age or older; **AND**
- Patient must not receive live attenuated vaccines prior to, during, or after venetoclax treatment until B-cell recovery occurs; **AND**
- Patient will not be on concomitant therapy with moderate or strong CYP3A-inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort)**; AND**
- Patient will not be on concomitant therapy with strong CYP3A-inhibitors (e.g., posaconazole, nefazadone, ritonavir, grapefruit juice, Seville oranges) during initiation and ramp-up phase

Diagnosis of **Acute Myeloid Leukemia (AML)**

- Patient must not receive live attenuated vaccines prior to, during, or after venetoclax treatment until B-cell recovery occurs; **AND**
- Patient will not be on concomitant therapy with moderate or strong CYP3A-inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort)**; AND**
- Patient is at least 60 years old, unable to receive intensive induction therapy due to comorbidities (e.g., PS ≥ 2, moderate hepatic impairment, severe cardiac or pulmonary disease, CL_{CR} < 45 mL/min), or declines intensive therapy; **AND**
  - Used in combination with azacitidine, decitabine, or low-dose cytarabine; **AND**
    - Patient has newly-diagnosed disease; **OR**
    - Used as post-induction therapy following response to previous lower intensity therapy with the same regimen; **OR**
- Patient has relapsed/refractory disease; **AND**
  - Used in combination with the initial successful induction regimen in patients with late relapse (≥ 12 months since induction regimen) if not administered continuously and not stopped due to development of clinical resistance; **OR**
  - Used in combination with azacitidine, decitabine, or low-dose cytarabine

Diagnosis of **Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)**

- Patient is 18 years of age or older; **AND**
- Patient must not receive live attenuated vaccines prior to, during, or after venetoclax treatment until B-cell recovery occurs; **AND**
- Patient will not be on concomitant therapy with moderate or strong CYP3A-inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort)**; AND**
- Used in combination with azacitidine, decitabine, or low-dose cytarabine
  - Patient has relapsed or refractory disease; **OR**
  - Patient has systemic disease with low performance status and/or nutritional status (i.e., serum albumin <3.2 g/dL)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Mantle Cell Lymphoma**

- Patient is 18 years of age or older; **AND**
- Patient must not receive live attenuated vaccines prior to, during, or after venetoclax treatment until B-cell recovery occurs; **AND**
- Patient will not be on concomitant therapy with moderate or strong CYP3A-inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort)**; AND**
- Used as second line or subsequent therapy; **AND**
  - Used as a single agent; **OR**
  - Used in combination with rituximab

Diagnosis of **Multiple Myeloma**

- Patient is 18 years of age or older; **AND**
- Patient must not receive live attenuated vaccines prior to, during, or after venetoclax treatment until B-cell recovery occurs; **AND**
- Patient will not be on concomitant therapy with moderate or strong CYP3A-inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort)**; AND**
- Patient had relapsed or refractory disease with t(11;14) translocation; **AND**
- Used in combination with dexamethasone

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., tumor lysis syndrome, severe neutropenia, severe infection); **AND**
- **Acute Myeloid Leukemia (AML)**
  - Disease stabilization or improvement as evidenced by a complete response [CR] (i.e., morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH.
- **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
    - Venetoclax/rituximab regimen: Patient has not received more than 24 months of therapy; **OR**
    - Venetoclax/obinutuzumab regimen: Patient has not received more than 12 cycles of therapy
- **All other indications**
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

VERQUVO (VERICIGUAT)

Length of Authorization:	1 year
Initiative:	MNC: Antihypertensive Medications (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is ≥ 18 years of age; **AND**
- Patient has a diagnosis of heart failure; **AND**
- Patient's ejection fraction < 45%; **AND**
- Patient meets ≥ 1 of the following criteria; **AND**:
  - Patient has required the use of intravenous diuretics as an outpatient in the past 3 months; **OR**
  - Patient was recently hospitalized for heart failure (within the last 6 months)
- Patient is on guideline-directed therapy for heart failure, unless contraindicated (e.g., beta-blocker, renin-angiotensin system inhibitors (ACE, ARBs, ARNI) and mineralocorticoid receptor antagonists/aldosterone antagonists); **AND**
- Patient is not taking another soluble guanylate cyclase (sGC) stimulator or phosphodiesterase-5 (PDE-5) inhibitor; **AND**
- If patient is of childbearing potential, patient is NOT pregnant AND is using contraception.

CLINICAL CRITERIA FOR RENEWAL

- Patient is ≥ 18 years of age; **AND**
- Patient has a diagnosis of heart failure; **AND**
- Patient's ejection fraction < 45%; **AND**
- Patient is on guideline-directed therapy for heart failure, unless contraindicated (e.g., beta-blocker, renin-angiotensin system inhibitors (ACE, ARBs, ARNI) and mineralocorticoid receptor antagonists/aldosterone antagonists); **AND**
- Patient is not taking another soluble guanylate cyclase (sGC) stimulator or phosphodiesterase-5 (PDE-5) inhibitor; **AND**
- If patient is of childbearing potential, patient is NOT pregnant AND is using contraception; **AND**
- Prescriber attestation that patient is responding positively to treatment (e.g., symptom improvement, slowing of decline); **AND**
- Patient has not experienced treatment-limiting adverse effects (e.g., symptomatic hypotension).

VERZENIO® (ABEMACICLIB)

Length of Authorization:	6 months, may be renewed Adjuvant treatment of early breast cancer can be authorized up to a maximum of two (2) years of therapy.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

CORE FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Standard, Precision/Plus, Core: For new starts only, patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Ibrance®.

Diagnosis of **Breast Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a cyclin-dependent kinase (CDK) 4 and 6 inhibitor (e.g., palbociclib, ribociclib); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with strong and CYP3A inhibitors (e.g., fluconazole, clarithromycin, erythromycin, grapefruit, grapefruit juice); if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with ketoconazole; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
- Patient has hormone receptor (HR)-positive disease; **AND**
  - Used for recurrent, unresectable, advanced, or metastatic disease **or** patient has inflammatory disease with no response to pre-operative systemic therapy; **AND**
    - Patient has no visceral crisis/disease or patient has asymptomatic visceral disease; **AND**
    - Patient is postmenopausal, premenopausal with ovarian ablation/suppression, or male with suppression of testicular steroidogenesis; **AND**
      - Used as initial therapy in combination with a non-steroidal aromatase inhibitor (e.g., anastrozole, letrozole) or fulvestrant; **OR**
      - Used as subsequent therapy in combination with fulvestrant; **OR**
  - Used as a single agent after progression on endocrine therapy and chemotherapy in the metastatic setting ***(no trial of Ibrance required)***; **OR**
  - Used as adjuvant treatment of early breast cancer at high risk of recurrence; **AND**
    - Disease is node-positive; **AND**
    - Patient has a Ki-67 score ≥ 20% as determined by a Food and Drug Administration (FDA)-approved or Clinical Laboratory Improvement Amendments (CLIA)-compliant test; **AND**
    - Used in combination with endocrine therapy (i.e., tamoxifen or an aromatase inhibitor) **(*no trial of Ibrance® required*)**

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: Grade 3 or 4 diarrhea, neutropenia, hepatotoxicity, venous thromboembolism, severe interstitial lung disease/pneumonitis, etc.

Breast Cancer (adjuvant treatment)

- Patient has not exceeded a maximum of 2 years of therapy

ENHANCED FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Breast Cancer**

- Patient is at least 18 years of age; **AND**
- Patient has not received previous therapy with a cyclin-dependent kinase (CDK) 4 and 6 inhibitor (e.g., palbociclib, ribociclib); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with strong and CYP3A inhibitors (e.g., fluconazole, clarithromycin, erythromycin, grapefruit, grapefruit juice); if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with ketoconazole; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
- Patient has hormone receptor (HR)-positive disease; **AND**
  - Used for recurrent, unresectable, advanced, or metastatic disease **or** patient has inflammatory disease with no response to pre-operative systemic therapy; **AND**
    - Patient has no visceral crisis/disease or patient has asymptomatic visceral disease; **AND**
    - Patient is postmenopausal, premenopausal with ovarian ablation/suppression, or male with suppression of testicular steroidogenesis; **AND**
      - Used as initial therapy in combination with a non-steroidal aromatase inhibitor (e.g., anastrozole, letrozole) or fulvestrant; **OR**
      - Used as subsequent therapy in combination with fulvestrant; **OR**
      - Used as a single agent after progression on endocrine therapy and chemotherapy in the metastatic setting; **OR**
  - Used as adjuvant treatment of early breast cancer at high risk of recurrence; **AND**
    - Disease is node-positive; **AND**
    - Patient has a Ki-67 score ≥ 20% as determined by an FDA-approved or CLIA-compliant test; **AND**
    - Used in combination with endocrine therapy (i.e., tamoxifen or an aromatase inhibitor)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: Grade 3 or 4 diarrhea, neutropenia, hepatotoxicity, venous thromboembolism, severe interstitial lung disease/pneumonitis, etc.

Breast Cancer (adjuvant treatment):

- Patient has not exceeded a maximum of 2 years of therapy

VIBERZI® (ELUXADOLINE)

Length of Authorization:	One year
Initiative:	MNC: Miscellaneous (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of irritable bowel syndrome with diarrhea (IBS-D); **AND**

- Patient is 18; **AND**
- Patient does not have any of the following: known or suspected biliary duct obstruction, sphincter of Oddi disease or dysfunction, Alcoholism or alcohol abuse, history of pancreatitis, severe hepatic impairment (Child-Pugh class C), chronic or severe constipation or known/suspected mechanical gastrointestinal obstruction

VIDAZA® (AZACITIDINE)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Myelodysplastic Syndrome (MDS)

- Patient is 18 years of age or older; **AND**
- Patient does not have advanced malignant hepatic tumors; **AND**
- Patient does not have a hypersensitivity to mannitol

Acute Myeloid Leukemia

- Patient is 18 years of age or older; **AND**
- Patient does not have advanced malignant hepatic tumors; **AND**
- Patient does not have a hypersensitivity to mannitol

Myelofibrosis (MF)

- Patient is 18 years of age or older; **AND**
- Patient does not have advanced malignant hepatic tumors; **AND**
- Patient does not have a hypersensitivity to mannitol

Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)

- Patient is 18 years of age or older; **AND**
- Patient does not have advanced malignant hepatic tumors; **AND**
- Patient does not have a hypersensitivity to mannitol; **AND**
- Used for relapsed or refractory disease in combination with venetoclax

MDS/MPN Overlap Neoplasms

- Patient is 18 years of age or older; **AND**
- Patient does not have advanced malignant hepatic tumors; **AND**
- Patient does not have a hypersensitivity to mannitol

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe cytopenias [anemia, neutropenia and thrombocytopenia]; severe hepatic and renal toxicities, tumor lysis syndrome); **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

VILTEPSO® (VILTOLARSEN)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Duchenne muscular dystrophy (DMD)**

- Patient is not on concomitant therapy with other DMD-directed antisense oligonucleotides (e.g., eteplirsen, golodirsen, casimersen); **AND**
- Patient does not have symptomatic cardiomyopathy; **AND**
- Patient serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio (UPCR) are measured prior to starting therapy and periodically during treatment; **AND**
- Patient must have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping; **AND**
- Patient has been on a stable dose of corticosteroids, unless contraindicated or intolerance, for at least 3 months; **AND**
- Patient retains meaningful voluntary motor function (e.g., patient is able to speak, manipulate objects using upper extremities, ambulate); **AND**
- Patient should be receiving physical and/or occupational therapy; **AND**
- Baseline documentation of one or more of the following:
  - Dystrophin level
  - 6-minute walk test (6MWT) or other timed function tests (e.g., time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB])
  - Upper limb function (ULM) test
  - North Star Ambulatory Assessment (NSAA)
  - Forced Vital Capacity (FVC) percent predicted

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: renal toxicity/proteinuria, etc.; **AND**
- Patient has responded to therapy compared to pretreatment baseline in one or more of the following (not all-inclusive):
  - Increase in dystrophin level
  - Stability, improvement, or slowed rate of decline in 6MWT or other timed function tests (e.g., time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB])
  - Stability, improvement, or slowed rate of decline in ULM test
  - Stability, improvement, or slowed rate of decline in NSAA
  - Stability, improvement, or slowed rate of decline in FVC% predicted
  - Improvement in quality of life

VIMIZIM® (ELOSULFASE ALFA)

Length of Authorization:	12 months, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Mucopolysaccharidosis IVA (MPS IVA, Morquio A Syndrome)**

- Patient is 5 years of age or older; **AND**
- Documented diagnosis of Mucopolysaccharidosis IVA with biochemical/genetic confirmation by one of the following:
  - Absence or marked reduction in N-acetylgalactosamine 6-sulfatase (GALNS) enzyme activity; **OR**
  - Detection of biallelic pathogenic mutations in the GALNS gene by genetic molecular testing (i.e., sequence analysis and/or deletion/duplication analysis); **AND**
- Documented baseline value for one or more of the following: endurance tests (e.g., six minute walk test [6-MWT] or timed 25-foot walk test [T25FW], three minute stair climb test [3-MSCT]), and/or pulmonary function tests (e.g., FVC), etc.

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., anaphylaxis and hypersensitivity reactions, acute respiratory complications, spinal/cervical cord compression); **AND**
- Patient has shown a response to therapy as evidenced by one or more of the following markers when compared to pretreatment baseline values:
  - Stability or improvement in six minute walk test (6-MWT), three minute stair climb test (3-MSCT)
  - Stability or improvement in pulmonary function tests

VISUDYNE® (VERTEPORFIN)

Length of Authorization:	1 infusion per eye every 3 months, may be renewed
Initiative:	SPC: Miscellaneous PA Required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Classic Subfoveal Choroidal Neovascularization (CNV)**

- Patient is at least 18 years of age; **AND**
- Must be used with activation process via light from a nonthermal diode laser; **AND**
- Must not be used in combination with any anti-angiogenic agents (e.g., bevacizumab, aflibercept, ranibizumab, pegaptanib, brolucizumab); **AND**
- Patient's condition is associated with one of the following:
  - Neovascular age-related macular degeneration (AMD); **OR**
  - Ocular histoplasmosis; **OR**
  - Pathologic myopia

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment, as indicated by an improvement in lines of visual acuity from baseline and/or reduction in the number of episodes of severe visual acuity loss; **AND**
- Absence of unacceptable toxicity from the drug (e.g., extravasation, decrease in visual acuity)

VITRAKVI® (LAROTRECTINIB)

Length of Authorization:	3 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Solid Tumors with NTRK gene fusion**

- Patient is at least 1 month of age; **AND**
- The healthcare provider must attest that they will comply with the requirements of the Vitrakvi® Commitment Program, including the following:
  - Complete the attestation form for patients who stop taking Vitrakvi® due to a lack of clinical benefit within 90 days of treatment initiation; **AND**
  - Submit the attestation form within 120 days of last prescription fulfilled within the program eligibility period; **AND**
- Will not be used in combination with another *NTRK*-inhibitor (i.e., entrectinib); **AND**
- Patient will avoid concomitant therapy with all the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., itraconazole, indinavir, nefazodone, grapefruit juice), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has infantile fibrosarcoma; **AND**
- Used as single agent therapy; **AND**
  - Tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion or fusion partner in ETV6-NTRK3***** without any known acquired resistance mutations as detected by an FDA-approved or CLIA compliant test; **AND**
  - Patient has metastatic disease or locally advanced disease and is not a candidate for surgery due to the potential of causing severe morbidity; **AND**
  - Patient has no satisfactory alternative treatments or disease has progressed following treatment

  OR
- Patient has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion or fusion partner positive tumor without any known acquired resistance mutation as detected by an FDA-approved or CLIA compliant test; **AND**
- Used as single agent therapy; **AND**
- Patient has one of the following solid tumors:
  - **Breast cancer**
    - Patient has no satisfactory alternative treatments or disease has progressed following treatment; **AND**
      - Patient has recurrent unresectable (local or regional) or stage IV (M1) disease; **OR**
      - Patient has not responded to preoperative systemic therapy

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Solid Tumors with NTRK gene fusion *(Continued)***

- **Central nervous system cancers**
  - Patient has recurrent or progressive low-grade (WHO grade 1 or 2) glioma; **AND**
    - Patient is at least 18 years of age; **AND**
    - Patient has received prior fractionated external beam radiation therapy; **OR**
  - Patient has recurrent anaplastic glioma or glioblastoma; **OR**
  - Patient has brain metastases from NTRK-gene fusion positive tumors as detected by an FDA-approved or CLIA compliant test; **AND**
    - Used as initial treatment in patients with small, asymptomatic brain metastases; **OR**
    - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
    - Patient has recurrent limited brain metastases; **OR**
    - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options
- **Colorectal adenocarcinoma**
  - Used as subsequent therapy for progression of metastatic disease
- **Cutaneous melanoma**
  - Used for unresectable or metastatic disease**; AND**
  - Used as subsequent therapy for disease progression or after maximum clinical benefit from BRAF targeted therapy
- **Gastric adenocarcinoma or esophageal/esophago-gastric junction (GEJ) adenocarcinoma/squamous cell carcinoma**
  - Used palliatively as subsequent therapy; **AND**
  - Patient has unresectable (or is not a surgical candidate) locally advanced, recurrent, or metastatic disease
- **Gastrointestinal Stromal Tumors**
  - Patient has unresectable, recurrent, or metastatic disease; **AND**
  - Disease has progressed after single-agent treatment with each of the following: imatinib, sunitinib, regorafenib, and ripretinib
- **Head and neck cancer**
  - Patient has salivary gland tumors; **AND**
  - Used for one of the following:
    - Recurrent disease with distant metastases; **OR**
    - Unresectable locoregional recurrence with prior radiation therapy (RT); **OR**
    - Unresectable second primary with prior RT

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Solid Tumors with NTRK gene fusion *(Continued)***

- **Hepatobillary cancer**
  - Patient has gallbladder cancer or cholangiocarcinoma (Intra/Extra – hepatic); **AND**
    - Patient has unresectable or metastatic disease; **OR**
  - Patient has hepatocellular carcinoma; **AND**
    - Used as subsequent treatment for progressive disease; **AND**
      - Patient has unresectable disease and is not a transplant candidate; **OR**
      - Patient has metastatic disease or extensive liver tumor burden; **OR**
      - Patient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease
- **Histiocytic Neoplasms – Langerhans Cell Histiocytosis (LCH)**
  - Patient has multisystem LCH with symptomatic or impending organ dysfunction; **OR**
  - Patient has pulmonary LCH; **OR**
  - Patient has multifocal single system bone disease not responsive to treatment with a bisphosphonate and > 2 lesions; **OR**
  - Patient has CNS lesion; **OR**
  - Patient has relapsed/refractory disease
- **Histiocytic Neoplasms – Erdheim-Chester Disease (ECD)**
  - Patient has symptomatic or relapsed/refractory disease
- **Histiocytic Neoplasms – Rosai-Dorfman Disease**
  - Patient has symptomatic unresectable unifocal disease; **OR**
  - Patient has symptomatic multifocal disease; **OR**
  - Patient has relapsed/refractory disease
- **Non-small cell lung cancer**
  - Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first line therapy OR as subsequent therapy following progression on first-line systemic therapy in patients who did not receive an NTRK1/2/3-targeted regimen in a previous line of therapy
- **Ovarian cancer (Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer)**
  - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **AND**
  - Patient has persistent, relapsed, or recurrent disease
- **Pancreatic adenocarcinoma**
  - Used as first-line therapy for metastatic disease in patients with poor performance status; **OR**
  - Used as subsequent therapy for locally advanced, metastatic, or recurrent disease
- **Small bowel adenocarcinoma/Advanced Ampullary Cancer**
  - Used as subsequent therapy for metastatic disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Solid Tumors with NTRK gene fusion *(Continued)***

- **Soft tissue sarcoma**
  - Will not be used as pre-operative or adjuvant therapy for non-metastatic disease; **AND**
    - Used for solitary fibrous tumors; **OR**
    - Used as first-line therapy for one of the following:
      - Advanced, unresectable, recurrent, or metastatic disease of the extremity/body wall/head-neck
      - Advanced, unresectable, or metastatic disease or post-operatively for sarcoma of the retroperitoneal or intra-abdominal area
- **Thyroid carcinoma**
  - Patient has follicular, Hürthle cell, or Papillary carcinoma; **AND**
    - Patient has unresectable locoregional recurrent or persistent disease OR metastatic disease; **AND**
    - Disease is not susceptible to radioactive iodine (RAI) therapy; **OR**
  - Patient anaplastic carcinoma; **AND**
    - Patient has metastatic disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe neurotoxicity, hepatotoxicity, etc.; **AND**
- Provider attests that the patient is receiving clinical benefit from therapy (refer to the above regarding Vitrakvi® commitment program requirements)

VIZIMPRO® (DACOMITINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer**

- Patient is at least 18 years of age; **AND**
- Patient will avoid coadministration with proton-pump inhibitors (PPIs), or if acid-reduction therapy is required, use of H2-receptor antagonists or antacids may be used at staggered administration times; **AND**
- Used as single-agent therapy; **AND**
- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Patient's tumor is EGFR mutation positive with exon 19 deletion or exon 21 L858R substitution mutations as confirmed by an FDA-approved or CLIA-compliant test; **AND**
  - Used as first-line therapy; **OR**
  - Used as continuation therapy following disease progression on dacomitinib for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions, or symptomatic systemic limited metastases

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: interstitial lung disease, severe/persistent diarrhea, and dermatologic adverse reactions (e.g., rash, exfoliative skin reactions), etc.

VOTRIENT® (PAZOPANIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Renal Cell Carcinoma**

- Patient is at least 18 years of age; **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment in patients at risk of cardiac dysfunction including prior anthracycline exposure; **AND**
- Patient has not had hemoptysis, cerebral hemorrhage, or clinically significant gastrointestinal hemorrhage within the prior 6 months; **AND**
- Patient has not had an arterial thromboembolic event within the previous 6 months; **AND**
- Patient will have an electrocardiogram (ECG) at baseline and will be assessed periodically during therapy; **AND**
- Used as single-agent therapy; **AND**
- Patient will avoid concomitant therapy all the following:
  - Coadministration with acid-reducing agents (e.g., proton-pump inhibitors, H2 receptor antagonists) or if therapy is required, consider short-acting antacids instead; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration of strong P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (e.g., ketoconazole, imatinib, HIV protease inhibitors) or if therapy is required, an alternative product should be considered; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration simvastatin or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used as single-agent therapy; **AND**
- Patient has advanced disease; **OR**
- Patient has relapsed or stage IV disease; **AND**
  - Used as first line or subsequent therapy for clear cell histology; **OR**
  - Used as systemic therapy for non-clear cell histology

Diagnosis of **Soft Tissue Sarcoma**

- Patient is at least 18 years of age; **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment in patients at risk of cardiac dysfunction including prior anthracycline exposure; **AND**
- Patient has not had hemoptysis, cerebral hemorrhage, or clinically significant gastrointestinal hemorrhage within the prior 6 months; **AND**
- Patient has not had an arterial thromboembolic event within the previous 6 months; **AND**
- Patient will have an electrocardiogram (ECG) at baseline and will be assessed periodically during therapy; **AND**
- Used as single-agent therapy; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Soft Tissue Sarcoma** *(Continued)*

- Patient will avoid concomitant therapy all the following:
  - Coadministration with acid-reducing agents (e.g., proton-pump inhibitors, H2 receptor antagonists) or if therapy is required, consider short-acting antacids instead; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration of strong P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (e.g., ketoconazole, imatinib, HIV protease inhibitors) or if therapy is required, an alternative product should be considered; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration simvastatin or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has advanced disease; **AND**
  - Patient must have received prior chemotherapy; **AND**
  - Patient does **not** have adipocytic disease; **OR**
- Used for one of the following:
  - Angiosarcoma
  - Retroperitoneal/intra-abdominal
    - Patient has advanced, unresectable, or metastatic disease; **AND**
      - Used in patients not eligible for intravenous (IV) chemotherapy as first-line or post-operative treatment; **OR**
    - Patient has recurrent unresectable or metastatic disease; **AND**
      - Used palliatively as subsequent lines of therapy in patients with non-adipocytic disease
  - Desmoid Tumors (Aggressive Fibromatosis)
    - Timeframe for a treatment response is more critical; **AND**
    - Used as primary treatment or for treatment of gross residual disease (R2 resection) in abdominal wall tumors; **AND**
      - Patient has ongoing progression with potential morbidity or significant symptoms in anatomic location where progression would not be morbid; **OR**
      - Patient has documented progression in anatomic location where progression would be morbid; **OR**
      - Patient has no documented progression in anatomic location where progression would be morbid but there are concerns for morbidity or significant symptoms
  - Rhabdomyosarcoma
    - Used for advanced or metastatic pleomorphic disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Soft Tissue Sarcoma** *(Continued)*

- Extremity/Body Wall, Head/Neck
  - Patient has advanced, metastatic, unresectable, or recurrent disease; **AND**
    - Used as first-line treatment in patients not eligible for intravenous (IV) chemotherapy; **OR**
  - Patient has advanced or metastatic disease; **AND**
    - Used palliatively as subsequent lines of therapy in patients with non-adipocytic disease
- Alveolar soft part sarcoma (ASPS)
- Solitary fibrous tumor

Diagnosis of **Chondrosarcoma**

- Patient is at least 18 years of age; **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment in patients at risk of cardiac dysfunction including prior anthracycline exposure; **AND**
- Patient has not had hemoptysis, cerebral hemorrhage, or clinically significant gastrointestinal hemorrhage within the prior 6 months; **AND**
- Patient has not had an arterial thromboembolic event within the previous 6 months; **AND**
- Patient will have an electrocardiogram (ECG) at baseline and will be assessed periodically during therapy; **AND**
- Used as single-agent therapy; **AND**
- Patient will avoid concomitant therapy all the following:
  - Coadministration with acid-reducing agents (e.g., proton-pump inhibitors, H2 receptor antagonists) or if therapy is required, consider short-acting antacids instead; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration of strong P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (e.g., ketoconazole, imatinib, HIV protease inhibitors) or if therapy is required, an alternative product should be considered; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration simvastatin or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has metastatic and widespread disease; **AND**
  - Patient has metastatic disease at presentation; **OR**
  - Patient has systemic recurrence of high grade (grade II or III), clear cell, or extracompartmental disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Gastrointestinal Stromal Tumors (GIST)**

- Patient is at least 18 years of age; **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment in patients at risk of cardiac dysfunction including prior anthracycline exposure; **AND**
- Patient has not had hemoptysis, cerebral hemorrhage, or clinically significant gastrointestinal hemorrhage within the prior 6 months; **AND**
- Patient has not had an arterial thromboembolic event within the previous 6 months; **AND**
- Patient will have an electrocardiogram (ECG) at baseline and will be assessed periodically during therapy; **AND**
- Used as single-agent therapy; **AND**
- Patient will avoid concomitant therapy all the following:
  - Coadministration with acid-reducing agents (e.g., proton-pump inhibitors, H2 receptor antagonists) or if therapy is required, consider short-acting antacids instead; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration of strong P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (e.g., ketoconazole, imatinib, HIV protease inhibitors) or if therapy is required, an alternative product should be considered; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration simvastatin or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has unresectable, recurrent, or metastatic disease; **AND**
- Disease has progressed after single-agent treatment with each of the following: imatinib, sunitinib, regorafenib, and ripretinib

Diagnosis of **Uterine Sarcoma**

- Patient is at least 18 years of age; **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment in patients at risk of cardiac dysfunction including prior anthracycline exposure; **AND**
- Patient has not had hemoptysis, cerebral hemorrhage, or clinically significant gastrointestinal hemorrhage within the prior 6 months; **AND**
- Patient has not had an arterial thromboembolic event within the previous 6 months; **AND**
- Patient will have an electrocardiogram (ECG) at baseline and will be assessed periodically during therapy; **AND**
- Used as single-agent therapy; **AND**
- Patient will avoid concomitant therapy all the following:
  - Coadministration with acid-reducing agents (e.g., proton-pump inhibitors, H2 receptor antagonists) or if therapy is required, consider short-acting antacids instead; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Uterine Sarcoma *(Continued)***

- Coadministration of strong P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (e.g., ketoconazole, imatinib, HIV protease inhibitors) or if therapy is required, an alternative product should be considered; **AND**
- Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Coadministration simvastatin or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**

- Patient has a diagnosis of high-grade endometrial stromal sarcoma (ESS), undifferentiated uterine sarcoma (UUS), or uterine leiomyosarcoma (uLMS); **AND**
- Patient has recurrent or metastatic disease that has progressed following prior cytotoxic chemotherapy

Diagnosis of **Thyroid Carcinoma**

- Patient is at least 18 years of age; **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment in patients at risk of cardiac dysfunction including prior anthracycline exposure; **AND**
- Patient has not had hemoptysis, cerebral hemorrhage, or clinically significant gastrointestinal hemorrhage within the prior 6 months; **AND**
- Patient has not had an arterial thromboembolic event within the previous 6 months; **AND**
- Patient will have an electrocardiogram (ECG) at baseline and will be assessed periodically during therapy; **AND**
- Used as single-agent therapy; **AND**
- Patient will avoid concomitant therapy all the following:
  - Coadministration with acid-reducing agents (e.g., proton-pump inhibitors, H2 receptor antagonists) or if therapy is required, consider short-acting antacids instead; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, indinavir, nefazodone), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration of strong P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (e.g., ketoconazole, imatinib, HIV protease inhibitors) or if therapy is required, an alternative product should be considered; **AND**
  - Coadministration with drugs that prolong QT/QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration simvastatin or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has medullary carcinoma; **AND**
  - Patient has recurrent or persistent distant metastatic disease; **AND**
  - Disease is symptomatic or progressive; **AND**
    - Treatment with clinical trials, vandetanib, or cabozantinib are not available or appropriate; **OR**
    - Disease progressed on vandetanib or cabozantinib; **OR**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Thyroid Carcinoma *(Continued)***

- Patient has follicular, Hürthle cell, or papillary carcinoma; **AND**
  - Patient has unresectable locoregional recurrent or persistent disease OR metastatic disease; **AND**
  - Treatment with clinical trials or other systemic therapies are not available or appropriate; **AND**
  - Patient has progressive and/or symptomatic disease that is not susceptible to radioactive iodine (RAI) therapy

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hepatotoxicity (severe changes in liver function tests), QT prolongation and Torsades de Pointes, cardiac dysfunction (e.g., decreased LVEF, congestive heart failure), hemorrhagic events, arterial thromboembolic events, venous thrombotic events (e.g., venous thrombosis, pulmonary embolus), thrombotic microangiopathy, gastrointestinal perforation/fistula, severe proteinuria/nephrotic syndrome, interstitial lung disease (ILD)/pneumonitis, reversible posterior leukoencephalopathy syndrome (RPLS), hypertension, impaired wound healing, hypothyroidism, infection, tumor lysis syndrome (TLS), etc.

VPRIV® (VELAGLUCERASE ALFA)

Length of Authorization:	12 months, may be renewed
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Type 1 Gaucher Disease**

- Patient age at least 4 years or older; **AND**
- Must be used as a single agent; **AND**
- Patient has a documented diagnosis of Type 1 Gaucher Disease as confirmed by beta-glucosidase leukocyte (BGL) test with significantly reduced or absent glucocerebrosidase enzyme activity; **AND**
- **Adults only (i.e., patients at least 18 years or older) –** Patient's disease results in one or more of the following:
  - Anemia (i.e., hemoglobin less than or equal to 11 g/dL [women] or 12 g/dL [men]) not attributed to iron, folic acid, or vitamin B12 deficiency **OR**
  - Moderate to severe hepatomegaly (liver size 1.25 or more times normal) **or** splenomegaly (spleen size 5 or more times normal); **OR**
  - Skeletal disease (e.g., lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis); **OR**
  - Symptomatic disease (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life); **OR**
  - Thrombocytopenia (platelet count less than or equal to 120,000/mm^3)

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by one or more of the following (compared to pre-treatment baseline):
  - Improvement in symptoms (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life)
  - Reduction in size of liver or spleen
  - Improvement in hemoglobin/anemia
  - Improvement in skeletal disease (e.g., increase in lumbar spine and/or femoral neck BMD, no bone crises or bone fractures)
  - Improvement in platelet counts; AND
- Absence of unacceptable toxicity from the drug (e.g., hypersensitivity reactions)

VYEPTI™ (EPTINEZUMAB-JJMR)

Length of Authorization:	Initial: 6 months, renewal: 12 months
Initiative:	SPC: Miscellaneous: PA required (IE 2462/ NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Preventative Treatment of Migraines:

- Patient must be 18 years or older; **AND**
- Other causes of headaches have been ruled out; **AND**
- Not used in combination with other calcitonin gene-related peptide (CGRP) antagonists indicated for prophylaxis (Note: use with CGRP therapies indicated for acute use is allowed); **AND**
- Patient is not on concurrent treatment with a botulinum toxin (e.g., abobotulinumtoxinA, incobotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient will continue to utilize prophylactic intervention modalities (e.g., pharmacotherapy, behavioral therapy, physical therapy); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Headache Impact Test [HIT]; monthly headache day [MHD]; Migraine Disability Assessment [MIDAS]; Migraine Physical Function Impact Diary [MPFID]); **AND**
- Patient has failed at least an 8-week trial of any two oral medications for the prevention of migraines (see list of prophylactic medications below for examples) prior to initiation of eptinezumab; **AND**
- Patient has a diagnosis of **chronic** migraines defined as 15 or more headache (tension-type-like and/or migraine-like) days per month for at least 3 months*; **AND**
  - Patient has had at least five attacks with features consistent with migraine (with and/or without aura)§; **AND**
  - On at least 8 days per month for at least 3 months:
    - Headaches have characteristics and symptoms consistent with migraine§; **OR**
    - Patient suspected migraines are relieved by a triptan or ergot derivative medication; **AND**
  - Patient had an inadequate response (or unable to tolerate) a minimum trial of at least two doses of a botulinum toxin; **OR**
- Patient has a diagnosis of frequent episodic migraines defined as at least 5 headache attacks lasting 4–72 hours (when untreated or unsuccessfully treated)*; **AND**
  - Headaches have characteristics and symptoms consistent with migraine without aura§; **AND**
  - Medication overuse headache has been ruled out by trial and failure of titrating off acute migraine treatments in the past

***Note**: Patients new to therapy must initiate treatment at the lower dosing regimen of the 100 mg dose before increasing to the subsequent 200 mg dose or 300 mg dose, if required.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Migraine-Prophylaxis Oral Medications *(list not all-inclusive)*
• Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline) • Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol) • Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan) • Anti-epileptics (e.g., divalproex, valproate, topiramate) • Calcium channels blockers (e.g., verapamil)
§Migraine Features
Migraine without aura • At least five attacks have the following: – Headache attacks lasting 4–72 hours (untreated or unsuccessfully treated) – Headache has at least two of the following characteristics: • Unilateral location • Pulsating quality • Moderate or severe pain intensity • Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs); **AND** – During headache at least one of the following symptoms: • Nausea and/or vomiting • Photophobia and phonophobia
Migraine with aura • At least two attacks have the following: – One or more of the following fully reversible aura symptoms: • Visual • Sensory • Speech and/or language • Motor • Brainstem • Retinal; **AND** – At least two of the following characteristics: • At least one aura symptom spreads gradually over ≥ 5 minutes, and/or two or more symptoms occur in succession • Each individual aura symptom lasts 5 to 60 minutes • At least one aura symptom is unilateral • The aura is accompanied, or followed within 60 minutes, by headache

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions); **AND**
- Disease response as evidenced by the following:
  - Reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline; **OR**
  - A clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures:
    - Reduction of ≥ 5 points when baseline score is 11–20 **or** Reduction of ≥ 30% when baseline scores > 20 in the MIDAS scores; **OR**
    - Reduction of ≥ 5 points in the MPFID score; **OR**
    - Reduction of ≥ 5 points in the HIT-6 score; **AND**
  - Dose escalation* (up to the maximum dose and frequency specified below) may occur upon clinical review on a case by case basis provided that the patient has:
    - Shown an initial improvement or response to therapy, as described above; **AND**
    - Had subsequent loss of response or no net decrease in frequency of headaches; **AND**
    - Received a minimum of two doses at the next stepped dose and interval specified below

  ***Note:** Patient must have a trial of 200 mg prior to escalating to the maximum dose of 300 mg

VYLEESI® (BREMELANOTIDE)

Length of Authorization:	8 weeks, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **acquired, generalized hypoactive sexual desire disorder (HSDD)**

- Patient is a premenopausal woman; **AND**
- Patient must be ≥ 18 years old; **AND**
- Has had HSDD associated symptoms for at least 6 months duration; **AND**
- Patient is not pregnant, as confirmed by a negative pregnancy test; **AND**
- Patient is using contraception; **AND**
- Patient is not postmenopausal; **AND**
- Patient is not diagnosed with cardiovascular disease; **AND**
- Patient does not have uncontrolled hypertension; **AND**
- HSDD is not due to a co-existing medical or psychiatric condition; **AND**
- HSDD is not due to problems with the relationship; **AND**
- HSDD is not due to the effects of a medication or drug substance; **AND**
- Prescriber attestation that HSDD causes marked distress or interpersonal difficult; **AND**
- Patient is not taking oral naltrexone-containing product.

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet the above criteria; **AND**
- Patient must have symptom improvement within 8 weeks; **AND**
- Patient has not experienced any treatment-restricting adverse effects (e.g., cardiovascular complications, uncontrolled hypertension, nausea/vomiting, focal hyperpigmentation)

VYNDAMAX™ (TAFAMIDIS)/VYNDAQEL® (TAFAMIDIS MEGLUMINE)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cardiomyopathy of Wild Type Transthyretin-Mediated Amyloidosis (ATTR-CM)**

- Patient must be at least 18 years old; **AND**
- Therapy must not be used in combination with other transthyretin (TTR) reducing agents (e.g., inotersen, patisiran, etc.); **AND**
- Patient has New York Heart Association (NYHA) class I or II heart failure (i.e., excludes patients with NYHA Class III and IV disease); **AND**
- Patient does not have primary (light chain) amyloidosis; **AND**
- Patient has not had a prior liver transplant; **AND**
- Patient does not have an implanted cardiac mechanical-assist device (e.g., left-ventricular assist device, etc.); **AN**D
- Patient has evidence of cardiac involvement by echocardiography with an end-diastolic interventricular septal wall thickness > 12 mm; **AND**
- Patient has a definitive diagnosis of ATTR amyloidosis as documented by amyloid deposition on tissue biopsy and identification of a pathogenic *TTR* variant and/or TTR precursor using molecular genetic testing (i.e., immunohistochemistry, scintigraphy or mass spectrometry); **AND**
  - Patient has a medical of heart failure which required at least 1 prior hospitalization; **OR**
  - Patient has clinical evidence of heart failure, without a prior history of hospitalization for disease, manifested by signs or symptoms of volume overload or elevated intracardiac pressure (e.g., elevated jugular venous pressure, shortness of breath or signs of pulmonary congestion on x-ray or auscultation, peripheral edema) which requires/required treatment with a diuretic; **AND**
- Patient has a baseline 6-minute walk-test distance exceeding 100 m

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug; **AND**
- Disease response with treatment as evidenced by one or more of the following
  - Decreased frequency of cardiovascular-related hospitalizations compared to pre-treatment baseline
  - Improvement in the total distance walked during 6-minute walk test (6MWT) compared to pre-treatment baseline

VYONDYS-53™ (GOLODIRSEN)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Miscellaneous: PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Duchenne Muscular Dystrophy (DMD)**

- Patient is not on concomitant therapy with other DMD-directed antisense oligonucleotides (e.g., eteplirsen, casimersen, viltolarsen); **AND**
- Patient serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio (UPCR) are measured prior to starting therapy and periodically during treatment; **AND**
- Patient had an inadequate response or has a contraindication or intolerance to viltolarsen; **AND**
- Patient must have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping; **AND**
- Patient has been on a stable dose of corticosteroids, unless contraindicated or intolerance, for at least 6 months; **AND**
- Patient retains meaningful voluntary motor function (e.g., patient is able to speak, manipulate objects using upper extremities, ambulate); **AND**
- Patient should be receiving physical and/or occupational therapy; **AND**
- Baseline documentation of one or more of the following:
  - Dystrophin level
  - 6-minute walk test (6MWT) or other timed function tests (e.g., time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB])
  - Upper limb function (ULM) test
  - North Star Ambulatory Assessment (NSAA)
  - Forced Vital Capacity (FVC) percent predicted

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: renal toxicity/proteinuria, etc.; **AND**
- Patient has responded to therapy compared to pretreatment baseline in one or more of the following (not all-inclusive):
  - Increase in dystrophin level
  - Stability, improvement, or slowed rate of decline in 6MWT or other timed function tests (e.g., time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB])
  - Stability, improvement, or slowed rate of decline in ULM test
  - Stability, improvement, or slowed rate of decline in NSAA
  - Stability, improvement, or slowed rate of decline in FVC% predicted
  - Improvement in quality of life

VYXEOS® (DAUNORUBICIN AND CYTARABINE) LIPSOME

Length of Authorization:	Coverage will be provided for a maximum of 2 cycles of induction (5 doses total) and 2 cycles of consolidation (4 doses total) within 6 months. Coverage may not be renewed.
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Acute Myeloid Leukemia (AML)**

- Patient is at least 18 years of age; **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits and will be reassessed prior to consolidation and as clinically required; **AND**
- Cumulative lifetime anthracycline (e.g., daunorubicin) dose does not exceed 550 mg/m^2 (or 400 mg/m^2 in patients who received radiation to the mediastinum); **AND**
- Will not be used in combination with other chemotherapy; **AND**
- Patient has one of the following sub-types of disease
  - Therapy-related acute myeloid leukemia (t-AML)
  - AML with myelodysplasia-related changes (AML-MRC)
  - Antecedent myelodysplastic syndrome/chronic myelomonocytic leukemia (antecedent MDS/CMML)
- Used for one of the following:
  - Patient is at least 1 year of age with newly diagnosed disease (*Note: For antecedent MDS/CMML, use is only allowed in patients age ≥ 60 years of age that are candidates for intensive remission induction therapy*); **OR**
  - Used as re-induction therapy after standard-dose cytarabine induction therapy; **AND**
    - Patients ≥ 60 years of age with residual disease; **OR**
    - Patients < 60 years of age with significant residual disease in the absence of a hypocellular marrow and core binding factor (CBF) abnormalities; **OR**
  - Used as post-remission therapy; **AND**
    - Patients ≥ 60 years of age with complete response to previous intensive therapy; **OR**
    - Patients < 60 years of age with treatment-related disease other than core binding factor (CBF) and/or unfavorable cytogenetics and/or molecular abnormalities

CLINICAL CRITERIA FOR RENEWAL

- Authorizations may not be renewed

WAKIX® (PITOLISANT)

Length of Authorization:	3 months, may be renewed
Initiative:	SPC: Narcolepsy Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Excessive Daytime Sleepiness (EDS) in Narcolepsy**

- Patient is 18 years of age or older; **AND**
- Patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with drugs that prolong the QT interval (e.g., quinidine, procainamide, disopyramide, amiodarone, sotalol, ziprasidone, chlorpromazine, thioridazine, moxifloxacin); **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, bupropion), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with centrally acting histamine-1 (H1) receptor antagonists (e.g., pheniramine maleate, diphenhydramine, promethazine, imipramine, clomipramine, mirtazapine)
- Patient does not have a history of prolonged QTc interval (i.e., QTc interval > 450 milliseconds); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh C); **AND**
- Patient does not have end stage renal disease (ESRD) (i.e., eGFR < 15 mL/minute/1.73 m^2); **AND**
- Patient does **not** have cataplexy; **AND**
- Patient has documented baseline daytime sleepiness as measured by a validated scale (e.g., Epworth Sleepiness Scale [ESS], Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or Visual Analog Scale); **AND**
- Patient has a mean sleep latency of ≤ 8 minutes **and** two or more sleep-onset rapid eye movement periods (SOREMPs) on a multiple sleep latency test (MSLT) performed according to standard techniques; **AND**
- **Note**: A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram (PSG) may replace one of the SOREMPs on the MSLT.
- Patient has a cerebral spinal fluid (CSF) hypocretin-1 concentration (measured by immunoreactivity) > 110 pg/mL **or** > 1/3 of mean values obtained in normal subjects with the same standardized assay **or** CSF hypocretin-1 concentration has not been measured; **AND**
- The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal**; AND**
- One of the following:
  - Patient has had a trial and failure, contraindication, or intolerance to one of the following:
    - Generic modafinil or generic armodafinil
    - Sunosi™
    - Generic amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate-based stimulant; **OR**
  - Patient has a history of or potential for a substance abuse disorder.

CLINICAL CRITERIA FOR INITIAL APPROVAL (*CONTINUED*)

Diagnosis of **Cataplexy in Narcolepsy**

- Patient is 18 years of age or older; **AND**
- Patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with drugs that prolong the QT interval (e.g., quinidine, procainamide, disopyramide, amiodarone, sotalol, ziprasidone, chlorpromazine, thioridazine, moxifloxacin); **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, bupropion), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with centrally acting histamine-1 (H1) receptor antagonists (e.g., pheniramine maleate, diphenhydramine, promethazine, imipramine, clomipramine, mirtazapine)
- Patient does not have a history of prolonged QTc interval (i.e., QTc interval > 450 milliseconds); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh C); **AND**
- Patient does not have end stage renal disease (ESRD) (i.e., eGFR < 15 mL/minute/1.73 m^2); **AND**
- Patient has cataplexy (i.e., sudden and transient loss of some or all muscle tone in which consciousness is maintained); **AND**
- Patient has documented baseline frequency of cataplexy attacks; **AND**
- Patient has the presence of at least one of the following:
  - A mean sleep latency of ≤ 8 minutes **and** two or more sleep-onset rapid eye movement periods (SOREMPs) on a multiple sleep latency test (MSLT) performed according to standard techniques; **AND**

    Note: A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram (PSG) may replace one of the SOREMPs on the MSLT
  - A cerebral spinal fluid (CSF) hypocretin-1 concentration (measured by immunoreactivity) ≤ 110 pg/mL **or** < 1/3 of mean values obtained in normal subjects with the same standardized assay

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., QT interval prolongation); **AND**

For Cataplexy in Narcolepsy:

- Response to treatment as defined by a reduced frequency of cataplexy attacks from pre-treatment baseline

For Excessive Daytime Sleepiness:

- Response to treatment as defined by a reduction in excessive daytime sleepiness from pre-treatment baseline as measured by a validated scale (e.g., Epworth Sleepiness Scale [ESS], Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale)

WEIGHT LOSS AGENTS

Length of Authorization:	12 weeks, may be renewed Saxenda: 16 weeks, may be renewed Wegovy: Initial: 6 months; Renewal: 12 months
Initiative:	MNC: Weight Loss Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

BELVIQ®, BELVIQ® XR, CONTRAVE®, QSYMIA® (QYSMIA® FALLS UNDER ANOREXIANT IN CRM; ALL OTHERS UNDER ANTI-OBESITY)

Diagnosis of **Obesity**

- Patient was counseled on diet, lifestyle, and goals for weight loss; **AND**
- Patient has had progressive weight gain; **AND**
- Patient has not achieved clinical improvement in weight related complications on lifestyle alone (i.e., less than 5 percent below baseline at 3 to 6 months); **AND**
- Patients of childbearing age must not be pregnant; **AND**
- For Qsymia® only: must provide documentation of a negative pregnancy test; **AND**
- Document current weight and body mass index (BMI) and date obtained; **AND**
- Patient has documented BMI of at least 30 kg/m^2 (no other risk factors required); **OR**
- Patient has documented BMI of at least 27 kg/m^2 **with** one of the following risk factors:
  - Hypertension; **OR**
  - Diabetes (type 1 or 2); **OR**
  - Dyslipidemia; **OR**
  - For patients with a BMI > 27 kg/m^2 who are experiencing weight **regain** following initial success on lifestyle therapy alone.
- ***In addition to the above clinical criteria:***
  - ***For Contrave®, patient must have a trial of Qysmia®***

SAXENDA® (FALLS UNDER ANTI-OBESITY IN CRM)

- Patient must be 12 years of age, **AND**
- Patients of childbearing age must not be pregnant; **AND**
- Must be an adjunct to a reduced calorie diet and increase physical activity for chronic weight management, **AND**
- Document current weight and BMI and date obtained; **AND**
- Adult patients must have an initial BMI of:
  - 30 kg/m^2 or greater (obese), **OR**
  - 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes, or dyslipidemia); **OR**
- Pediatric patients must have:
  - a body weight above 60 kg, **AND**
  - an initial BMI corresponding to 30 kg/m^2 for adults (obese) by international cut-offs

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

BENZPHETAMINE, DIETHYLPROPION, PHENDIMETRAZINE, PHENTERMINE (ALL FALL UNDER ANOREXIANTS IN CRM)

- The patient does **not** have any current or history of the following indications:
  - Cardiovascular disease, hyperthyroidism, glaucoma, monoamine oxidase (MAO) inhibitor therapy, agitated states, pregnancy, breast feeding, heart disease, poorly controlled hypertension, pulmonary hypertension, or history of addiction or drug abuse; **AND**
- Patient has documented BMI of at least 30 kg/m^2 (no other risk factors required); **OR**
- Patient has documented BMI of at least 27 kg/m^2 **with** one of the following risk factors:
  - Hypertension; **OR**
  - Diabetes (type 1 or 2); **OR**
  - Dyslipidemia; **AND**

XENICAL (FALLS UNDER ANTI-OBESITY IN CRM)

- BMI > 30 without risk factors or a BMI > 27 with risk factors such as hypertension, diabetes, dyslipidemia, hyperinsulinemia
- Patient is on a reduced fat and caloric diet (1,800 calories or less) with nutritional counseling regarding adherence to dietary guidelines. This must be confirmed with faxed chart notes.
- Document the date the patient was last seen and the current weight.

CLINICAL CRITERIA FOR RENEWAL

- 1st renewal: The patient has had weight loss since baseline weight
- 2nd renewal (6 months of therapy or longer): patient has had weight loss of 5% or more from baseline weight.
  Note: If weight loss does not achieve 5 percent or more in six months with one of these agents, it should be discontinued, and another agent tried (if deemed appropriate)
- Subsequent renewals: Patient continues to achieve weight loss of at least 5 percent or more from **baseline** weight

WEGOVY

INITIAL CRITERIA

- Patient must be 18 years of age; **AND**
- Must be an adjunct to a reduced calorie diet and increased physical activity for chronic weight management, **AND**
- Document current weight and BMI and date obtained; **AND**
- Patients must have an initial body mass index (BMI) of:
  - 30 kg/m^2 or greater (obese), **OR**
  - 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes, or dyslipidemia); **AND**
- Patient is not taking another GLP-1 receptor agonist; **AND**
- Patient does not have any of the following: a personal or family history of medullary thyroid carcinoma (MTC), Multiple Endocrine Neoplasia syndrome type 2, or a history of pancreatitis; **AND**
- Patients of childbearing age must not be pregnant.

RENEWAL CRITERIA

- Patient has lost at least 5% of baseline body weight; **AND**
- Patient has achieved dose titration to 2.4 mg once weekly.

  Notes:
  - During escalation: consider delaying dose escalation for 4 weeks.
  - With 2.4 mg maintenance dose: Can temporarily decrease to 1.7 mg once weekly, for a max. of 4 weeks. After 4 weeks, the dose should be increased to 2.4 mg. Discontinue if the patient cannot tolerate the 2.4 mg dose.

WELIREG™ (BELZUTIFAN)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Von Hippel-Lindau Disease (VHL)**

- Patient is 18 years of age or older; **AND**
- Women of child-bearing age must have a confirmed negative pregnancy test prior to therapy; **AND**
- Women of child-bearing age must be using effective NON-hormonal contraception during treatment; **OR**
  - Men with female partners of child-bearing age must use effective contraception during treatment; **AND**
- Patient has a serum hemoglobin level of at least 9 mg/dL: **AND**
- Will not be used in combination with erythropoiesis stimulating agents (ESAs); **AND**
- Patient oxygen saturation will be monitored prior to initiation of therapy and periodically throughout therapy; **AND**
- Patient will avoid coadministration with UGT2B17-inhibitors (e.g., green teas, quercetin, red wine, etc.) or CYP2C19 inhibitors (e.g., fluvoxamine, quercetin, ketoconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has not received prior treatment with another HIF-2α inhibitor; **AND**
- Patient has a diagnosis of VHL based on a germline VHL-alteration; **AND**
- Patient has one or more of the following associated tumors;
  - Renal cell carcinoma (RCC) [*note: may only be confirmed radiologically*]; **OR**
  - CNS hemangioblastomas; **OR**
  - Pancreatic neuroendocrine tumors (pNET); **AND**
- Patient does not have an immediate need for surgical intervention for tumor treatment OR have evidence of metastatic disease

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe anemia, severe hypoxia, etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

WINLEVI (CLASCOTERONE)

Length of Authorization:	1 year
Initiative:	MNC: Dermatological Agents (IE 2462 / NCPDP 75 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient is 12 years of age or older; **AND**
- Diagnosis of acne vulgaris; **AND**
- Patient has tried and failed or has a contraindication or experienced intolerance/adverse reaction to ≥ 2 preferred topical products for acne vulgaris of different treatment classes

CLINICAL CRITERIA FOR RENEWAL

- Patient must continue to meet the above criteria; **AND**
- Patient must have disease improvement and/or stabilization; **AND**
- Patient has no treatment-limiting adverse effects (e.g., local irritation reactions, hypothalamic-pituitary-adrenal [HPA] axis suppression).

XALKORI® (CRIZOTINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years old; **AND**
- Must be used as a single agent; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong or moderate CYP3A inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, aprepitant, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with drugs that prolong the QT-interval (e.g., fluoroquinolone or macrolide antibiotics, venlafaxine, fluoxetine, quetiapine, ziprasidone, sumatriptan, zolmitriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with drugs that cause bradycardia (e.g., beta-blockers, non-dihydropyridine calcium channel blockers, clonidine, digoxin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrent or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Patient has anaplastic lymphoma kinase (ALK) positive disease as detected by an FDA- approved or CLIA compliant test; **OR**
  - Patient has ROS-1 rearrangement positive disease as detected by an FDA-approved or CLIA compliant test; **OR**
  - Patient has MET exon 14 skipping mutation positive tumors; **OR**
- Patient has metastatic disease with high level MET amplification

Diagnosis of **Inflammatory Myofibroblastic Tumor (IMT) – Soft Tissue Sarcoma**

- Patient is at least 18 years old; **AND**
- Must be used as a single agent; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong or moderate CYP3A inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, aprepitant, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with drugs that prolong the QT-interval (e.g., fluoroquinolone or macrolide antibiotics, venlafaxine, fluoxetine, quetiapine, ziprasidone, sumatriptan, zolmitriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with drugs that cause bradycardia (e.g., beta-blockers, non-dihydropyridine calcium channel blockers, clonidine, digoxin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has anaplastic lymphoma kinase (ALK) positive disease.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Anaplastic Large Cell Lymphoma (ALCL) – T-Cell Lymphomas**

- Patient is at least 1 year of age; **AND**
- Must be used as a single agent; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong or moderate CYP3A inhibitors (e.g., ketoconazole, clarithromycin, grapefruit juice, aprepitant, diltiazem, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with drugs that prolong the QT-interval (e.g., fluoroquinolone or macrolide antibiotics, venlafaxine, fluoxetine, quetiapine, ziprasidone, sumatriptan, zolmitriptan, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with drugs that cause bradycardia (e.g., beta-blockers, non-dihydropyridine calcium channel blockers, clonidine, digoxin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has anaplastic lymphoma kinase (ALK) positive disease as detected by an FDA-approved or CLIA compliant test; **AND**
- Used as subsequent therapy for relapsed or refractory disease

CLINICAL CRITERIA FOR RENEWAL

- Disease response as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hepatotoxicity (severe changes in liver function tests), interstitial lung disease/pneumonitis, QT prolongation, bradycardia, severe vision loss, gastrointestinal toxicity in patients with ALCL, etc

XELODA® (CAPECITABINE)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents: (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Diagnosis of **anal squamous cell carcinoma**
- Diagnosis of **breast cancer**
- Diagnosis of **central nervous system cancers** (brain metastases)
- Diagnosis of **colorectal adenocarcinoma**
- Diagnosis of **esophageal and esophagogastric junction cancers**
- Diagnosis of **gastric adenocarcinoma**
- Diagnosis of **gestational trophoblastic neoplasia**
- Diagnosis of **head and neck cancers**
- Diagnosis of **hepatobiliary adenocarcinoma** (includes gallbladder cancer, intra/extra-hepatic cholangiocarcinoma)
- Diagnosis of **carcinoid tumors** (includes GI tract, lung, and thymus)
- Diagnosis of **neuroendocrine tumors** (includes pancreas and poorly differentiated/large or small cell)
- Diagnosis of **occult primary cancer**
- Diagnosis of **ovarian cancer**
- Diagnosis of **pancreatic adenocarcinoma**
- Diagnosis of **penile cancer**
- Diagnosis of **small bowel adenocarcinoma**
- Diagnosis of **squamous cell skin cancer**
- Diagnosis of **thymomas and thymic carcinomas**

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., coagulopathy, severe diarrhea, cardiotoxicity, dihydropyridine dehydrogenase deficiency, dehydration/renal failure, severe mucocutaneous and dermatologic toxicity, hyperbilirubinemia [grade 2 or 4], hematologic [neutrophil counts < 1.5 x 10^9/L or thrombocyte counts < 100 x 10^9/L], hepatic insufficiency)

XEOMIN® (INCOBUTULINUM TOXIN A)

Length of Authorization:	6 months, may be renewed Preoperative use in Ventral Hernia may **not** be renewed
Initiative:	SPC: Botulinum Toxin (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Note: NOT APPROVABLE FOR COSMETIC USE.

Note: For denials due to quantity requests over the FDA limit, please use the following initiative and reason code:

- SPC: Botulinum Toxin
- DCDD: Denial: Does not Meet FDA criteria for Diagnosis and Dose.

For all shared FDA approved indications with Dysport®, the patient must have a documented failure, contraindication, or intolerance to Dysport® prior to the consideration of Xeomin®

Note: For Core Formulary, all botulinum toxin products are non-formulary.

Diagnosis of **Cervical Dystonia**

- Patient is at least 18 years of age; **AND**
- Patient evaluated for any disorder which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, onabotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient has a history of recurrent involuntary contraction of one or more muscles in the neck; **AND**
  - Patient has sustained head tilt; **OR**
  - Abnormal posturing with limited range of motion in neck; **AND**
- ***Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Dysport®***

Diagnosis of **Blepharospasm**

- Patient is at least 18 years of age; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, onabotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient evaluated for any disorder which may contribute to respiratory or swallowing difficulty

Diagnosis of **Spastic Conditions**

- Patient is at least 18 years of age; **AND**
- Patient evaluated for any disorder which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, onabotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient has one of the following:
  - Upper Limb spasticity in adults (i.e., used post-stroke for spasms)
  - Pediatric upper limb spasticity in patients 2 years to 17 years of age, excluding spasticity caused by cerebral palsy
- ***Patient must have a documented failure, contraindication, intolerance, or ineffective response to a trial of Dysport®***

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Prophylaxis for Chronic Migraines**

- Patient is at least 18 years of age; **AND**
- Patient evaluated for any disorders which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, onabotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Not used in combination with prophylactic calcitonin gene-related peptide (CGRP) inhibitors (e.g., eptinezumab, erenumab, galcanezumab, fremanezumab) *[Note: This does not include CGRP inhibitors used for acute treatment (e.g., ubrogepant)]*; **AND**
- Patient is utilizing prophylactic intervention modalities (e.g., pharmacotherapy, behavioral therapy, physical therapy); **AND**
- **Documentation (e.g., clinical notes) is required to be submitted to demonstrate appropriate trials of required alternative medications and failures**
- Patient has failed at least an 8-week trial of any two oral medications (16 weeks total) for the prevention of migraines, such as (not all inclusive):
  - Antidepressants (e.g., amitriptyline, fluoxetine, nortriptyline)
  - Beta blockers (e.g., propranolol, metoprolol, nadolol, timolol, atenolol, pindolol)
  - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan)
  - Anti-epileptics (e.g., divalproex, valproate, topiramate)
  - Calcium channels blockers (e.g., verapamil)
- Patient has 15 or more headache (tension-type-like and/or migraine-like) days per month for at least 3 months **(supported through clinical documentation/clinical notes)**; **AND**
  - Patient has had at least five attacks with features consistent with migraine (with and/or without aura)§; **AND**
  - On at least 8 days per month for at least 3 months:
    - Headaches have characteristics and symptoms consistent with migraine; **OR**
    - Patient suspected migraines are relieved by a triptan or ergot derivative medication

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Migraine Features
Migraine without aura • At least five attacks have the following: – Headache attacks lasting 4–72 hours (untreated or unsuccessfully treated) – Headache has at least two of the following characteristics: • Unilateral location • Pulsating quality • Moderate or severe pain intensity • Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs); **AND** – During headache, at least one of the following: • Nausea and/or vomiting • Photophobia and phonophobia
Migraine with aura • At least two attacks have the following: – One or more of the following fully reversible aura symptoms: • Visual • Sensory • Speech and/or language • Motor • Brainstem • Retinal; **AND** – At least three of the following characteristics • At least one aura symptom spreads gradually over ≥ 5 minutes • Two or more symptoms occur in succession • Each individual aura symptom lasts 5–60 minutes • At least one aura symptom is unilateral • At least one aura symptom is positive (e.g., scintillations and pins and needles) • The aura is accompanied, or followed within 60 minutes, by headache

Diagnosis of **Incontinence Due to Neurogenic Detrusor Overactivity**

- Patient is at least 18 years of age; **AND**
- Patient evaluated for any disorder which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, onabotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient has detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) that is confirmed by urodynamic testing; **AND**
- **Documentation (e.g., clinical notes) is required to be submitted to demonstrate appropriate trials of required alternative medications and failures; AND**
- Patient has failed a 1-month or longer trial of two medications from either antimuscarinic (i.e., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) or beta-adrenergic (i.e., mirabegron) classes.

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Overactive Bladder (OAB)**

- Patient is at least 18 years of age; **AND**
- Patient evaluated for any disorder which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, onabotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient has symptoms of urge urinary incontinence, urgency, and frequency; **AND**
- **Documentation (e.g., clinical notes) is required to be submitted to demonstrate appropriate trials of required alternative medications and failures**
- Patient has failed a 1-month or longer trial of two medications from either the antimuscarinic (i.e., darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium) or beta-adrenergic (i.e., mirabegron) classes

Diagnosis of **Severe Primary Axillary Hyperhidrosis**

- Patient is at least 18 years of age; **AND**
- Patient evaluated for any disorder which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, onabotulinumtoxinA, rimabotulinumtoxinB); **AND**
- **Documentation (e.g., clinical notes) is required to be submitted to demonstrate appropriate trials of required alternative medications and failures**
- Patient has tried and failed ≥ 1-month trial of a topical agent (e.g., aluminum chloride, glycopyrronium)
  - Patient has history of medical complications such as skin infections or significant functional impairments; **OR**
  - Patient has had a significant burden of disease or impact to activities of daily living due to condition (e.g., impairment in work performance/productivity, frequent change of clothing, difficulty in relationships and/or social gatherings)

Diagnosis of **Chronic Sialorrhea**

- Patient is at least 18 years of age; **AND**
- Patient evaluated for any disorder which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, onabotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient has a history of troublesome sialorrhea for at least a 3-month period; **AND**
  - Patient has Parkinson's disease, atypical Parkinsonism, stroke, or traumatic brain injury; **OR**
  - Patient has a severe developmental delay; **OR**
  - Patient has cerebral palsy, other genetic or congenital disorders, or traumatic brain injury; **AND**
    - Patient is at least 2 years of age

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Ventral Hernia**

- Patient is at least 18 years of age; **AND**
- Patient evaluated for any disorder which may contribute to respiratory or swallowing difficulty; **AND**
- Patient does not have a hypersensitivity to any botulinum toxin product; **AND**
- Patient does not have an active infection at the proposed injection site; **AND**
- Patient is not on concurrent treatment with another botulinum toxin (e.g., abobotulinumtoxinA, onabotulinumtoxinA, rimabotulinumtoxinB); **AND**
- Patient has a large ventral hernia with loss of domain or contaminated ventral hernia; **AND**
- Used preoperatively in patients scheduled to receive abdominal wall reconstruction (AWR)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include symptoms of a toxin spread effect (e.g., asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, breathing difficulties), hypersensitivity reactions, corneal exposure/ulceration, ectropion in patients treated for blepharospasm, etc.; **AND**
- Disease response as evidenced by the following **(Documentation/clinical notes must be submitted to demonstrate objective response)**:
  - Blepharospasms
    - Improvement of severity and/or frequency of eyelid spasms
  - Cervical dystonia
    - Improvement in the severity and frequency of pain; **AND**
    - Improvement of abnormal head positioning
  - Upper limb spasticity
    - Decrease in tone and/or resistance, of affected areas, based on a validated measuring tool (e.g., Ashworth Scale, Physician Global Assessment, Clinical Global Impression [CGI])
  - Severe primary axillary hyperhidrosis
    - Significant reduction in spontaneous axillary sweat production; **AND**
    - Patient has a significant improvement in activities of daily living
  - Prophylaxis for chronic migraines
    - Not used in combination with calcitonin gene-related peptide (CGRP) inhibitors (e.g., erenumab); **AND**
    - Significant decrease in the number, frequency, and/or intensity of headaches; **AND**
    - Improvement in function; **AND**
    - Patient continues to utilize prophylactic intervention modalities (e.g., pharmacotherapy, behavioral therapy, physical therapy)
  - Incontinence due to detrusor overactivity
    - Significant improvements in weekly frequency of incontinence episodes; **AND**
    - Patient's post-void residual (PVR) periodically assessed as medically appropriate
  - Overactive bladder (OAB)
    - Significant improvement in daily frequency of urinary incontinence or micturition episodes and/or volume voided per micturition; **AND**
    - Patient's post-void residual (PVR) periodically assessed as medically appropriate

CLINICAL CRITERIA FOR RENEWAL

- Chronic sialorrhea
  - Significant decrease in saliva production
- Ventral hernia
  - May not be renewed

DOSAGE AND ADMINISTRATION

- When initiating treatment, the lowest recommended dose should be used.
- Unless otherwise stated, re-treatment should occur no sooner than 12 weeks from the prior injection.

Note: For denials due to quantity requests over the FDA limit, please **use the following initiative and reason code:**

- SPC: Botulinum Toxin
- DCDD: Denial: Does not Meet FDA criteria for Diagnosis and Dose.

Indication	Dose
Cervical Dystonia	120 units divided among the affected muscles every 12 weeks or longer, as necessary
Blepharospasm	1.25–5.6 units per injection site, not to exceed 50 units per eye (maximum of 35 units per eye for initial dose), every 12 weeks or longer, as necessary
Upper Limb Spasticity	The dosage, frequency, and number of injection sites should be tailored to the individual patient based on the size, number, and location of muscles to be treated, severity of spasticity, presence of local muscle weakness, patient's response to previous treatment, and adverse event history with Xeomin. Localization of the involved muscles with electromyographic guidance, nerve stimulation, or ultrasound techniques is recommended. **Adults:** • Up to 400 units total, repeated no sooner than every 12 weeks **Pediatrics:** • 8 units/kg, divided among affected muscles, up to a maximum dose of 200 units per single upper limb. If both upper limbs are treated, total XEOMIN dosage should not exceed 16 units/kg, up to a maximum of 400 units, repeated no sooner than every 12 weeks
Chronic Migraine	Up to 200 units divided among the affected muscles every 12 weeks
Severe Primary Axillary Hyperhidrosis	50 units intradermally per axilla every 16 weeks
Neurogenic Bladder/ Detrusor Overactivity	Up to 200 units per treatment divided among the affected muscles every 12 weeks.
Overactive Bladder (OAB)	Up to 100 units per treatment divided among the affected muscles every 12 weeks

Indication	Dose
Sialorrhea	**Adults:** 30 units per parotid gland and 20 units per submandibular gland (50 units per each side of the face for a total recommended dose of 100 units per treatment session), repeated no sooner than every 16 weeks **Pediatrics:** Dosing is based on body weight as noted below and is repeated no sooner than every 16 weeks • 12 kg to < 15 kg: 6 units per parotid gland and 4 units per submandibular gland (10 units per each side of the face for a total recommended dose of 20 units per treatment session) • 15 kg to < 19 kg: 9 units per parotid gland and 6 units per submandibular gland (15 units per each side of the face for a total recommended dose of 30 units per treatment session) • 19 kg to < 23 kg: 12 units per parotid gland and 8 units per submandibular gland (20 units per each side of the face for a total recommended dose of 40 units per treatment session) • 23 kg to < 27 kg: 15 units per parotid gland and 10 units per submandibular gland (25 units per each side of the face for a total recommended dose of 50 units per treatment session) • 27 kg to < 30 kg: 18 units per parotid gland and 12 units per submandibular gland (30 units per each side of the face for a total recommended dose of 60 units per treatment session) • 30 kg or more: 22.5 units per parotid gland and 15 units per submandibular gland (37.5 units per each side of the face for a total recommended dose of 75 units per treatment session)
Ventral Hernia	500 units divided among abdominal muscles, injected 2-4 weeks prior to AWR surgery. *May not be renewed.*

Max Units (per dose and over time):

Indication	# vials to build in FirstTrax℠	Per # days*
Cervical dystonia	1 (200-unit vial)	84
Blepharospasms	1 (100-unit vial)	84
Upper Limb Spasticity	2 (200-unit vial)	84
Prophylaxis for Chronic Migraines	1 (200-unit vial)	84
Incontinence Due to Neurogenic Detrusor Overactivity	1 (200-unit vial)	84
Overactive bladder (OAB)	1 (100-unit vial)	84
Severe Primary Axillary Hyperhidrosis	1 (100-unit vial)	112
Sialorrhea	1 (100-unit vial)	112
Ventral Hernia	5 (100-unit vial)	N/A

Available in 50-unit, 100-unit and 200-unit vials

* The plan may only allow for a max of 30 days to be billed at a time; no days' supply override needs to be placed to allow these to pay. The pharmacy may process as the 30 days. These limitations will not allow the member to fill more than the allotted vials per max days' supply (i.e., 84, 112, or 168).

XERMELO® (TELOTRISTAT ETHYL)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Carcinoid Syndrome Diarrhea**

- Patient is at least 18 years old; **AND**
- Patient has been receiving therapy with the FDA-approved maximum (or highest tolerated) dose of a somatostatin analog therapy (SSA) (i.e., octreotide solution/depot or lanreotide depot) for at least 3 months; **AND**
- Patient will continue to receive this SSA therapy in combination with telotristat ethyl; **AND**
- Patient has a carcinoid/neuroendocrine tumor and has been diagnosed with carcinoid syndrome; **AND**
- Patient has had an inadequate response to antidiarrheals (e.g., loperamide);**AND**
- Patient's baseline bowel movements per day are ≥ 4

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe constipation, abdominal pain); **AND**
- Patient has responded to therapy as indicated by a reduction in the number of bowel movements per day from pre-treatment baseline

XGEVA® (DENOSUMAB)

Length of Authorization:	12 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Prevention of skeletal-related events in patients with multiple myeloma OR bone metastases from solid tumors**

- Administer calcium and vitamin D as necessary to treat or prevent hypocalcemia; **AND**
- Patients must be 18 years of age or older; **AND**
  - Patient must try and have an inadequate response, contraindication, or intolerance to at least a 3-month trial of Zoledronic Acid; **OR**
  - Patient has metastatic breast cancer, metastatic castration-resistant prostate cancer, or metastatic lung cancer (both SCLC and NSCLC)

Diagnosis of **Giant Cell cancer of the bone**

- Administer calcium and vitamin D as necessary to treat or prevent hypocalcemia; **AND**
- Patient must be an adult or ≥ 13 years old and skeletally mature; **AND**
- Disease is unresectable or surgical resection is likely to result in severe morbidity; **OR**
- Disease is localized, recurrent, or metastatic; **AND**
  - Used a single agent; **OR**
  - Used in combination with interferon alpha, serial embolization, or radiation therapy

Diagnosis of **Hypercalcemia of malignancy**

- Administer calcium and vitamin D as necessary to treat or prevent hypocalcemia; **AND**
- Patient is at least 18 years of age**; AND**
- Patient must have a diagnosis of cancer (malignancy); **AND**
- Patient must have a diagnosis of refractory hypercalcemia of malignancy defined as an albumin-corrected calcium of > 12.5 mg/dL (3.1 mmol/L) despite treatment with a minimum 7-day trial on previous therapy with intravenous (IV) bisphosphonates such as ibandronate (Boniva) or zoledronic acid (Reclast); **OR**
- Patient has a documented contraindication or intolerance to IV bisphosphonates such as ibandronate (Boniva) or zoledronic acid (Reclast)

Diagnosis of **Systemic Mastocytosis**

- Administer calcium and vitamin D as necessary to treat or prevent hypocalcemia; **AND**
- Patient has osteopenia or osteoporosis and coexisting bone pain; **AND**
- Used as second line therapy; **AND**
  - Patient is not responding to bisphosphonate therapy; **OR**
  - Patient is not a candidate for bisphosphonate therapy due to renal insufficiency

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., severe symptomatic hypocalcemia, osteonecrosis of the jaw, atypical femoral fractures, dermatological adverse reactions, severe infection) **AND**
- Disease response as indicated by the following:
  - **Multiple Myeloma OR Bone metastases from solid tumors:** absence/delay in skeletal-related events (e.g., pathologic fracture, radiation therapy to bone, surgery to bone, or spinal cord compression)
  - **Giant Cell Tumor of the Bone:** stabilization of disease or decrease in size of tumor or spread of tumor
  - **Hypercalcemia of Malignancy:** corrected serum calcium ≤ 11.5 mg/dL (2.9 mmol/L)
  - **Systemic Mastocytosis**: improvement or resolution of bone pain as compared to pretreatment baseline

XIAFLEX® (COLLAGENASE CLOSTRIDIUM HISTOLYTICUM)

Length of Authorization:	Dupuytren's contracture: 3 months, eligible for renewal (max of 3 injections per joint) Peyronie's disease: 6 weeks, eligible for renewal (max of 4 treatment cycles for each plaque causing the curvature deformity)
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Peyronie's Disease**

- Patient is at least 18 years of age; **AND**
- Patient has palpable plaque on penis; **AND**
- Prescriber is enrolled in the Xiaflex® REMS program; **AND**
- Patient has stable disease with penis curvature deformity of > 30° and < 90°; **AND**
- Patient has intact erectile function (with or without use of medications); **AND**
- Patient does not have isolated hourglass deformity or calcified plaque; **AND**
- Plaque(s) do not involve the penile urethra; **AND**
- Will be used in combination with penile modeling procedures; **AND**
- Patient has not exceeded 4 treatment cycles for each plaque causing the curvature deformity; **AND**
- The patient has not received a collagenase injection for this condition within the past 6 weeks

Diagnosis of **Dupuytren's Contracture**

- Patient is at least 18 years of age; **AND**
- Patient has a palpable cord; **AND**
- Documented flexion contracture of 20° to 100° in a metacarpophalangeal (MP) joint or 20° to 80° in a proximal interphalangeal (PIP) joint; **AND**
- Documentation of a positive "table top test" defined as the inability to simultaneously place the affected finger(s) and palm flat against a table top; **AND**
- Documentation that the flexion deformity results in functional limitations

CLINICAL CRITERIA FOR RENEWAL

Dupuytren's Contracture only

- Absence of unacceptable toxicity from the drug (e.g., anaphylaxis and allergic reactions; abnormal coagulation; tendon ruptures or other serious injury to the injected extremity); **AND**
- Disease response with treatment as defined by reduction in contracture of the selected primary joint compared to baseline; **AND**
- Patient has not exceeded 3 injections per joint/cord.
- Patient has not received a collagenase injection for this condition within the past 4 weeks

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

Peyronie's Disease only

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: anaphylaxis and allergic reactions, abnormal coagulation, corporal rupture (penile fracture) or other serious injury to the penis, acute post-injection back pain reactions, etc.; **AND**
- Disease response with treatment as defined by the reduction in curvature of the penis to <15 degrees after the previous treatment cycle(s); **AND**
- Further treatment is only clinically indicated if the patient has penis curvature deformity of ≥ 15 degrees after the previous treatment cycle(s); **AND**
- Patient has not exceeded 4 treatment cycles for each plaque causing the curvature deformity; **AND**
- Patient has not received a collagenase injection for this condition within the past 6 weeks

XOFIGO® (RADIUM RA 223 DICHLORIDE)

Length of Authorization:	6 months, may not be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Prostate Cancer**

- Patient is 18 years of age or older; **AND**
- Patient has castration-resistant disease; **AND**
- Patient has symptomatic bone metastases; **AND**
- Patient does not have any known visceral metastases; **AND**
- Must be used as a single agent

XOLAIR® (OMALIZUMAB)

Length of Authorization:	6 months initial, May be renewed (Management of Immune Checkpoint Inhibitor-Related Toxicity may **not** be renewed)
Initiative:	SPC: Respiratory Agents: (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **moderate-to-severe persistent allergic asthma:**

- Patient is at least 6 years of age; **AND**
- Must not be used in combination with another anti-IL4 or anti-IL5 monoclonal antibody (e.g., benralizumab mepolizumab, reslizumab, dupilumab); **AND**
- Will not be used for treatment of acute bronchospasm, status asthmaticus, or allergic conditions (other than indicated); **AND**
- Patient has a positive skin test or in vitro reactivity to a perennial allergen; **AND**
- Patient must weigh between 20 kg (44 lb.) and 150 kg (330 lb.); **AND**
- Patient has a serum total IgE level, measured before the start of treatment, of either:
  - ≥ 30 IU/mL and ≤ 700 IU/mL in patients age ≥ 12 years; **OR**
  - ≥ 30 IU/mL and ≤ 1300 IU/mL in patients ages 6 to < 12 years; **AND**
- Patient has documented ongoing symptoms of moderate-to-severe asthma* with a minimum (3) month trial on previous combination therapy including medium or high-dosed inhaled corticosteroids **PLUS** another controller medication (e.g., long-acting beta-2 agonist, leukotriene receptor antagonist, theophylline); **AND**
- Baseline measurement of at least one of the following for assessment of clinical status:
  - Use of inhaled rescue medication
  - Use of inhaled or systemic corticosteroids
  - Reported disease severity symptoms (e.g., number of hospitalizations, ER visits, unscheduled visits to healthcare provider due to condition, asthma attacks, chest tightness or heaviness, coughing or clearing throat, difficulty taking deep breath or difficulty breathing out, shortness of breath, sleep disturbance, night wakening, or symptoms upon awakening, tiredness, wheezing/heavy breathing/fighting for air)
  - Forced expiratory volume in 1 second (FEV_1)

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

***Components of severity for classifying asthma as MODERATE may include any of the following (not all inclusive):**
• Daily symptoms • Nighttime awakenings > 1 time per week but not nightly • SABA use for symptom control occurs daily • Some limitation to normal activities • Lung function (percent predicted FEV_1) > 60%, but < 80% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to mild asthma
***Components of severity for classifying asthma as SEVERE may include any of the following (not all inclusive):**
• Symptoms throughout the day • Nighttime awakenings, often 7 times per week • SABA use for symptom control occurs several times daily • Extremely limited in normal activities • Lung function (percent predicted FEV_1) < 60% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Chronic idiopathic urticaria:**

- Patient is at least 12 years of age; **AND**
- The underlying cause of the patient's condition has been ruled out and is not considered to be any other allergic condition(s) or other form(s) of urticaria; **AND**
- Patient is avoiding triggers (e.g., NSAIDs); **AND**
- Must not be used in combination with another anti-IL4 or anti-IL5 monoclonal antibody (e.g., benralizumab mepolizumab, reslizumab, dupilumab); **AND**
- Documented baseline score from an objective clinical evaluation tool, such as: urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL); **AND**
- Patient had an inadequate response to a one-, or more, month trial on previous therapy with scheduled dosing of a second-generation H1-antihistamine product**; **AND**
- Patient had an inadequate response to a one-, or more, month trial on previous therapy with scheduled dosing of at least one of the following:
  - Up-dosing/dose advancement (up to 4-fold) of a second generation H1-antihistamine**
  - Add-on therapy with a leukotriene antagonist (e.g., montelukast, zafirlukast)
  - Add-on therapy with another H1 antihistamine**
  - Add-on therapy with a H2-antagonist (e.g., ranitidine)
  - Add-on therapy with cyclosporine

Note: renewal will require submission of a current (within 30 days) score from an objective clinical evaluation tool (i.e., UAS7, AAS, DLQI, AE-QoL or CU-Q_2oL).

H1 Antihistamine Products (not all inclusive)
• fexofenadine • loratadine • desloratadine • cetirizine • levocetirizine • clemastine • diphenhydramine • chlorpheniramine • hydroxyzine • cyproheptadine • brompheniramine • triprolidine • dexchlorpheniramine • carbinoxamine

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)**

- Patient is at least 18 years of age; **AND**
- Must not be used in combination with another anti-IL4 or anti-IL5 monoclonal antibody (e.g., benralizumab mepolizumab, reslizumab, dupilumab); **AND**
- Patient has bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks; **AND**
- Patient has failed at least 8 weeks of daily intranasal corticosteroid therapy; **AND**
- Other causes of nasal congestion/obstruction have been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Therapy will be used in combination with intranasal corticosteroids unless not able to tolerate or is contraindicated

Diagnosis of **Management of Immune Checkpoint Inhibitor-Related Toxicity:**

- Patient is at least 18 years of age; **AND**
- Must not be used in combination with another anti-IL4 or anti-IL5 monoclonal antibody (e.g., benralizumab mepolizumab, reslizumab, dupilumab); **AND**
- Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab); **AND**
- Patient has refractory and severe (i.e., grade 3: intense or widespread, constant, limiting self-care activities of daily living or sleep) pruritis; **AND**
- Patient has an increased serum IgE level above the upper limit of normal of the laboratory reference value.

Diagnosis of **Systemic Mastocytosis:**

- Patient is at least 18 years of age; **AND**
- Must not be used in combination with another anti-IL4 or anti-IL5 monoclonal antibody (e.g., benralizumab mepolizumab, reslizumab, dupilumab); **AND**
- Used for the prevention of one of the following:
  - Chronic mast-cell-mediator-related cardiovascular (e.g., pre-syncope, tachycardia) or pulmonary (e.g., wheezing, throat-swelling) symptoms insufficiently controlled by conventional therapy (e.g., H1 or H2 blockers or corticosteroids); **OR**
  - Unprovoked anaphylaxis; **OR**
  - Hymenoptera or food-induced anaphylaxis in patients with a negative test for specific IgE antibodies or a negative skin test; **OR**
- Used to improve tolerance while on immunotherapy (i.e., venom immunotherapy [VIT])

CLINICAL CRITERIA FOR RENEWAL

- Must not be used in combination with another anti-IL4 or anti-IL5 monoclonal antibody (e.g., benralizumab mepolizumab, reslizumab, dupilumab); **AND**
- Absence of unacceptable toxicity from the drug (e.g., symptoms of anaphylaxis [bronchospasm, hypotension, syncope, urticaria, and/or angioedema]; malignancy; symptoms similar to serum sickness [fever, arthralgia, and rash]; eosinophilic conditions, including vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy, especially upon reduction of oral corticosteroids); **AND**
- **For Moderate-to-severe persistent allergic asthma:**
  - Patient must weigh between 20 kg (44 lb.) and 150 kg (330 lb.); **AND**
  - Treatment has resulted in clinical improvement as documented by one or more of the following:
    - Decreased utilization of rescue medications; **OR**
    - Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids); **OR**
    - Improvement in lung function (increase in percent predicted FEV1 or PEF) from pre-treatment baseline; **OR**
    - Reduction in reported disease severity symptoms, as evidenced by decreases in frequency or magnitude of one or more of the following symptoms:
      - Hospitalizations, ER Visits, unscheduled visits to healthcare provider; **OR**
      - Asthma attacks; **OR**
      - Chest tightness or heaviness; **OR**
      - Coughing or clearing throat; **OR**
      - Difficulty taking deep breath or difficulty breathing out; **OR**
      - Shortness of breath; **OR**
      - Sleep disturbance, night wakening, or symptoms upon awakening; **OR**
      - Tiredness; **OR**
      - Wheezing/heavy breathing/fighting for air; **AND**
    - Patient is periodically checked to reassess the need for continued therapy based upon the patient's disease severity and level of asthma control
- **For Chronic idiopathic urticaria:**
  - Treatment with Xolair® (omalizumab) has resulted in clinical improvement as documented by improvement from baseline using objective clinical evaluation tools such as the urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire (CU-Q_2oL); **AND**
  - Submitted current UAS7, AAS, DLQI, AE-QoL, or Cu-Q_2oL was recorded within the past 30 days.
- **For Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):**
  - Disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool (e.g., nasal polyposis score [NPS], nasal congestion [NC] symptom severity score, sino-nasal outcome test-22 [SNOT-22]); **AND**
  - Patient had an improvement in at least one (1) of the following response criteria:
    - Reduction in nasal polyp size
    - Reduction in need for systemic corticosteroids
    - Improvement in quality of life
    - Improvement in sense of smell
    - Reduction of impact of comorbidities

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

- **Management of Immune Checkpoint Inhibitor-related Toxicity:**
  - May not be renewed
- **Systemic Mastocytosis:**
  - Disease response as indicated by improvement in signs and symptoms compared to baseline or a decreased frequency of exacerbations

DOSAGE AND ADMINISTRATION

•

Indication	Dose
Allergic Asthma	75–375 mg administered subcutaneously by a health care provider every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See tables below. The pre-filled syringe formulation may be self-administered after the initial 3 doses are administered in the healthcare setting AND the healthcare provider determines that self-administration is appropriate based on assessment of risk for anaphylaxis and mitigation strategies. See criteria below
Chronic idiopathic urticaria	150 or 300 mg administered subcutaneously by a health care provider every 4 weeks. Dosing is not dependent on serum IgE (free or total) level or body weight. The pre-filled syringe formulation may be self-administered after the initial 3 doses are administered in the healthcare setting AND the healthcare provider determines that self-administration is appropriate based on assessment of risk for anaphylaxis and mitigation strategies. See criteria below
Nasal Polyps	75–600 mg administered subcutaneously by a health care provider every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See table below. The pre-filled syringe formulation may be self-administered after the initial 3 doses are administered in the healthcare setting AND the healthcare provider determines that self-administration is appropriate based on assessment of risk for anaphylaxis and mitigation strategies. See criteria below.
Management of Immune Checkpoint Inhibitor-Related Toxicity and Systemic Mastocytosis	150 or 300 mg administered subcutaneously every 4 weeks. Dosing is not dependent on serum IgE (free or total) level or body weight. **Must ONLY be administered by a health care provider.

Criteria for Selection of Patients for Self-Administration of Xolair Prefilled Syringe
• Patient should have no prior history of anaphylaxis, including to Xolair® or other agents, such as foods, drugs, biologics, etc.; **AND** • Patient should receive at least 3 doses of Xolair under the guidance of a healthcare provider with no hypersensitivity reactions; **AND** • Patient or caregiver is able to recognize symptoms of anaphylaxis; **AND** • Patient or caregiver is able to treat anaphylaxis appropriately; **AND** • Patient or caregiver is able to perform subcutaneous injections with Xolair prefilled syringe with proper technique according to the prescribed dosing regimen and Instructions for Use
Note: Xolair prefilled syringes for patients under 12 years of age should be administered by a caregiver.

Max mL or vial (per dose and over time):

Indication	# mL to build in FirstTrax℠	Per # days*
Moderate to severe persistent allergic asthma	Utilize tables below as dosing is dependent on age, weight and IgE levels. The limitations for each strength are: 1 mL (2 of the 75 mg pre-filled syringe) 4mL (4 of the 150 mg pre-filled syringe) 6 vials of 150 mg powder for injection Enter the amount the patient will need based on age, weight, IgE level, and if dosing every 2 or 4 weeks.	 28 28 28
Chronic idiopathic urticaria	1 mL if 150 mg is requested or 2 mL if 300 mg is requested	28
Nasal Polyps	Utilize tables below as dosing is dependent on weight and IgE levels. The limitations for each strength are: 1 mL (2 of the 75 mg pre-filled syringe) 8mL (8 of the 150 mg pre-filled syringe) 8 vials of 150 mg powder for injection Enter the amount the patient will need based on weight, IgE level, and if dosing every 2 or 4 weeks.	 28 28 28
All other indications	1 mL if 150 mg is requested or 2 mL if 300 mg is requested	28

DOSAGE AND ADMINISTRATION *(CONTINUED)*

Asthma Omalizumab Doses Administered Every 4 Weeks (mg) in patients ≥ 12 years				
Pre-treatment serum IgE (IU/mL)	**Body weight (kg)**			
	30 to 60	**> 60 to 70**	**> 70 to 90**	**> 90 to 150**
≥ 30 to 100	150	150	150	300
> 100 to 200	300	300	300	See the following table.
> 200 to 300	300	See the following table.	See the following table.	See the following table.

Asthma Omalizumab Doses Administered Every 2 Weeks (mg) in patients ≥ 12 years				
Pre-treatment serum IgE (IU/mL)	**Body weight (kg)**			
	30 to 60	**> 60 to 70**	**> 70 to 90**	**> 90 to 150**
> 100 to 200	See previous table.	See previous table.	See previous table.	225
> 200 to 300	See previous table.	225	225	300
> 300 to 400	225	225	300	Do not dose.
> 400 to 500	300	300	375	Do not dose.
> 500 to 600	300	375	Do not dose.	Do not dose.
> 600 to 700	375	Do not dose.	Do not dose.	Do not dose

Asthma Omalizumab Doses Administered Every 2 or 4 Weeks (mg) for Pediatric Patients Who Begin Xolair® Between the Ages of 6 to <12 Years											
Pre-treatment IgE (IU/mL)	Dosing Freq. (weeks)	Body Weight (kg)									
		20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
30-100	4	75	75	75	150	150	150	150	150	300	300
>100-200		150	150	150	300	300	300	300	300	225	300
>200-300		150	150	225	300	300	225	225	225	300	375
>300-400		225	225	300	225	225	225	300	300		
>400-500		225	300	225	225	300	300	375	375		
>500-600		300	300	225	300	300	375				
>600-700		300	225	225	300	375					
>700-900	2	225	225	300	375						
>900-1100		225	300	375							
>1100-1200		300	300								
>1200-1300		300	375								

Do Not Dose

Nasal Polyps Omalizumab Doses Administered Every 2 or 4 Weeks (mg)									
Pre-treatment IgE (IU/mL)	Dosing Freq. (weeks)	Body Weight (kg)							
		>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
30-100	4	75	150	150	150	150	150	300	300
>100-200		150	300	300	300	300	300	450	600
>200-300		225	300	300	450	450	450	600	375
>300-400		300	450	450	450	600	600	450	525
>400-500		450	450	600	600	375	375	525	600
>500-600		450	600	600	375	450	450	600	
>600-700		450	600	375	450	450	525		
>700-800	2	300	375	450	450	525	600		
>800-900		300	375	450	525	600			
>900-1000		375	450	525	600				
>1000-1100		375	450	600					
>1100-1200		450	525	600					
>1200-1300		450	525						
>1300-1500		525	600						

Do Not Dose

XOSPATA® (GILTERITINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Acute Myeloid Leukemia (AML)**

- Patient is at least 18 years old; **AND**
- Patient has had a baseline electrocardiogram (ECG); **AND**
- Not used in combination with other FMS-like tyrosine kinase (FLT)-inhibitors (e.g., midostaurin, sorafenib, etc.); **AND**
- Patient will avoid concomitant therapy with P-glycoprotein and strong CYP3A inducers (e.g., rifampin, etc.);; **AND**
- Patient will avoid concomitant therapy with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have active, uncontrolled central nervous system (CNS) leukemia; **AND**
- Patient's disease is FMS-like tyrosine kinase-3 (FLT3) mutation-positive (FLT3+), *(includes ITD or TKD positive mutations)*, as confirmed by an FDA-cleared, or CLIA-compliant, test*; **AND**
- Used as single-agent therapy; **AND**
  - Patient has a hematological relapse after achieving complete remission (CR), complete remission with incomplete hematologic recovery (CRi), or complete remission with incomplete platelet recovery (CRp) on initial therapy; **OR**
  - Patient has refractory disease to initial induction therapy as defined as not having achieved a CR, CRi, or CRp

Diagnosis of **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**

- Patient is at least 18 years old; **AND**
- Patient has had a baseline electrocardiogram (ECG); **AND**
- Not used in combination with other FMS-like tyrosine kinase (FLT)-inhibitors (e.g., midostaurin, sorafenib, etc.); **AND**
- Patient will avoid concomitant therapy with P-glycoprotein and strong CYP3A inducers (e.g., rifampin, etc.); **AND**
- Patient will avoid concomitant therapy with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, nefazodone, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient does not have active, uncontrolled central nervous system (CNS) leukemia; **AND**
- Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible); **AND**
  - Patient has lymphoid, myeloid, or mixed lineage neoplasm with eosinophilia; **AND**
  - Patient has FLT3 rearrangement in blast phase; **OR**
- Patient has myeloid or lymphoid neoplasms with eosinophilia; **AND**
  - Patient has FLT3 rearrangement in chronic phase

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., posterior reversible encephalopathy syndrome [PRES], prolonged QT-interval [i.e., interval ≥ 500 ms and/or interval prolongation with signs and symptoms of severe arrhythmia], pancreatitis, anaphylaxis); **AND**
- Disease stabilization or improvement as evidenced by a complete response (CR) (i.e., morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH.

XPOVIO® (SELINEXOR)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Multiple Myeloma**

- Patient is at least 18 years of age; **AND**
- Patient has relapsed, refractory, or progressive disease; **AND**
  - Used in combination with bortezomib and dexamethasone; **OR**
  - Used in combination with daratumumab and dexamethasone; **OR**
  - Used in combination with pomalidomide and dexamethasone; **AND**
    - Patient has received at least **two** prior therapies including an immunomodulatory agent (e.g., thalidomide, lenalidomide, pomalidomide) and a proteasome inhibitor (e.g., bortezomib, ixazomib, carfilzomib); **AND**
    - Patient has had disease progression on or within 60 days of completion of the last therapy; **OR**
  - Used in combination with dexamethasone; **AND**
    - Patient is refractory to at least **four** prior anti-myeloma treatment regimens which must include the following:
      - Patient failed at least two proteasome inhibitors (e.g., bortezomib, ixazomib, carfilzomib); **AND**
      - Patient failed at least two immunomodulatory agents (e.g., thalidomide, lenalidomide, pomalidomide, etc.); **AND**
      - Patient failed an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab-irfc)

Diagnosis of **Diffuse Large B-Cell Lymphoma (DLBCL)**

- Patient is at least 18 years of age; **AND**
- Patient has histologically transformed DLBCL from Follicular lymphoma; **AND**
  - Used as subsequent therapy; **AND**
  - Patient has received two or more lines of chemoimmunotherapy for indolent or transformed disease; **OR**
- Patient has DLBCL, not otherwise specified, including DLBCL arising from follicular lymphoma; **AND**
  - Patient has a partial response, no response, relapsed, progressive or refractory disease (includes patients with disease progression after transplant or CAR-T cell therapy); **AND**
  - Patient has failed on at least two prior systemic treatment regimens

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include thrombocytopenia, neutropenia, gastrointestinal toxicity (e.g., nausea/vomiting/diarrhea, anorexia/weight loss), hyponatremia, infections, neurological toxicity (e.g., dizziness/confusion), new onset or exacerbation of cataract, etc.

XTANDI® (ENZALUTAMIDE)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

STANDARD FORMULARY CRITERIA

PRECISION/PLUS FORMULARY CRITERIA

ENHANCED FORMULARY CRITERIA

CORE FORMULARY CRITERIA

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Prostate Cancer**

- Patient is at least 18 years of age; **AND**
- Patient is receiving gonadotropin-releasing hormone (GnRH) therapy OR has had prior bilateral orchiectomy; **AND**
- Will not be used in combination with other androgen receptor inhibitors (e.g., darolutamide, apalutamide); **AND**
- Patient will avoid concomitant therapy with all of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented:
  - Coadministration with strong CYP2C8 inhibitors (e.g., clopidogrel, gemfibrozil); **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., carbamazepine, rifampin, phenytoin, St. John's Wort); **AND**
- Patient has castration-resistant prostate cancer (CRPC); **OR**
- Patient has metastatic castration-sensitive prostate cancer (mCSPC)

For Standard, Precision, Enhanced, and Core Formularies (NO GRANDFATHERING):

For patients with non-metastatic castration-resistant prostate cancer (NM-CRPC), in addition to the above criteria:

- Patient has a documented failure (minimum three-month trial), contraindication or intolerance to Nubeqa

For patients with metastatic castration-resistant prostate cancer (M-CRPC), in addition to the above criteria:

- Patient has a documented failure (minimum three-month trial), contraindication or intolerance to abiraterone

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., seizures, posterior reversible encephalopathy syndrome [PRES], hypersensitivity reactions, ischemic heart disease, falls/fractures)

XYREM® (SODIUM OXYBATE), XYWAV™ (CALCIUM, MAGNESIUM, POTASSIUM, AND SODIUM OXYBATES)

Length of Authorization:	3 months (90 days), may be renewed
Initiative:	SPC: Narcolepsy Agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Coverage is provided for the following Food and Drug Administration (FDA)-approved indications **only** (coverage for any other use will **not** be provided)

Diagnosis of **Cataplexy in Narcolepsy**

- Patient is at least 7 years of age; **AND**
- Patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months; **AND**
- Patient must not have succinic semialdehyde dehydrogenase deficiency; **AND**
- Patient was evaluated for history of drug abuse prior to initiating therapy; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the Xywav™ and Xyrem® REMS Program; **AND**
- Patient must not use in combination with sedative hypnotic agents (e.g., zolpidem, eszopiclone, zaleplon, benzodiazepines, barbiturates) while on therapy; **AND**
- Patient must not use in combination with alcohol while on therapy; **AND**
- Patient will receive continuous monitoring for signs of misuse or abuse of sodium oxybate (gamma-hydroxybutyrate [GHB]) including, but not limited to, the following: use of increasingly larger doses, increased frequency of use, drug-seeking behavior, feigned cataplexy, etc.); **AND**
- Patient will avoid concomitant use with divalproex sodium, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Xyrem® and Xywav™ will not be used concomitantly; **AND**
- Patient has cataplexy (i.e., sudden loss of some or all muscle tone in which consciousness is maintained); **AND**
- Patient has documented baseline frequency of cataplexy attacks; **AND**
- Patient has the presence of at least one of the following:
  - A mean sleep latency of ≤ 8 minutes **and** two or more sleep-onset rapid eye movement periods (SOREMPs) on a multiple sleep latency test (MSLT) performed according to standard techniques
    Note: A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram (PSG) may replace one of the SOREMPs on the MSLT.
  - A cerebral spinal fluid (CSF) hypocretin-1 concentration (measured by immunoreactivity) ≤ 110 pg/mL **or** < 1/3 of mean values obtained in normal subjects with the same standardized assay

Diagnosis of **Excessive Daytime Sleepiness (EDS) in Narcolepsy**

- Patient is at least 7 years of age; **AND**
- Patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months; **AND**
- Patient must not have succinic semialdehyde dehydrogenase deficiency; **AND**
- Patient was evaluated for history of drug abuse prior to initiating therapy; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the Xywav® and Xyrem™ REMS Program; **AND**
- Patient must not use in combination with sedative hypnotic agents (e.g., zolpidem, eszopiclone, zaleplon, benzodiazepines, barbiturates) while on therapy; **AND**
- Patient must not use in combination with alcohol while on therapy; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient will receive continuous monitoring for signs of misuse or abuse of sodium oxybate (gamma-hydroxybutyrate [GHB]) including, but not limited to, the following: use of increasingly larger doses, increased frequency of use, drug-seeking behavior, feigned cataplexy, etc.); **AND**
- Patient will avoid concomitant use with divalproex sodium. If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Xyrem and Xywav will not be used concomitantly; **AND**
- Patient does not have cataplexy; **AND**
- Patient has documented baseline daytime sleepiness as measured by a validated scale (e.g., Epworth Sleepiness Scale [ESS], Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale); **AND**
- Patient has a mean sleep latency of ≤ 8 minutes **and** two or more sleep-onset rapid eye movement periods (SOREMPs) on a multiple sleep latency test (MSLT) performed according to standard techniques; **AND**

  Note: A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram (PSG) may replace one of the SOREMPs on the MSLT
- Patient has a cerebral spinal fluid (CSF) hypocretin-1 concentration (measured by immunoreactivity) > 110 pg/mL **or** > 1/3 of mean values obtained in normal subjects with the same standardized assay OR CSF hypocretin-1 concentration has not been measured; **AND**
- The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal; **AND**
- **Adult patients only**: Patient has a documented inadequate response, contraindication, or intolerance to monotherapy with a wake-promoting agent (e.g., modafinil, armodafinil, pitolisant); **AND**
- **Both** of the following:
  - Trial and failure, contraindication, or intolerance to **both** of the following:
    - Generic modafinil or armodafinil
    - Sunosi®; **AND**
  - Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate-based stimulant

Diagnosis of **Idiopathic Hypersomnia (Xywav™ only)**

- Patient is at least 18 years of age; **AND**
- Patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months; **AND**
- Patient must not have succinic semialdehyde dehydrogenase deficiency; **AND**
- Patient was evaluated for history of drug abuse prior to initiating therapy; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the Xywav® and Xyrem™ REMS Program; **AND**
- Patient must not use in combination with sedative hypnotic agents (e.g., zolpidem, eszopiclone, zaleplon, benzodiazepines, barbiturates) while on therapy; **AND**
- Patient must not use in combination with alcohol while on therapy; **AND**
- Patient will receive continuous monitoring for signs of misuse or abuse of sodium oxybate (gamma-hydroxybutyrate [GHB]) including, but not limited to, the following: use of increasingly larger doses, increased frequency of use, drug-seeking behavior, feigned cataplexy, etc.); **AND**
- Patient will avoid concomitant use with divalproex sodium. If therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Xyrem® and Xywav™ will not be used concomitantly; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

- Patient does not have cataplexy; **AND**
- Patient has documented baseline daytime sleepiness as measured by a validated scale (e.g., Epworth Sleepiness Scale [ESS], Stanford Sleepiness Scale, Karolinska Sleepiness Scale, or a Visual Analog Scale); **AND**
- Patient has < 2 sleep-onset rapid eye movement periods (SOREMPs) on a multiple sleep latency test (MSLT) performed according to standard techniques, or has no SOREMPs if the REM sleep latency on the preceding nocturnal polysomnogram (PSG) was ≤ 15 minutes; **AND**
- Patient has the presence of at least one of the following:
  - A mean sleep latency of ≤ 8 minutes
  - Total 24-hour sleep time ≥ 660 minutes (typically 12 to 14 hours) on 24-hour polysomnography monitoring or by wrist actigraphy in association with a sleep log; **AND**
- Insufficient sleep syndrome has been ruled out; **AND**
- The hypersomnolence and/or MSLT findings are not better explained by another sleep disorder, other medical or psychiatric disorder, or use of drugs or medications

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include central nervous system (CNS) depression (e.g., clinically significant respiratory depression, obtundation), severe depression and suicidality, other behavioral or psychiatric adverse reactions (e.g., anxiety, hallucinations, paranoia, psychosis, aggression, agitation, confusion), parasomnias, life-threatening respiratory depression, and sleep-disordered breathing, etc.; **AND**
- **Cataplexy in Narcolepsy**
  - Response to treatment as defined by a reduced frequency of cataplexy attacks from pre-treatment baseline
- **Excessive Daytime Sleepiness (EDS) in Narcolepsy**
  - Response to treatment as defined by a reduction in excessive daytime sleepiness from pre-treatment baseline as measured by a validated scale (e.g., Epworth Sleepiness Scale [ESS], Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale)
- **Idiopathic Hypersomnia (Xywav™ only)**
  - Response to treatment as defined by a reduction in excessive daytime sleepiness from pre-treatment baseline as measured by a validated scale (e.g., Epworth Sleepiness Scale [ESS], Stanford Sleepiness Scale, Karolinska Sleepiness Scale, a Visual Analog Scale)

YERVOY® (IPILIMUMAB)

Length of Authorization:	• **Renal Cell Carcinoma (RCC)/ Cutaneous Melanoma *(excluding adjuvant therapy)*/Colorectal Cancer (CRC)/Small Bowel Adenocarcinoma/Advanced Ampullary Cancer /Hepatocellular Carcinoma (HCC)/Uveal Melanoma/CNS Metastases from Melanoma (combination therapy with nivolumab)**: – Coverage will be provided for 12 weeks (may be extended to 16 weeks if 4 doses were not administered within the 12-week time frame) and may not be renewed **Requests for Cutaneous Melanoma may be renewed if the patient meets the provisions for re-induction therapy* • **Non-Small Cell Lung Cancer (NSCLC)/ Malignant Pleural Mesothelioma**: – 6 months, may be renewed every 6 months. Coverage will be provided for up to a maximum of 2 years of therapy • **Cutaneous Melanoma (maintenance adjuvant therapy)**: – Coverage for adjuvant treatment will be provided for 6 months and may be renewed every 6 months. Coverage will be provided for up to a maximum of 3 years of therapy
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cutaneous Melanoma**

- Patient is 18 years of age or older, unless otherwise indicated ; **AND**
- Used as first-line therapy for unresectable or metastatic disease in combination with nivolumab; **OR**
- Used as subsequent therapy for unresectable or metastatic* disease; **AND**
  - Used after disease progression or maximum clinical benefit from BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib); **AND**
    - Used as a single agent in patients at least 12 years of age if not previously used alone or in combination with anti-PD-1 immunotherapy; **OR**
    - Used in combination with nivolumab if not previously used or for patients who progress on single agent anti-PD-1 immunotherapy; **OR**
    - Used in combination with pembrolizumab if not previously used or for patients who progress on single agent anti-PD-1 immunotherapy; **OR**
  - Used for retreatment of disease as re-induction as a single agent or in combination with anti-PD-1 immunotherapy in patients who experienced disease control (i.e., complete or partial response or stable disease), but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **AND**
    - Patient has completed initial induction ipilimumab therapy (completion of 4 cycles within a 16-week period); **OR**
- Used as a single agent for adjuvant therapy; **AND**
  - Patient has pathologic involvement of regional lymph nodes of more than 1 mm and has undergone complete resection including total lymphadenectomy; **OR**
  - Patient has previously received anti-PD-1 therapy (e.g., nivolumab or pembrolizumab); **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Cutaneous Melanoma** *(Continued)*

- Patient has local satellite/in-transit recurrence and has no evidence of disease (NED) after complete excision; **OR**
- Patient has undergone therapeutic lymph node dissection (TLND) and/or complete resection of nodal recurrence; **OR**
- Patient has undergone complete resection of distant metastatic disease

**Metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease*

Diagnosis of **Uveal Melanoma**

- Patient is 18 years of age or older; **AND**
- Used as a single agent or in combination with nivolumab; **AND**
- Patient has distant metastatic disease; **AND**

Diagnosis of **Renal Cell Carcinoma (RCC)**

- Patient is 18 years of age or older; **AND**
- Used in combination with nivolumab for clear cell histology; **AND**
  - Used as first-line therapy in patients with advanced, relapsed, or stage IV disease with poor or intermediate risk; **OR**
  - Used as first-line therapy in patients with relapsed or stage IV disease with favorable risk; **OR**
  - Used as subsequent therapy in patients with relapsed or stage IV disease

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is 18 years of age or older; **AND**
- Used for recurrent, advanced or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Used as first-line therapy; **AND**
  - Used for one of the following:
    - Patients with PS 0-1 who have tumors that are negative for actionable molecular markers** and PD-L1 <1%
    - Used in patients with PS 0-1 who are positive for one of the following molecular markers: BRAF V600E-mutation, NTRK 1/2/3 gene fusion, MET exon 14 skipping mutation
    - PD-L1 expression positive (PD-L1 ≥ 1%) tumors, as detected by an FDA or CLIA compliant test, that are negative for actionable molecular markers; **AND**
  - Used in combination with nivolumab; **OR**
  - Used in combination with nivolumab and platinum-doublet chemotherapy (e.g., pemetrexed and either carboplatin or cisplatin for non-squamous cell histology, paclitaxel and carboplatin for squamous cell histology); **OR**
- Used as subsequent therapy; **AND**
  - Used for one of the following:
    - Patients with PS 0-1 who ROS1 positive tumors and have received prior targeted therapy
    - Patients with PS 0-1 who are positive for one of the following molecular markers: BRAF V600E mutation, NTRK 1/2/3 gene fusion, or MET exon 14 skipping mutation; **AND**

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)** *(Continued)*

- Used in combination with nivolumab; **OR**
- Used in combination with nivolumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; **OR**
- Used in combination with nivolumab, paclitaxel and carboplatin for squamous cell histology; **OR**

- Used as continuation maintenance therapy in combination with nivolumab; **AND**
  - Patient has achieved a response or stable disease following first-line therapy with nivolumab and ipilimumab with or without chemotherapy

> *** Note: Actionable molecular genomic biomarkers include EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, and RET rearrangement. If there is insufficient tissue to allow testing for all of EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET, and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

Diagnosis of **Malignant Pleural Mesothelioma**

- Patient is 18 years of age or older; **AND**
- Used in combination with nivolumab; **AND**
  - Used as subsequent therapy; **OR**
  - Used as first-line therapy in patients with stage IIIB or IV disease, sarcomatoid histology, medically inoperable tumors, or unresectable disease

Diagnosis of **Central Nervous System Cancers**

- Patient is 18 years of age or older; **AND**
- Used for the treatment of brain metastases in patients with melanoma; **AND**
- Used in combination with nivolumab or as a single agent; **AND**
  - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
  - Used for relapsed disease in patients with limited brain metastases and either stable systemic disease or reasonable systemic treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

Diagnosis of **Colorectal Cancer**

- Patient is 12 years of age or older; **AND**
- Patient's disease must be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); **AND**
- Used in combination with nivolumab; **AND**
  - Used for advanced or metastatic disease that progressed following treatment with one of the following:
    - Fluoropyrimidine-, oxaliplatin-, and/or irinotecan-based chemotherapy; **OR**
    - Non-intensive therapy**; OR**
  - Used as primary treatment for unresectable or medically inoperable, locally advanced, or metastatic disease***** *(excluding use as neoadjuvant therapy in rectal cancer)*; **OR**
  - Used for unresectable (or medically inoperable) metastases that remains unresectable after primary systemic therapy*****

** Single agent nivolumab should be used in patients who are not candidates for intensive therapy*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Small Bowel Adenocarcinoma/Advanced Ampullary Cancer**

- Patient is 18 years of age or older; **AND**
- Patient has advanced or metastatic disease that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR): **AND**
- Patient has not previously received treatment with a checkpoint inhibitor (e.g., nivolumab, pembrolizumab); **AND**
- Used in combination with nivolumab; **AND**
  - Used as initial therapy; **OR**
  - Uses as subsequent therapy for patients with no prior oxaliplatin exposure in the adjuvant treatment setting and no contraindication to oxaliplatin therapy

Diagnosis of **Hepatocellular Carcinoma (HCC)**

- Patient is 18 years of age or older; **AND**
- Used in combination with nivolumab; **AND**
- Patient has unresectable or metastatic disease, inoperable (i.e., by performance status, comorbidity or with minimal or uncertain extrahepatic-disease) liver-confined disease, or disease with extensive liver tumor burden; **AND**
- Used as subsequent therapy; **AND**
- Patient has Child-Pugh Class A disease

Genomic Aberration/Mutational Driver Targeted Therapies (Note: *not all inclusive, refer to guidelines for appropriate use*) §				
Sensitizing *EGFR* mutation-positive tumors	*ALK* rearrangement-positive tumors	*ROS1* rearrangement-positive tumors	*BRAF* V600E-mutation positive tumors	*NTRK* Gene Fusion positive tumors
Afatinib Erlotinib Dacomitinib Gefitinib Osimertinib Amivantamab *(exon-20 insertion)*	Alectinib Brigatinib Ceritinib Crizotinib Lorlatinib	Ceritinib Crizotinib Entrectinib	Dabrafenib ± Trametinib Vemurafenib	Larotrectinib Entrectinib
PD-1/PD-L1 expression-positive tumors (≥1%)	*MET* Exon-14 skipping mutations	*RET* rearrangement-positive tumors	KRAS G12C mutations	
Pembrolizumab Atezolizumab Nivolumab ± ipilimumab	Capmatinib Crizotinib Tepotinib	Selpercatinib Cabozantinib Vandetanib Pralsetinib	Sotorasib	

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include immune-mediated reactions (e.g., colitis, hepatitis, dermatitis/skin adverse reactions, pneumonitis, nephritis/renal dysfunction, endocrinopathies), severe infusion reactions, etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Coverage may **not** be renewed for the following indications:
  - Renal cell carcinoma (RCC)
  - Colorectal cancer *(disease progression or after primary treatment)*
  - Small bowel adenocarcinoma (SBA)/advanced ampullary cancer
  - Hepatocellular carcinoma (HCC)
  - Cutaneous melanoma (*first-line or subsequent therapy)*
  - Uveal melanoma
  - CNS metastases from melanoma (combination therapy with nivolumab)
- **Cutaneous melanoma (re-induction therapy)**
  - Refer to initial criteria. Used for retreatment of disease as re-induction
- **Cutaneous melanoma maintenance therapy (adjuvant treatment)**
  - Patient has not exceeded a maximum of 3 years of therapy
- **Non-Small Cell Lung Cancer (in combination with nivolumab with or without platinum-doublet chemotherapy)**
  - Patient has not exceeded a maximum of 2 years of therapy

Non-Small Cell Lung Cancer (maintenance therapy)

  - Refer to initial criteria.
- **Malignant pleural mesothelioma (MPM)**
  - Patient has not exceeded a maximum of 2 years of therapy.

YESCARTA® (AXICABTAGENE CILOLEUCEL)

Length of Authorization:	1 treatment course (1 dose of Yescarta®) and may not be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Submission of medical records related to the medical necessity criteria is **required** on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation via direct upload through the PA web portal or by fax.

Diagnosis of **B-Cell Lymphomas**

- Patient is 18 years old or older; **AND**
- Patient does not have a clinically significant active systemic infection or inflammatory disorder; **AND**
- Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccine during axicabtagene ciloleucel treatment and until immune recovery following treatment; **AND**
- Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- Prophylaxis for infection will be followed according to local guidelines; **AND**
- Healthcare facility has enrolled in the YESCARTA & TECARTUS REMS Program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; **AND**
- Patient has not received prior CAR-T therapy; **AND**
- Patient has not received prior anti-CD19 therapy, (e.g., blinatumomab) **or** patient previously received anti-CD19 therapy and re-biopsy indicates CD19-positive disease; **AND**
- Used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); **AND**
- Patient did not receive prior allogeneic hematopoietic stem cell transplantation (HSCT); **AND**
- Patient has an ECOG performance status of 0-1; **AND**
- Patient does not have primary central nervous system lymphoma; **AND**
- Patient has histologic transformation of follicular lymphoma or nodal marginal zone lymphoma to diffuse large B-cell lymphoma (DLBCL) **or** Richter's transformation of CLL to DLBCL; **AND**
  - Patient received two (2) or more prior lines of chemoimmunotherapy which must have included an anthracycline or anthracenedione-based regimen, unless contraindicated; **OR**
- Patient has AIDS-related large B-cell lymphoma (e.g., diffuse large B-cell lymphoma, primary effusion lymphoma, and HHV8-positive diffuse large B-cell lymphoma, not otherwise specified), DLBCL, primary mediastinal large B-cell lymphoma (PMBCL), high grade B-cell lymphoma, or monomorphic post-transplant lymphoproliferative disorder (B-cell type); **AND**
  - Used as additional therapy for patients with intention to proceed to transplant who have partial response following second-line therapy for relapsed or refractory disease; **OR**
  - Used for treatment of disease that is in second or greater relapse; **OR**
- Patient has grade 1-2 follicular lymphoma; **AND**
  - Disease is relapsed, refractory, or progressive after two (2) or more prior lines of therapy

CLINICAL CRITERIA FOR RENEWAL

- May not be renewed

YONDELIS® (TRABECTEDIN)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Soft Tissue Sarcoma**

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Used as single agent therapy; **AND**
- Patient has unresectable or metastatic liposarcoma or leiomyosarcoma; **AND**
  - Used as subsequent therapy after an anthracycline-containing regimen (e.g., doxorubicin, etc.); **OR**
- Used as neo-adjuvant or adjuvant therapy for myxoid liposarcoma; **AND**
  - Patient has a diagnosis of one of the following sub-types of soft tissue sarcoma:
    - Retroperitoneal/Intra-abdominal; **AND**
      - Used pre-operatively for primary or recurrent disease; **OR**
      - Used post-operatively for disease at high risk of local recurrence or becoming metastatic (excludes use for low-grade tumors)
    - Extremity/body wall, head/neck; **AND**
      - Used for stage II-IV disease
- Used as palliative therapy; **AND**
  - Patient has a diagnosis of one of the following sub-types of soft tissue sarcoma:
    - Angiosarcoma
    - Rhabdomyosarcoma; **AND**
      - Used as subsequent therapy for advanced or metastatic pleomorphic rhabdomyosarcoma
    - Retroperitoneal/Intra-abdominal; **AND**
      - Used as subsequent therapy for recurrent unresectable or stage IV disease
    - Extremity/body wall, head/neck; **AND**
      - Used as subsequent therapy for advanced or metastatic disease with disseminated metastases
    - Solitary fibrous tumor

Diagnosis of **Uterine Sarcoma**

- Patient is at least 18 years of age; **AND**
- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Used as single agent therapy; **AND**
- Patient has uterine leiomyosarcoma; **AND**
- Used as subsequent therapy after an anthracycline-containing regimen (e.g., doxorubicin, etc.); **AND**
  - Patient has unresectable, metastatic or recurrent disease; **OR**
  - Patient has disease that is not suitable for primary surgery

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., cardiomyopathy, rhabdomyolysis, hepatotoxicity and/or severe hepatic impairment, capillary leak syndrome [CPS], severe neutropenia/neutropenic sepsis, extravasation resulting in tissue necrosis); **AND**
- Left ventricular ejection fraction (LVEF) has not had an **absolute** decrease of ≥ 15% from baseline OR is not below the lower limit of normal (LLN) with an absolute decrease of ≥ 5% (LVEF results must be within the previous 3 months)

YUTIQ™ (FLUOCINOLONE ACETONIDE IMPLANT)

Length of Authorization:	Coverage will be provided for 1 implant per eye every 36 months and may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic non-infectious uveitis affecting the posterior segment of eye**

- Patient is at least 18 years of age; **AND**
- Patient is free of ocular and periocular infections; **AND**
- Must not be used in combination with other sustained-release intravitreal corticosteroids (e.g., dexamethasone implant); **AND**
- Patient does not have a torn or ruptured posterior lens capsule; **AND**
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Patient's intraocular pressure is measured at baseline and periodically throughout therapy; **AND**
- Patient has had chronic disease for at least one year; **AND**
- Other causes of uveitis have been ruled out (e.g., infectious, malignancy)

CLINICAL CRITERIA FOR RENEWAL

- Absence of unacceptable toxicity from the drug (e.g., cataract formation, endophthalmitis, increased intra-ocular pressure); **AND**
- Disease response as indicated by:
  - Stabilization of visual acuity or improvement in BCVA score when compared to baseline; **OR**
  - Improvement in vitreous haze score (decrease in inflammation).

ZALTRAP® (ZIV-AFLIBERCEPT)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Colorectal Cancer**

- Patient is at least 18 years of age; **AND**
- Must be used in combination with irinotecan or FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen; **AND**
  - Patient has metastatic disease that is resistant to or has progressed following an oxaliplatin-containing regimen (e.g., FOLFOX, CapeOX); **OR**
  - Used as primary treatment for patients with unresectable metachronous metastases; **AND**
    - Patient received previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months; **OR**
  - Used as subsequent therapy for progression of advanced or metastatic disease in patients **not** previously treated with irinotecan-based therapy.

CLINICAL CRITERIA FOR RENEWAL

Coverage can be renewed based upon the following criteria:

- Disease response with treatment a defined by stabilization of disease or decrease in size or spread of tumor; **AND**
- Absence of unacceptable toxicity from the drug (e.g., hemorrhage, gastrointestinal perforation, fistula formation, uncontrolled hypertension, hypertensive crisis, hypertensive encephalopathy, wound healing complications, arterial thromboembolic events, proteinuria [≥ 2 g/24 hours], nephrotic syndrome, thrombotic microangiopathy [TMA], neutropenic complications, reversible posterior leukoencephalopathy syndrome [RPLS], severe diarrhea/dehydration)

ZAVESCA® (MIGLUSTAT)

Length of Authorization:	12-month and may be renewed
Initiative:	SPC: Enzyme Deficiency (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Type 1 Gaucher Disease**

- Patient is 18 years of age or older; **AND**
- Must be used as a single agent; **AND**
- Patient is not a candidate (e.g. due to allergy, hypersensitivity, or poor venous access) for enzyme replacement therapy (e.g., imiglucerase, taliglucerase alfa, velaglucerase alfa)
- Patient has a documented diagnosis of Type 1 Gaucher Disease as confirmed by a beta-glucosidase leukocyte (BGL) test with significantly reduced or absent glucocerebrosidase enzyme activity; **AND**
- Patient's disease results in one or more of the following conditions:
  - Anemia (i.e., hemoglobin less than or equal to 11 g/dL [women] or 12 g/dL [men]) not attributed to iron, folic acid or vitamin B12 deficiency; **OR**
  - Moderate to severe hepatomegaly (liver size 1.25 or more times normal) or splenomegaly (spleen size 5 or more times normal); **OR**
  - Skeletal disease (e.g., lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis); **OR**
  - Symptomatic disease (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life); **OR**
  - Thrombocytopenia (platelet count less than or equal to 120,000/mm^3)

CLINICAL CRITERIA FOR RENEWAL

Coverage can be renewed based on the following criteria:

- Disease response with treatment as defined by one or more of the following (compared to pre-treatment baseline):
  - Improvement in symptoms (e.g. bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life, peripheral neuropathy)
  - Reduction in size of liver or spleen
  - Improvement in hemoglobin/anemia
  - Improvement in skeletal disease (e.g. increase in lumbar spine and/or femoral neck BMD, no bone crises or bone fractures)
  - Improvement in platelet counts; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe diarrhea and weight loss, severe tremors, peripheral neuropathies, thrombocytopenia, etc.

ZEJULA® (NIRAPARIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Ovarian Cancer (Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer)**

- Patient must be 18 years of age or older; **AND**
- Patient has not received prior treatment with a PARP-inhibitor (i.e., olaparib, rucaparib, or talazoparib) prior to initiating therapy; **AND**
- Used as single agent therapy for maintenance treatment; **AND**
  - Patient has recurrent disease; **AND**
    - Patient is in complete or partial response after most recent platinum-based chemotherapy (i.e., platinum-sensitive); **AND**
    - Patient has completed two or more lines of previous platinum-based therapy; **OR**
  - Patient has advanced disease; **AND**
    - Used as first-line maintenance therapy; **AND**
    - Patient is in a complete or partial response to first-line platinum-based therapy; **AND**
    - Patient will start treatment no later than 12 weeks after their most recent platinum-containing regimen; **AND**
    - Laboratory value for platelet count is current (i.e., within the previous 28 days); **OR**
  - Patient has stage II–IV carcinosarcoma in CR/PR following primary therapy with or without bevacizumab; **AND**
    - Patient has germline or somatic BRCA1/2 mutation; **OR**
  - Patient has stage III–IV high-grade serous or grade 2/3 endometrioid carcinoma; **AND**
    - Patient is in complete or partial response after primary therapy with or without bevacizumab; **OR**
- Used as treatment of advanced, persistent, or recurrent disease; **AND**
  - Used as single-agent subsequent therapy after at least three prior chemotherapy regimens; **AND**
    - Patient has homologous recombination deficiency (HRD) positive disease as defined by one of the following:
      - Patient has a deleterious or suspected deleterious BRCA mutation as detected by a CLIA-compliant or FDA-approved test; **OR**
      - Patient has a genomic instability score (GIS) of ≥ 42 and has progressed more than six months after an initial response to the last platinum-based chemotherapy; **OR**
- Used in combination with bevacizumab for platinum-sensitive disease; **AND**
  - Patient has persistent or recurrent disease; **AND**
  - Patient has experienced radiographic and/or clinical relapse at least 6 months after a previous complete remission from prior chemotherapy regimen

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., development of myelodysplastic syndrome/acute myeloid leukemia [MDS/AML], bone marrow suppression [e.g., thrombocytopenia, anemia, neutropenia], cardiovascular effects [hypertension/hypertensive crisis]), posterior reversible encephalopathy syndrome (PRES), allergic-type reactions (including bronchial asthma) to FD&C Yellow No. 5 (tartrazine), etc.; **AND**

First-line maintenance treatment of advanced disease

- Patient has laboratory value for platelet count that is current (i.e., within the previous 28 days)

ZELBORAF® (VEMURAFENIB)

Length of Authorization:	6 months, may be renewed Coverage for the adjuvant treatment of melanoma is up to a maximum of 1 year of therapy
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cutaneous Melanoma**

- Patient is at least 18 years of age; **AND**
- Patient does not have long QT syndrome; **AND**
- Baseline electrocardiogram (ECG) QTc >500 milliseconds prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole), if therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin), if therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Drugs known to prolong the QT interval (e.g., amitriptyline, amiodarone); **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib) unless otherwise specified; **AND**
- Patient has BRAF V600 mutation-positive disease as detected by a Food and Drug Administration (FDA)-approved or Clinical Laboratory Improvement Amendments (CLIA)-compliant test; **AND**
  - Patient has unresectable or metastatic** disease; **AND**
    - Used in combination with atezolizumab and cobimetinib as first-line therapy; **OR**
    - Used in combination with cobimetinib **or** as a single agent if BRAF/MEK inhibitor combination therapy is contraindicated; **AND**
      - Used as initial therapy or subsequent therapy; **OR**
      - Used as re-induction therapy for patients who experience disease control (i.e., complete response, partial response, or stable disease) from prior BRAF inhibitor therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**
  - Used as adjuvant therapy in combination with cobimetinib in patients with unacceptable toxicities to dabrafenib/trametinib; **AND**
    - Patient has lymph node involvement following complete resection, complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; **OR**
    - Patient has clinical satellite/in-transit metastases or local satellite/in-transit recurrence with no evidence of disease (NED) after complete excision to clear margins

***Metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease.*

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Histiocytic Neoplasms**

- Patient is at least 18 years of age; **AND**
- Patient does not have long QT syndrome; **AND**
- Baseline electrocardiogram (ECG) QTc >500 milliseconds prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Drugs known to prolong the QT interval (e.g., amitriptyline, amiodarone); **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib); **AND**
- Patient has BRAF V600E mutation-positive disease; **AND**
- Used as a single agent; **AND**
- Patient has one of the following:
  - Erdheim-Chester disease (note: can be used for other BRAF-V600 mutations); **OR**
  - Langerhans cell histiocytosis (LCH); **AND**
    - Patient has multisystem disease with symptomatic or impending organ dysfunction; **OR**
    - Patient has pulmonary disease; **OR**
    - Patient has multifocal single system bone disease not responsive to treatment with a bisphosphonate and >2 lesions; **OR**
    - Patient has central nervous system (CNS) lesions; **OR**
    - Patient has relapsed or refractory disease

Diagnosis of **Central Nervous System (CNS) Cancers**

- Patient is at least 18 years of age; **AND**
- Patient does not have long QT syndrome; **AND**
- Baseline electrocardiogram (ECG) QTc >500 milliseconds prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Drugs known to prolong the QT interval (e.g., amitriptyline, amiodarone); **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib); **AND**
- Patient has BRAF V600E mutation-positive disease; **AND**
- Used in combination with cobimetinib; **AND**
  - Used as adjuvant treatment in a patient with incomplete resection, biopsy, or surgically inaccessible location; **AND**
    - Patient has pilocytic astrocytoma **or** pleomorphic xanthoastrocytoma (PXA) **or** ganglioglioma; **OR**
  - Used for treatment of recurrent or progressive low-grade glioma; **OR**
  - Used for treatment of recurrent anaplastic glioma or glioblastoma

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**

- Patient is at least 18 years of age; **AND**
- Patient does not have long QT syndrome; **AND**
- Baseline electrocardiogram (ECG) QTc >500 milliseconds prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Drugs known to prolong the QT interval (e.g., amitriptyline, amiodarone); **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib); **AND**
- Patient has BRAF V600E mutation- positive disease; **AND**
- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Used as a single agent if the combination of dabrafenib plus trametinib is not tolerated; **AND**
  - Used as first line therapy; **OR**
  - Used as subsequent therapy following progression on first-line therapy with a non-BRAF-targeted regimen

Diagnosis of **Hairy Cell Leukemia**

- Patient is at least 18 years of age; **AND**
- Patient does not have long QT syndrome; **AND**
- Baseline electrocardiogram (ECG) QTc >500 milliseconds prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Drugs known to prolong the QT interval (e.g., amitriptyline, amiodarone); **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib); **AND**
- Used as a single agent; **AND**
  - Patient had a less than complete response to initial purine analog therapy (e.g., cladribine or pentostatin); **OR**
  - Patient relapsed within 2 years of a complete response; **OR**
- Used with or without rituximab for progression after therapy for relapsed or refractory disease

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

Diagnosis of **Differentiated Thyroid Carcinoma (Papillary, Follicular, or Hürthle Cell)**

- Patient is at least 18 years of age; **AND**
- Patient does not have long QT syndrome; **AND**
- Baseline electrocardiogram (ECG) QTc > 500 milliseconds prior to initiating therapy and will be assessed at regular intervals during treatment; **AND**
- Patient will avoid coadministration with all of the following:
  - Strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin). If therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications will be implemented
  - Drugs known to prolong the QT interval (e.g., amitriptyline, amiodarone); **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib); **AND**
- Patient has progressive and/or symptomatic BRAF mutation-positive disease; **AND**
- Patient has unresectable locoregional recurrent disease, persistent disease, or distant metastases; **AND**
- Disease is not susceptible to radioactive-iodine (RAI) therapy; **AND**
- Alternative therapies (e.g., clinical trial or systemic therapy) are not available or appropriate; **AND**
- Used as a single agent

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: new primary malignancies, uveitis, severe dermatologic reactions (e.g., Stevens-Johnson syndrome, toxic epidermal necrolysis), severe photosensitivity reactions, severe hepatotoxicity, renal failure, QTc prolongation (e.g., QTc ≤ 500 milliseconds), severe hemorrhagic events, severe radiation sensitization/recall, severe Dupuytren's Contracture and plantar fascial fibromatosis, severe hypersensitivity reactions, etc.; **AND**
- Adjuvant treatment of Melanoma 2
  - Treatment has not exceeded 1 year of therapy
- **Cutaneous Melanoma (re-induction therapy)**
  - Refer to initial criteria. (See **Cutaneous Melanoma** – used as re-induction therapy)

ZEMPLAR® (PARICALCITOL)

Length of Authorization:	6 months
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis, prevention, or treatment of **secondary hyperparathyroidism associated with chronic renal failure.**

ZEPZELCA™ (LURBINECTEDIN)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Small Cell Lung Cancer**

- Patient is at least 18 years of age; **AND**
- Used as single agent therapy; **AND**
- Used for metastatic disease after disease progression on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin); **OR**
- Used for relapsed or primary progressive disease as subsequent therapy

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., myelosuppression, hepatotoxicity)

ZEVALIN® (IBRITUMOMAB TIUXETAN)

Length of Authorization:	Coverage will be provided for one administration and cannot be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Relapsed, Refractory, or Progressive, Low-Grade or Follicular B-Cell Non-Hodgkin Lymphoma (NHL)**

- Patient is 18 years of age or older; **AND**
- Patient must not have a platelet count < 100,000 cells/mm^3; **AND**
- Must be used as a single agent following two doses of rituximab (see dosage/administration); **AND**
- Patient has adequate marrow cellularity of > 15%; **AND**
- Patient has < 25% involvement of lymphoma in bone marrow**; AND**
- Ibritumomab was not previously given

Diagnosis of **Previously Untreated Follicular NHL**

- Patient is 18 years of age or older; **AND**
- Patient must not have a platelet count < 100,000 cells/mm^3; **AND**
- Must be used as a single agent following two doses of rituximab (see dosage/administration); **AND**
- Patient has adequate marrow cellularity of > 15%; **AND**
- Patient has < 25% involvement of lymphoma in bone marrow; **AND**
- Patient achieved a partial or complete response to first-line chemotherapy

Diagnosis of **Diffuse Large B-cell Lymphoma (DLBCL)**

- Patient is 18 years of age or older; **AND**
- Patient must not have a platelet count < 100,000 cells/mm^3; **AND**
- Must be used as a single agent following two doses of rituximab (see dosage/administration); **AND**
- Patient has adequate marrow cellularity of > 15%; **AND**
- Patient has < 25% involvement of lymphoma in bone marrow; **AND**
- Used as second-line or subsequent therapy for relapsed or refractory primary cutaneous disease of the leg type

CLINICAL CRITERIA FOR RENEWAL

- May **not** be renewed

ZILRETTA® (TRIAMCINOLONE ACETONIDE ER)

Length of Authorization:	Coverage will be provided for one dose per knee and cannot be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Osteoarthritis of the Knee**

- Patient is at least 18 years of age; **AND**
- Patient does not have any conditions which would preclude intra-articular injections (e.g., active joint infection, unstable joint); **AND**
- Patient has not received therapy with intra-articular hyaluronic acid derivative drugs within the previous 6 months of therapy; **AND**
- Patient has not received therapy with intra-articular short-acting corticosteroid type drugs within the previous 3 months of therapy; **AND**
- Patient has a radiographically confirmed diagnosis of osteoarthritis of the knee; **AND**
- The patient has had a trial and failure to BOTH of the following conservative methods which have not resulted in functional improvement after at least three (3) months:
  - Non-Pharmacologic (i.e., physical, psychosocial, or mind-body approach [e.g., exercise-land based or aquatic, physical therapy, tai chi, yoga, weight management, cognitive behavioral therapy, knee brace or cane]); **AND**
  - Pharmacologic Approach (e.g., topical NSAIDs, oral NSAIDs with or without oral proton pump inhibitors, COX-2 inhibitors, topical capsaicin, acetaminophen, tramadol, duloxetine); **AND**
- The patient has failed to adequately respond to, or has a contraindication to, aspiration and injection of a short-acting intra-articular corticosteroid; **AND**
- The patient reports pain which interferes with functional activities (e.g., ambulation, prolonged standing)

CLINICAL CRITERIA FOR RENEWAL

- May **not** be renewed

ZINECARD® (DEXRAZOXANE)

Length of Authorization:	6 months
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **anthracycline-induced cardiomyopathy prophylaxis or extravasations**

- Either:
  - Diagnosis of any malignancy or cancer; **AND**
  - Patient has received a cumulative doxorubicin dose of 300 mg/m^2**; OR**
- All of the following must be met
  - Diagnosis of advance breast cancer; **AND**
  - Patient is responding to anthracycline-based chemotherapy (e.g., Adriamycin/doxorubicin); **AND**
  - Patient will continue to receive one of the following: Ellence (epirubicin) or Adriamycin (doxorubicin); **AND**
  - Prescribed by an oncologist.

ZOKINVY™ (LONAFARNIB)

Length of Authorization:	12 months, may be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Progeria Syndrome**

- Patient is 12 months of age or older; **AND**
- Patient does NOT have other non-laminopathy Progeroid Syndromes or processing-proficient Progeroid Laminopathies or Laminopathies with no progeria features (mutation in the *LMNA* gene with no clinical characteristic features); **AND**
- Patient has a body-surface area of at least 0.39 m^2; **AND**
- Patient will have periodic ophthalmological examinations during treatment; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with midazolam; **AND**
  - Coadministration with HMG-CoA reductase inhibitors (e.g., lovastatin, simvastatin or atorvastatin); **AND**
  - Coadministration with strong or moderate CYP3A inhibitors (e.g., fluconazole, itraconazole, etc.); **AND**
  - Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with strong or moderate CYP2C9 inhibitors (e.g., voriconazole, metronidazole, Fluvastatin, sulfamethoxazole, etc.. Iif therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient has at least one or more of the following clinical features suggestive of progeria:
  - Profound failure to thrive during the first year
  - Characteristic facial appearance (e.g., micrognathia, prominent eyes, and circumoral cyanosis)
  - Sclerodermatous skin changes (e.g., taut, thickened, fibrotic, indurated, or rippled)
  - Alopecia and/or prominent scalp veins
  - Decreased joint range of motion and joint contractures
  - X-ray findings (e.g., distal clavicular, terminal phalangeal resorption, coxa valga, delayed/incomplete primary tooth eruption, etc.)
  - Severe atherosclerosis and/or cardiac disease (e.g., myocardial infarction or heart failure, cerebrovascular disease (stroke), etc.); **AND**
- Patient has a diagnosis of one of the following:
  - Hutchinson-Gilford Progeria Syndrome (HGPS); **AND**
    - Patient has had a confirmatory mutational analysis with a G608G mutation in the lamin A gene [*LMNA* gene] (i.e., c.1824C>T); **OR**
  - Processing-deficient Progeroid Laminopathies; **AND**
    - Heterozygous *LMNA* mutation with progerin-like protein accumulation (i.e., pathogenic variant in either the exon 11 splice junction or intron 11 of *LMNA* gene); **OR**
    - Homozygous or compound heterozygous *ZMPSTE24* mutations

CLINICAL CRITERIA FOR RENEWAL

- Patient continues to meet indication-specific relevant criteria identified in initial criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe laboratory abnormalities, severe nephrotoxicity, severe retinal toxicity, etc.; **AND**
- Disease response as indicated by improvement or stabilization in patient's signs and/or symptoms and/or disease status (e.g., no new or worsening heart failure, no stroke incidence, evidence of decreased carotid-femoral pulse wave velocity, evidence of decrease carotid artery wall echodensity, etc.)

ZOLEDRONIC ACID (ZOMETA®, RECLAST®) (INTRAVENOUS)

Length of Authorization:	Zometa: 12 months, may be renewed Reclast: • Prevention of osteoporosis in post-menopausal women: Coverage is provided for 24 months and may be renewed. • All other indications: Coverage is provided for 12 months and may be renewed (unless otherwise specified)
Initiative:	SPC: Osteoporosis Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

ZOMETA®

- Reclast®/Zometa® should not be used in combination with one another, other bisphosphonates, denosumab, romosozumab, or parathyroid hormone analogs/related peptides; **AND**
- Patient does not have hypocalcemia (supplement adequately with calcium and vitamin D); **AND**
- Patient must have a CrCl ≥ 30 mL/min; **AND**
- Coverage is provided in the following conditions:
  - Hypercalcemia of malignancy
  - Multiple myeloma
  - Bone metastases from solid tumors (in conjunction with standard antineoplastic therapy)
  - Prevention of skeletal related events in men with castration-recurrent prostate cancer
  - Prevention of bone loss associated with aromatase inhibitor therapy for breast cancer in post-menopausal women or premenopausal women on adjuvant ovarian suppression
  - Prevention of bone loss associated with androgen deprivation therapy in men with prostate cancer
  - Treatment of osteopenia/osteoporosis in patients with systemic mastocytosis
  - Langerhans Cell Histiocytosis

RECLAST®

- Reclast®/Zometa® should not be used in combination with one another, other bisphosphonates, denosumab, romosozumab, or parathyroid hormone analogs/related peptides; **AND**
- Patient does not have hypocalcemia (supplement adequately with calcium and vitamin D); **AND**
- Patient must have a CrCl ≥ 35 mL/min and no evidence of acute renal impairment; **AND**
- Coverage is provided in the following conditions:
  - Treatment and prevention of postmenopausal osteoporosis
    - Patient experienced severe intolerance, ineffective response±, or has contraindications* to oral bisphosphonate therapy; **OR**
    - Patient had a prior fragility fracture or is at especially high fracture risk

Note: Patients discontinuing treatment with denosumab due to a reduction in fracture risk (i.e., no longer high or very high risk) require subsequent antiresorptive therapy in order to prevent accelerated bone mineral density loss and increase in fracture risk. Coverage is provided for **one** administration for this use prior to temporary discontinuation of intravenous antiresorptive therapy

  - Treatment to increase bone mass in men with osteoporosis
    - Patient experienced severe intolerance, ineffective response±, or has contraindications* to oral bisphosphonate therapy; **OR**
    - Patient had a prior fragility fracture or is at especially high fracture risk

CLINICAL CRITERIA FOR INITIAL APPROVAL *(CONTINUED)*

RECLAST® *(CONTINUED)*

- Treatment and prevention of glucocorticoid-induced osteoporosis
  - Patient experienced severe intolerance, ineffective response±, or has contraindications* to oral bisphosphonate therapy; **OR**
  - Patient had a prior fragility fracture or is at especially high fracture risk
- Treatment of Paget's disease of bone in men and women
  - Serum alkaline phosphatase is two times or higher than the upper limit of the age-specific reference range; **OR**
  - Patient is symptomatic; **OR**
  - Patient is at risk for complications from their disease
- Prevention or treatment of osteoporosis in men with prostate cancer during androgen deprivation therapy

± Ineffective response is defined as one or more of the following:
• Decrease in T-score in comparison with baseline T-score from DXA scan • Patient has a new fracture while on bisphosphonate therapy
*** Examples of contraindications to oral bisphosphonate therapy include the following:**
• Documented inability to sit or stand upright for at least 30 minutes • Documented pre-existing gastrointestinal disorder such as inability to swallow, Barrett's esophagus, esophageal stricture, dysmotility, or achalasia

CLINICAL CRITERIA FOR RENEWAL

Absence of unacceptable toxicity from the drug (e.g., renal toxicity, osteonecrosis of the jaw, atypical femoral fractures, hypocalcemia, incapacitating pain in the bone/joint/muscle); **AND**

RECLAST®

- Disease response as indicated by the following:
  - Osteoporosis indications:
    - Absence of fractures; **OR**
    - Increase in bone mineral density compared to pretreatment baseline; **AND**
      - Patients who have received 3 years of bisphosphonate therapy should be re-evaluated with a DXA or serum marker for bone turnover (i.e., serum C-terminal crosslinking telopeptide [CTX]); **AND**
      - Those patients at low-to-moderate risk of fractures should be considered for a temporary discontinuation of bisphosphonate for up to 5 years (re-assess risk at 2 to 4 year intervals to determine if earlier re-initiation is necessary)
    - **Paget's Disease:** normalization of serum alkaline phosphatase (SAP) or a reduction of ≥ 75% from baseline in total SAP excess (defined as the difference between the measured level and midpoint of normal range)

CLINICAL CRITERIA FOR RENEWAL *(CONTINUED)*

ZOMETA®

- Disease response as indicated by the following:
  - **Bone metastases/MM**: absence/delay in skeletal-related events (e.g., pathologic fracture, radiation therapy to bone, surgery to bone, or spinal cord compression)
  - **Hypercalcemia of Malignancy**: corrected serum calcium ≤ 11.5 mg/dL
  - **Prevention of bone loss/SRE in cancer patients/Osteoporosis or Osteopenia in Systemic Mastocytosis**:
    - Absence of fractures; **OR**
    - Increase in bone mineral density compared to pretreatment baseline
  - **Langerhans Cell Histiocytosis**:
    - Improvement in bone pain; **OR**
    - Improvement/resolution in active bone lesions compared to pretreatment baseline

ZOLGENSMA® (ONASEMNOGENE ABEPARVOVEC-XIOI)

Length of Authorization:	One dose, may not be renewed
Initiative:	SPC: Miscellaneous PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Submission of medical records related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation via direct upload through the PA web portal or by fax.

Diagnosis of **Spinal Muscular Atrophy (SMA)**

- Patient must be less than 2 years of age; **AND**
- Patient has a diagnosis of 5q spinal muscular atrophy confirmed by either bi-allelic deletion or dysfunctional point mutation of the *SMN1* gene; **AND**
- Patient must have SMA phenotype 1 confirmed by one or more of the following:
  - Patient must have 1–2 copies of the *SMN2* gene; **OR**
  - Patient has 3 copies of the *SMN2* gene in the absence of the c.859G>C single base substitution modification in exon 7; **AND**
- Patient must have a baseline anti-AAV9 antibody titer of ≤ 1:50 measured by ELISA; **AND**
- Patient does not have pre-existing hepatic insufficiency; **AND**
- Must be used concomitantly with parenteral corticosteroids (see dosage/administration below); **AND**
- Patient must not have advanced disease (e.g., complete limb paralysis, permanent ventilation support); **AND**
- Patient will not use in combination with other agents for SMA (e.g., nusinersen, risdiplam)

CLINICAL CRITERIA FOR RENEWAL

- May **not** be renewed

ZOLINZA® (VORINOSTAT)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Cutaneous T-Cell Lymphoma (Mycosis Fungoides/Sézary Syndrome)**

- Patient is at least 18 years of age; **AND**
- Patient has progressive, persistent, or recurrent disease following treatment with two systemic therapies; **OR**
- Patient has stage IA – IV disease *(excluding use for stage IA – IIA MF with B1 blood involvement)*

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., pulmonary embolism, deep vein thrombosis, myelosuppression [e.g., thrombocytopenia, anemia], gastrointestinal toxicity, hyperglycemia, clinical chemistry abnormalities, severe thrombocytopenia with other histone deacetylase [HDAC] inhibitors)

ZONTIVITY® (VORAPAXAR)

Length of Authorization:	12 months
Initiative:	MNC: Miscellaneous PA required (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of reduction of thrombotic cardiovascular event in patients with a history of ONE of the following:

- At least **two** weeks of post-myocardial infarction; **OR**
- Peripheral arterial disease (PAD); **AND**
  - Used in combination with aspirin and/or clopidogrel therapy; **AND**
  - Patient does not have a history of ALL of the following:
    - Stroke
    - Transient ischemic attack (TIA)
    - Intracranial hemorrhage (ICH)

CLINICAL CRITERIA FOR RENEWAL

- Documentation of positive clinical response to Zontivity therapy; **AND**
- Used in combination with aspirin and/or clopidogrel therapy; **AND**
- Patient does not have a history of any of the following:
  - Stroke
  - Transient ischemic attack (TIA)
  - Intracranial hemorrhage (ICH).

ZYDELIG® (IDELALISBIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL)**

- Patient is at least 18 years of age**; AND**
- Patient will avoid concomitant therapy with all the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has not received previous therapy with a small-molecule inhibitor (phosphtidylinositol-3 kinase inhibitor [PI3-K]) therapy (e.g., alpelisib, copanlisib, duvelisib, umbralisib); **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will receive prophylactic therapy for *Pneumocystis jirovecii* (PJP) while on treatment with idelalisib; **AND**
- Baseline ALT and AST will be obtained prior to initiating treatment and monitored periodically while on treatment; **AND**
- Patient has relapsed or refractory disease; **AND**
- Used as subsequent therapy as a single agent or in combination with rituximab

Diagnosis of **B-Cell Lymphomas**

- Patient is at least 18 years of age**; AND**
- Patient will avoid concomitant therapy with all the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort); **AND**
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**
- Patient has not received previous therapy with a small-molecule inhibitor (phosphtidylinositol-3 kinase inhibitor [PI3-K]) therapy (e.g., alpelisib, copanlisib, duvelisib, umbralisib); **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will receive prophylactic therapy for *Pneumocystis jirovecii* (PJP) while on treatment with idelalisib; **AND**
- Baseline ALT and AST will be obtained prior to initiating treatment and monitored periodically while on treatment; **AND**
- Patient has relapsed, refractory, or progressive***** disease
- Used as subsequent therapy after at least two (2) prior therapies; **AND**
- Used a single agent; **AND**
- Patient has a diagnosis of one of the following:
  - Follicular lymphoma (grade 1–2)
  - Gastric MALT lymphoma
  - Non-gastric MALT lymphoma (noncutaneous)
  - Nodal marginal zone lymphoma
  - Splenic marginal zone lymphoma

****** *Only applies to Follicular Lymphoma*

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include serious infections, neutropenia, severe diarrhea or colitis, hepatoxicity, pneumonitis, intestinal perforation, severe cutaneous reactions [Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)], hypersensitivity reactions/anaphylaxis, etc.

ZYKADIA® (CERITINIB)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology Agents (IE 2462 / NCPDP 75, 50081 and 2193)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Non-Small Cell Lung Cancer**

- Patient is 18 years of age or older; **AND**
- Used as a single agent; **AND**
- Patient has advanced, metastatic, or recurrent disease (excluding locoregional recurrent or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Patient's disease is anaplastic lymphoma kinase (ALK)-positive as detected by FDA-approved test or CLIA-compliant test; **AND**
    - Used as first-line therapy; **OR**
    - Patient is intolerant to crizotinib; **OR**
    - Used as subsequent therapy; **AND**
      - Patient has previously failed on first-line treatment with crizotinib, except in cases of symptomatic systemic disease with limited metastases; **OR**
      - Used as continuation of therapy if used first-line, except in cases of symptomatic systemic disease with multiple lesions; **OR**
  - Patient's disease is ROS-1 positive as detected by an FDA-approved test or CLIA-compliant test; **AND**
    - Used as first-line therapy

Diagnosis of **Soft Tissue Sarcoma (Inflammatory Myofibroblastic Tumor [IMT])**

- Patient is 18 years of age or older; **AND**
- Used as a single agent; **AND**
- Patient's disease is ALK-positive as detected by an FDA-approved test or CLIA-compliant test

Diagnosis of **Central Nervous System (CNS) Cancers (Limited or Extensive Brain Metastases)**

- Patient is 18 years of age or older; **AND**
- Used as a single agent; **AND**
- Patient has ALK-positive Non-Small Cell Lung Cancer as detected by an FDA-approved test or CLIA-compliant test; **AND**
  - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
  - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **OR**
  - Used as continuation of therapy if used first-line, except in cases of symptomatic systemic disease with multiple lesions; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hepatotoxicity, bradycardia, hyperglycemia, QT interval prolongation, interstitial lung disease (ILD)/pneumonitis, severe gastrointestinal adverse reactions, pancreatitis, etc.

ZYNLONTA® (LONCASTUXIMAB TESIRINE-LPYL)

Length of Authorization:	6 months, may be renewed
Initiative:	SPC: Oncology agents (IE 2462 / NCPDP 75)

CLINICAL CRITERIA FOR INITIAL APPROVAL

Diagnosis of **Large B-Cell Lymphoma**

- Patient is at least 18 years of age; **AND**
- Patient has been advised to minimize or avoid exposure to direct natural or artificial sunlight including exposure through glass windows; **AND**
- Used as single agent therapy; **AND**
- Patient has not received prior anti-CD19 therapy, (e.g., tafasitamab, CAR-T) **or** patient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**
- Patient does not have active graft-versus-host disease; **AND**
- Patient has not had an autologous stem cell transplant (ASCT) within 30 days or allogeneic stem cell transplant (AlloSCT) with 60 days, prior to start of therapy; **AND**
- Patient does not have active central nervous system (CNS) lymphoma (**includes leptomeningeal disease**); **AND**
- Patient does not have a clinically significant active infection (e.g., grade 3 or 4 infections); **AND**
- Patient does not have any clinically significant third space fluid accumulation (i.e., ascites requiring drainage or pleural effusion that is either requiring drainage or associated with shortness of breath); **AND**
- Patient has relapsed or refractory disease (**includes diffuse large B-cell lymphoma [DLBCL] not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma**); **AND**
- Patient has received at least two prior lines of therapy

CLINICAL CRITERIA FOR RENEWAL

- Disease response with treatment defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe effusion and edema (e.g., pleural effusion, pericardial effusion, ascites, peripheral edema, and general edema), myelosuppression, infections, severe cutaneous reactions (e.g., photosensitivity, rash), etc.

REVISION HISTORY

Date	Issues/Updates
01/01/2022	Updated: Darzalex, Kepivance, Mektovi, Vyndamax, Vynadqel, Visudyne, Zilretta, Abecma, Abraxane, Adcetris, Aliqopa, Asparlas, Baraclude, Bavencio, Beovu, Bevacizumab ophthalmic, Eylea, Macugen, Ozurdex, Bevacizumab oncology, Berinert, Cinryze, Haegarda, Firazyr, Kalbitor, Ruconest, Orladeyo, Takhyzro, Besponsa, Braftovi, Breyanzi, Brukinsa, Cabozantinib, Calquence, Caprelsa, Cayston, Cerdelga, Cerezyme, Zolgensma, Cinqair, Cotellic, Cyramza, Dacogen, Darzalex Faspro, Dupixent, Egrifta, Zavesca, Elelyso, Empaveli, Enspryng, Entyvio, Erbitux, Erivedge, Erwinaze, Evomela, Exondys-51, Fasenra, Gazyva, Osteoarthritis agents, Hepsera , Ibrance, Imbruvica, Increlex, Inqovi, Inrebic, IVIG, Immune globulins, Yescarta, Zelboraf, Jakafi, Jemperli, Kadcyla, Kalydeco, Keytruda, Kisqali, Koselugo, Krystexxa, Kymriah, Kyprolis, Lemtrada, Ocrevus, Tysabri, Lenvima, Lupron-Depot, Levonogestrel-releasing intrauterine systems, Libtayo, Lumizyme, Mekinist, Monjuvi, Mozobil, Mycapssa, Octreotide, Somatuline, Ninlaro, Nucala, Oncaspar, Yervoy, Xiaflex, Onpattro, Onureg, Opdivo, Orkambi, Xyrem, Xywav, Vpriv, Vyondys, Padcev, Wakix, PAH, Pemetrexed, Pepaxto, Perjeta, Vivitrol, Photofrin, Pomalyst, Poteligeo, Pulmozyme, Ranibizumab, Repatha, istodax, romidepsin, Signifor LAR, Sogroya, Soliris, Viltepso, Spinraza, Stivarga, Supprelin, Symdeko, Synarel, tafinlar, Talzenna, Tasigna, Tecartus, Verzenio, Vectibix, Tecentriq, Tegsedi, Temodar IV, Temodar oral, Testopel, Ultomiris, Triptodur, Tobramycin, Tibsovo, Uplinza, Trikafta, Trastuzumab, abiraterone, duxeis, Gilotif, Iressa, Tarceva, Xtandi, albuterol products, Erleada, Added: Aveed, Nexviazyme, Rylaze, Saphnelo, Rezurock, Welireg, Amondys-45, Bylvay, Licart, Emsam, Brexafemme, Kerendia, Brand Lidoderm patch, Myfembree, Wegovy Removed: aptiom, elepsia xr
12/01/2021	Beta agonists, test strips standard formulary, Cosentyx, Ilumya, Infliximab, Olumiant, Otezla, Rinvoq, Rituxan, Skyrizi, Stelara, Xeljanz, Zelnorm, Tecfidera
10/26/2021	Updated: Off-label Use section
10/12/2021	Updated: Off-label Use section
10/01/2021	Added: Abecma, Aduhelm, Jemperli, Nulibry, Rybrevant, Zynlonta, Empaveli, Lumakras, Ryplazim, Truseltiq, Pepaxto Updated: Adcetris, Azedra, Elitek, Gazyva, Abiraterone, Abraxane, Actimmune, Alecensa, Alunbrig, Hemlibra, Feiba, Aranesp, Ayvakit, Balversa, Bavencio, bevacizumab, Bosulif, Botox, Paraplatin, Copiktra, Crysvita, Cyramza, Darzalex, Daurismo, Dysport, Epclusa, Epogen, Procrit, Retacrit, Erbitux, Erleada , Evomela, AlphaNine SD, Alprolix, BeneFIX, Idelvion, Ixinity, Mononine, Profilnine, Rebinyn, Rixubis , Novoseven, Sevenfact, Obizur, Advate, Adynovate, Afstyla, Eloctate, Esperoct, Hemofil M, Koate, Koate-DVI, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha/Xyntha Solofuse, Jivi, Alphanate, Humate-P, Wilate, Coagadex, Corifact, Tretten, Fotivda, Gavreto, Gemzar, Gilotrif, growth hormone, Harvoni, Hicon, Iclusig, Idhifa, Imlygic, Infugem, Inlyta, Intron-A, Iressa, Ixempra, Jelmyto, Kadcyla, Keytruda, Kyprolis, Leuprolide products, Libtayo, Lonsurf, Lutathera, Mavyret, Metastron, Myobloc, Nerlynx, Nexavar, Nubeqa, Odomzo, Opdivo, Padcev, Tyvaso, Pegintron, Pegasys, Perma-zyme, Alimta, Pemfexy, Perjeta, Piqray, Polivy, Qinlock, Quadramet, Retevmo, Ribavirin, Rozlytrek, Sovaldi, Sprycel, Sutent, Tabrecta, Tarceva, Targretin, Tasigna, Tazverik, Tecentriq , Tepmetko, Torisel, Trastuzumab, Trikafta, Trodelvy, Tukysa, Tykerb, Ukoniq, Ultomiris, Vectibix, Venclexta, Vidaza, Vitrakvi, Vizimpro, Vosevi, Votrient, Vonvendi, Xeloda, Xeomin, Xofigo, Xolair, Xpovio, Xtandi, Yervoy, Zepatier, Zeposia, Zevalin, Zolinza, Zydelig, anticonvulsants, antiparasitics, immune globulins, lipotropics, bile acid agents, antibiotics tetracyclines, CGRP antagonists, dermatologics steroids, dermatologics topical retinoids, dermatologics vitamin D analog, diabetic supplies, hypoglycemics insulins, hypoglycemics SGLT2 inhibitor, immunomodulators, iron chelators, multiple sclerosis, ophthalmics dry eye agents, Tiglutik, Truxima, urinary tract antispasmodics, vaccines, Dupixent, Fasenra, Orilissa, Oriahnn, Nucala

Date	Issues/Updates
07/01/2021	Added: Breyanzi, Bronchitol, Cosela, Evkeeza, Lupkynis, Tepmetko, Ukoniq, Cabenuva, Vocabria, Gemtesa, Verquvo, RediTrex, Klisyri Updated: Abraxane, Adcetris, Evenity, Akynzeo, Aloxi, Cinvanti, Emend, Sustol, Aldurazyme, Alpha 1 proteinase inhibitors, Ampyra, Arcalyst, Arzerra, Aubagio, Avonex, Bafiertam, Extavia, Rebif, Gilenya, Copaxone, Betaseron, Mavenclad, Kesimpta, Mayzent, Tecfidera, Vumerity, Zeposia, Bavencio, Beleodaq, Bendamustine, Benlysta, Bevacizumab, Blincyto, Bortezomib, Cabozantinib, Cholbam, Cyramza, Darzalex Faspro, Darzalex, Prolia, Xgeva, Elaprase, Elzonris, Enhertu, Erbitux, Fabrazyme, Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria, Neupogen, Nivestym, Zarxio, Granix, Gazyva, Halaven, Imfinzi, Jevtana, Juxtapid, Kadcyla, Keytruda, Leukine, Nplate, Fusilev, Khapzory, Libtayo, Lorbrena, Lynparza, Onivyde, Opdivo, Alimta, Pemfexy, Perjeta, Phesgo, Praluent, Repatha, Promacta, Ruxience, Truxima, Rituxan Hycela, Rubraca, Sarclisa, Rydapt, Sucraid, Talzenna, Tavalisse, Tecentriq, Tepezza, Teriparatide, Samsca, Jynarque, trastuzumab, Herceptin Hylecta, Tymlos, Vectibix, Vyepti, Vyxeos, Xalkori, Xenazine, Xospata, Yervoy, Yescarta, Relistor injection, Otovel, Zerviate, Nexletol, HIV agent, Erectile Dysfunction, Antipsychotics , Zipsor, Zejula, Zepzelca , Tafinlar, Sandostatin LAR, Gilotrif, Diabetic supplies, Actemra, Humira, Infliximab, Olumiant, Orencia, Rituxan, Siliq, Skyrizi, Stelara, Removed: Plaquenil, Chloroquine, Adoxa
05/01/2021	• Rituxan, Tremfya, Truxima, Xeljanz, inhaled beta agonists (enhanced formulary and core), Inhaled glucocorticoids (enhanced formulary), Kevzara, Kineret, Oriahnn, Orilissa, Ruxience
04/01/2021	• Updated: buprenorphine products for opiate addiction, Zilxi, Noritate, Budesonide/formoterol, Cetraxal, Cipro HC, Addyi, Lyumjev, Saxenda, Cyramza, Gazyva, Levonorgestrel-releasing intrauterine systems, Ravicti, Sensipar, Synribo, Vectibix, Abraxane, Adcetris, Afinitor, Arcalyst, Arranon, Bavencio, Benlysta, Bevacizumab, Camptosar, Darzalex, doxorubicin, Eloxatin, Erbitux, Farydak, Foltyn, Gamifant, Gavreto, Gleevec, Hetlioz, Hycamtin, Iclusig, Imfinzi, Kadcyla, Keveyis, Keytruda, Lenvima, Luxturna, Marqibo, Myalept, Navelbine, Opdivo, Oxbryta, PAH, Pemetrexed, Perjeta, Proleukin, Revlimid, Sylvant, Tagrisso, Taxol, Taxotere, Tecentriq, Tepezza, Thalomid, Trastuzumab, Trikafta, Unituxin, Xeomin, Xolair, Xpovio, Yondelis, Colony stimulatory factors, Atripla, • Added: Eysuvis, Winlevi, Danyelza, Margenza, Oxlumo, Orgovyx, Orladeyo, Zokinvy, Adakveo, Givlaari, Nyvepria, Imcivree • Added core and enhanced to: diabetic supplies, blood formation modifiers, Hypoglycemics: insulin, Inhaled beta agonists combinations, Yonsa, Antipsychotics, bevacizumab, Bosulif, Antibiotics: tetracyclines, Dermatologics: topical antibiotic agents for acne/rosacea, Irritable bowel syndrome, inhaled glucocorticoids, Ulcerative colitis therapy, analgesics long acting, anaphylaxis agents, Botox, Cinqair, Fasenra, Gastrointestinals: Pancrelipase, Hematopoietic agents , Epclusa, sofosbuvir/velpatasvir, Harvoni, ledipasvir/sofosbuvir, Mavyret, Sovaldi, Viekira, Vosevi, Zepatier, Herceptin, Herceptin Hylecta, DPP4 inhibitors, Incretin mimetics, SGLT2 inhibitors, Anticholinergics, Inhaled beta agonists, Kisqali, Makena, Ampyra, MS medications, Myobloc, Osteoarthritis Agents, Rituxan Hycela, Ruxience, Verzenio, Xeomin, Xtandi, Gleevec, Iclusig, Sprycel, Tasigna
03/01/2021	• Updated: Orencia, Infliximab, Enbrel, Duobrii, Simponi, Actemra, Xeljanz, Descovy, Iron Chelators, Injectafer, Dificid
01/25/2021	• Added one-week override guidance, added language for MVG, etc. under medical necessity criteria • Updated: Pomalyst, Glaucoma agents, Cinqair, Fasenra, Nucala, Xolair, Dupixent • Removed PPIs from quantity limit table
01/01/2021	• Added: Alkindi, Relafen, Relafen DS, Conjupri, Adapalene Lotion/Swab/solution, Differin, Tazorac, Intrarosa, Femring, Alora, Menostar, Minivelle, Vivelle, Gimoti, Mitigare, Gloperba, Semglee, Airduo

Date	Issues/Updates
	Digihaler, ArmonAir Digihaler, Lampit, Upneeq, Cetraxal, Cipro HC, Otovel, Blenrep, Kepivance, Monjuvi, Phesgo, Photofrin, Tecartus, Viltepso, Enspryng, Evrysdi, Gavreto, Inqovi, Mycapssa, Onureg, Sogroya, Vyondys, Xywav, Pemfexy, Bafiertam, Kesimpta, Dojolvi, Fintepla, Ortikos • Updated: Xcopri, Caplyta, Fanapt, Durlaza, Finacea, Fabior, test strips (changed preferred to contour), Incruse Ellipta, Inhaled bet agonists, Lucemyra, Noctiva, Nocdurna, Oriahnn, Reyvow, Vaccines, Contrave, Exondys, Firmagon, Increlex, Libtayo, Trogarzo, Vivitrol, Zaltrap, Abraxane, Adcetris, Aliqopa, Arcalyst, Asparlas, Bavencio, Beleodaq, Bendamustine, Beovu, Berinert, Besponsa, Bevacizumab, Blincyto, Velcade, Botox, Braftovi, Brukinsa, Calquence, Caprelsa, Cayston, Cinqair, Cinryze, Cotellic, Cyramza, Dacogen, Darzalex, Egrifta, Empliciti, Enhertu, Erbitux, Erivedge, Erwinaze, Esbriet, Eylea, Fasenra, Nucala, Faslodex, Firazyr, Gazyva, Hyaluronic Acid Derivatives, Haegarda, Halaven, Ibrance, Imbruvica, Imfinzi, Inrebic, Immune globulins, Jakafi, Kadcyla, Kalbitor, Kalydeco, Keytruda, Kisqali, Krystexxa, Kymriah, Kyprolis, Lemtrada, Mirena, Lucentis, Lumoxiti, Macugen, Mekinist, Mektovi, Mylotarg, Ninlaro, Ocrevus, Ofev, Oncaspar, Opdivo, Orkambi, Xyrem, Alimta, Perjeta, Pomalyst, Poteligeo, Pulmozyme, Qutenza, Radicava, Reblozyl, Istodax, Ruconest, Sarclisa, Signifor, Soliris, Spinraza, Stivarga, Supprelin, Symdeko, Synarel, Vyndamax, Vyndaqel, Tafinlar, Takhzyro, Tecentriq, Tegsedi, Temodar IV, Temodar oral, Testopel, tobramycin, trastuzumab, Herceptin Hylecta, Trikafta, Triptodur, Trodelvy, Tukysa, Tysabri, Ultomiris, Uplizna, Vectibix, Velcade, Verzenio, Vyxeos, Wakix, Xeomin, Xiaflex, Xolair, Xtandi, Yervoy, Yescarta, Yondelis, Zelboraf, Zepzelca, Zilretta, Zolgensma, Kineret, Otezla, Stelara, Humira, Dupixent • Removed: Zurampic, Duzallo
12/08/2020	• Updated Truxima, Rituxan, Ruxience
11/06/2020	• Updated: Actemra, Cosentyx, Enbrel, Entyvio, Ilumya, Infliximab, Kevzara, Olumiant, Orencia, Rinvoq, Rituxan, Siliq, Skyrizi, Stelara, Taltz, Tremfya, Xeljanz, Descovy • Added Bactroban Nasal
11/01/2020	• Updated: Tasigna, Sprycel, Iclusig • Removed tables from Brand/generic initiative • Added step for Pravachol, Crestor, Lescol, Lipitor and Zocor, Cystadrops
10/01/2020	• Update: Zipsor non preferred on precision, Pennsaid, diclofenac 1% gel, androgens (beers list year), tetracyclines, Felbatol, Trokendi XR, Luzu brand excluded on precision, Sunosi, Antipsychotics, Retin-A micro, Vectical, diabetic supplies, Soliqua on precision, Xultophy, Invokana and Invokamet eGFR, Arcapta, Dulera, generic budesonide/formoterol, Airduo, Juxtapid, Libtayo, Abraxane, Adcetris, Alimta, Bavencio, Beleodaq, Bortezomib, Cyramza, Darzalex, Enhertu, Erbitux, Faslodex, Gazyva, Growth Hormone, Halaven, Imfinzi, Kadcyla, Keytruda, Kyprolis, Leuprolide products, Lynparza, Opdivo, Neulasta, Fulphila, Udenyca, Ziextenzo, Perjeta, Pomalyst, Rituxan Hycela, Rubraca, Sarclisa, Tecentriq, Trastuzumab, Herceptin Hylecta, Vectibix, Yervoy, Yondelis, Zaltrap, Zejula, Alecensa, Alunbrig, Ayvakit, Boniva, Bosulif, Carboplatin, Cerdelga, Cerezyme, Copiktra, Crysvita, Daurismo, Elelyso, Elitek, Feraheme, Iclusig, Idhifa, Ilaris, Injectafer, Inlyta, Iressa, Lonsurf, Lutathera, Monoferric, Ferriprox, Mylotarg, Nerlynx, Nexavar, octreotide, Odomzo, Padcev, Piqray, Polivy, Reblozyl, Rozlytrek, Sprycel, Sutent, Targretin, Tasigna, Tazverik, Tibsovo, Visudyne, Vitrakvi, Vizimpro, Votrient, VPRIV, Vyxeos, Xpovio, Zavesca, Zevalin, Zoledronic, Zolinza, Zydelig, Abiraterone, Balversa, Bevacizumab ophthalmic, Botox, Braftovi, Cabozantinib, Dysport, Epclusa, Erleada, Evenity, Gemzar, Gilotrif, Harvoni, Iluvien, Imbruvica, Imlygic, Fertility agents, Infugem, Intron-A, Ixempra, Jetrea, Lorbrena, Mavyret, Myobloc, Nubeqa, Ozurdex, Peg-Intron, Pegasys, Retisert, Ribavirin, Sandostatin LAR, Serostim, Sovaldi, Tagrisso, Tarceva, Forteo, Bonsity, Torisel, Tykerb, Tymlos, Venclexta, Vidaza, Vosevi, Xalkori, Xeloda, Xeomin,

Date	Issues/Updates
	Xermelo, Xtandi, Yutiq, Zepatier, Zilretta, Zorbtive, Zykadia, Cosentyx, Ilumya, Imbruvica, Immune Globulins, Infliximab, Ferriprox, Deferasirox, Jadenu, Exjade, Olumiant, Siliq, Skyrizi, Xyrem, Avastin, Mvasi, Zirabev, Blincyto, Spravato, Entyvio, Stelara, Xeljanz, Teriparatide • Removed: Potiga, Rhofade, Amzeeq, Prevpac, Pylera, Soliqua from standard, Striverdi, generic Proventil hfda made by par • Added: Xcopri, renewal criteria for isotretinoin, Riomet, Lyumjev, Impavido, Nexletol, Oriahnn, Darzalex Faspro, Evomela, Trodelvy, Uplizna, Zepzelca, Jelmyto, Qinlock, Retevmo, Tabrecta, Isturisa, Kynmobi, Koselugo, Pemazyre, Tukysa, Bynfezia, Sevenfact, Zeposia • Added step for Exelderm, sulconazole, Naftin, naftifine, Oxistat, oxiconazole, Ecoza, Ertaczo, azelastine/fluticasone spray, Dayvigo, clotrimazole betamethasone lotion, Loprox, Extina foam
08/25/2020	• Added to Quantity limit
07/01/2020	• Updated: long acting narcotics (Xtampza preferencing), Androgens, Dificid, Alinia, Jublia, Kerydin, Nuvigil and Provigil (added trial language for generics), Freestyle Libre, look back period for diabetic supplies, Brand Travatan Z, Rocklatan, year on Uceris guideline to 2019, Akynzeo, Aldurazyme, Ampyra, Feiba, Aubagio, Avonex, Brineura, Cholbam, Doptelet, Elaprase, Elzonris, Exondys51, Factor IX products, NovoSeven, Factor VII products, Coagadex, Wilate, Firdapse, Galafold, Keytruda, Kytril, Lumizyme, Mavenclad, Mayzent, Mepsevii, Mulpleta, Naglazyme, Nplate, Neulasta, Fulphila, Udenyca, Ziextenzo, Promacta, Revcovi, Rubraca, Rydapt, Sucraid, Talzenna, Tavalisse, Tecfidera, Jynarque, Samsca, Turalio, Vimizim, Vonvendi, Xenazine, Xospata, Zejula, Zofran IV, Abraxane, Adcetris, Alimta, Bavencio, Beleodaq, Bendamustine, Berinert, Bevacizumab, Blincyto, Bortezomib, Cinryze, Cyramza, Darzalex, Erbitux, Faslodex, Firazyr, Gazyva, Haegarda, Halaven, Imfinzi, Kadcyla, Kalbitor, Kyprolis, Libtayo, Nerlynx, Ninlaro, Opdivo, Perjeta, Ruconest, Takhzyro, Tecentriq, Trastuzumab, Herceptin Hylecta, Vectibix, Yervoy, Yondelis, Provenge, H.P. Acthar, Aloxi, Alpha-1-proteinase inhibitors, Hemlibra, Aranesp, Arzerra, Benlysta, Calquence, Cinvanti, Emend, Epogen, Procrit, Retacrit, Nivestym, Neupogen, Zarxio, Granix, Leukine, Lupron, Eligard, Fusilev, Khapzory, Mircera, Onfi, Onivyde, Praluent, Prolia, Xgeva, Reblozyl, Repatha, Sandostatin LAR, Sustol, Trelstar, Zoladex, Truvada, Descovy, Syprine, Gilenya, Basaglar, Ryzodeg, Relistor tablets, SGLT2 inhibitors (Invokana/Invokamet non-preferred, Farxiga/Xigduo preferred), Off-Label, Taltz, Xeljanz, Kevzara, Kineret • Added: Secuado, Caplyta, Nurtec, Ubrelvy, Consensi, Zerviate, Ozobax, Reyvow, Enhertu, Monoferric, Tepezza, Ayvakit, Tazverik, Sarclisa, Palforzia, generic insulin lispro junior, generic insulin lispro protamine/insulin lispro, Vyepti • Removed: Pataday, Patanol from precision criteria, Rocklatan, Vyzulta from standard, Symjepi
06/15/2020	• Removed COVID 19 indication from hydroxychloroquine and chloroquine
06/05/2020	• Removed CDK line from Kisqali and Verzenio
06/01/2020	• Off-label, Chloroquine, Hydroxychloroquine, Kaletra, Olumiant, Orencia, Rayos, Actemra, Duexis, Vimovo, Cimzia, Enbrel, Lynparza, LDD link
05/08/2020	• Updated Covid 19 instructions for hydroxychloroquine and chloroquine
05/01/2020	• Updated Gleevec, Iclusig, Sprycel, Tasigna, Rituxan Hycela, Rituxan, Incretin mimetic/insulin, incretin mimetics, Xeljanz, Tremfya, Ibrance, Kisqali, Verzenio, Herceptin, Truxima
04/02/2020	• Removed Clarinex from brand step therapy list, Bactroban • Qmiiz moved to excluded on precision, fenoprofen 200mg excluded on precision, Apadaz, Oxtellar XR, Clobetasol propionate 0.05% foam, Lexette, Triamcinolone acetonide 0.147 aerosol spray, Freestyle libre

Date	Issues/Updates
	• Updated: androgens, Dificid, Baxdela, Seysara, Lyrica CR, Savella, Stimulants, Corlanor, Azelaic acid, Vitamin D analog, Vitamin D analog/anti-inflammatory steroids, PPIs, Xhance, ophthalmics: allergic conjunctivitis, Hycamtin, Lenvima, Sylvant, Unituxin, Avastin, Abraxane, Acthar, Adcetris, Afinitor, Alimta, Arranon, Bavencio, Beleodaq, bendamustine, bortezomib, Botox, Calquence, Camptosar, Cyramza, Darzalex, Doxorubicin, Dysport, Eloxatin, Erbitux, Farydak, Faslodex, Foltyn, Gazyva, Gleevec, Halaven, Herceptin Hylecta, Hetlioz, Ibrance, Imfinzi, Infugem, Kadcyla, Keveyis, Keytruda, Kymriah, Kyprolis, Levonorgestrel-releasing intrauterine systems, Libtayo, Luxturna, Lynparza, Marqibo, Mvasi, Mylotarg, Myobloc, Natpara, Navelbine, Neulasta, Nplate, Opdivo, PAH, Perjeta, Proleukin, Qutenza, Ravicti, Revlimid, Signifor, Sylatron, Synribo, Taxol, Taxotere, Tecentriq, Thalomid, Ultomiris, Vectibix, Velcade, Xeomin, Xtandi, Yervoy, Yescarta, Zaltrap, Zirabev, Wakix, Herceptin, Iclusig, Rituxan, Rituxan Hycela, Ruxience, Truxima, Descovy, Truvada, Kaletra, Albuterol • Added: Sporanox, Kerydin to precision formulary, Amzeeq, Aklief, Proair Digihaler, budesonide/formoterol, Pretomanid, Padcev, Scenesse, Reblozyl, Brukinsa, Oxbryta, Trikafta, Vumerity, Ziextenzo, Nourianz, Gloperba, generic naloxone auto injector, Hydroxychloroquine, Chloroquine
03/01/2020	• Added: Rybelsus, Duaklir, generic insulin aspart, generic insulin aspart protamine/insulin aspart • Updated: Vascepa, Cresemba, Invega Trinza, Olumiant, Simponi, Humira • Removed: Tanzeum
01/14/2020	• Updated: Afinitor • Added MNC: Hypoglycemics: GLP1 agonists initiative
01/01/2020	• Updated: Hysingla Er and Oxycontin (moved to non-preferred), Treximet, Corlanor, Cosmetic agents (added Dysport), topical retinoids, Rocklatan, generic insulin lispro, vaccine section, Contrave-nonformulary for precision, Synagis, Calquence, Esbriet, Kyprolis, Vyndamax, Abraxane, Aliqopa, MS, Avastin, Bavencio, Bendamustine, Berinert, Besponsa, Blincyto, Bortezomib, Botox, Braftovi, Caprelsa, Cayston, Cinqair, Cinryze, Cotellic, Crysvita, Cyramza, Darzalex, Doptelet, Entyvio, Erivedge, Erleada, Erwinaze, Obizur, Alphanate, Humate-P, Wilate, Fasenra, Faslodex, Firazyr, Gazyva, HA derivatives, Haegarda, Ilaris, Imbruvica, Increlex, Istodax, Immune Globulins, Kalbitor, Kalydeco, Keytruda, Kisqali, Kymriah, Lenvima, Levoleucovorin, Libtayo, Lumoxiti, Mavyret, Mekinist, Mektovi, Mylotarg, Myobloc, Ninlaro, Nucala, Sandostatin, Ofev, Oncaspar, Onpattro, Opdivo, Orkambi, Pomalyst, Ruconest, Hizentra, Hyqvia, Cuvitru, Soliris, Somatuline, Sovaldi, Stivarga, Symdeko, Synarel, Tafinlar, Takhzyro, Tecentriq, Tegsedi, Temodar oral, Temodar IV, Teriparatide, Testopel, Tobramycin, Triptodur, Trogarzo, Verzenio, Vivitrol, Vonvendi, Xeomin, Xiaflex, Xolair, Xyrem, Yervoy, Yescarta, Zejula, Zelboraf, Zirabev, Actemra, Enbrel, Kevzara, Olumiant, Orencia, Otezla, Rituxan, Taltz, Afinitor, Cabometyx, Inlyta, Lenvima, Nexavar, Votrient, Cosentyx, Entyvio, Ilumya, Kineret, Rituxan, Siliq, Xeljanz • Added: Indocin suspension, Indocin Suppository, Aptiom, Katerzia, Neupro, Zelnorm, Sunosi, Xenleta, Vyleesi, Beovu, Feraheme, Zirabev, Inrebic, Rozlytrek, Turalio, Wakix, Xpovio, Xyntha Solofuse, Brand/generic step therapy initiative, Rinvoq, Banzel, Ezallor excluded precision, Lovaza, Vascepa • Removed: Freestyle, Dexcom
11/19/2019	• Updated Butrans and Seysara
11/08/2019	• Updated Mavenclad
11/01/2019	• Updated: Actemra, Enbrel, Entyvio, Kevzara, Kineret, Olumiant, Orenica, Rituxan, Siliq, Stelara, Taltz, Xeljanz, Avastin, Spravato, Denavir, Zovirax Cream • Added: Nubeqa, Mvasi

Date	Issues/Updates
10/01/2019	• Added: Sancuso, Adhansia XR, Jornay PM, Carac, Duobrii, Vitamin D analogs (Dovonex, Sorilux, Vectical), Evoclin, Dyrenium and triamterene, febuxostat, Sucraid, Thiola, Kanjinti, Polivy, Zolgensma, Piqray, Ruzurgi, Vyndamax, Vyndaqel, Belrapzo, Herzuma, Ogivri, Ontruzant, Zoledronic Acid, Trazimera, Mavenclad • Updated: Vimovo (moved to NSAID oral section), Antihyperkinesis medications, BPH medications, Emgality (cluster headache), Dupixent, DPP4 inhibitors- trial duration, SGLT2 inhibitors- trial duration, Actemra, Cosentyx, Enbrel, Ilumya, Siliq, Skyrizi, Taltz, Xeljanz, Lonhala, Motegrity(added to precision), Cysteamine, Darzalex, Faslodex, Idhifa, Imfinzi, Libtayo, Rituxan Hycela, Tibsovo, Vectibix, Xofigo, Abraxane, Actimmune, Adcetris, Alecensa, Alimta, Avastin, Baraclude, Bavencio, Beleodaq, Treanda, Bendeka, Boniva IV, Bortezomib, Bosulif, Paraplatin, Cerdelga, Cerezyme, Copiktra, Cyramza, Daurismo, Elelyso, Elitek, Erbitux, Eylea, Firdapse, Fulphila, Gazyva, Hyaluronic Acid Derivatives, Halaven, Hepsera, Herceptin Hylecta, Herceptin, Iclusig, Inlyta, Iressa, Jakafi, Juxtapid, Kadcyla, Kalydeco, Keytruda, Kynamro, Lonsurf, Lutathera, Nerlynx, Neulasta, Nexavar, Odomzo, Opdivo, Perjeta, Praluent, Repatha, Revlimid, Spinraza, Sprycel, Sutent, Symdeko, Targretin (oral and topical), Tasigna, Tecentriq, Tibsovo, Udenyca, Velcade, Venclexta, Visudyne, Vizimpro, Votrient, VPRIV, Yervoy, Zaltrap, Zavesca, Zevalin, Zolinza, Zydelig, Fully funded law section, Precision formulary exception process, appeals, Infliximab, Xtandi • Removed: Tolak, Omeclamox pak, Inveltys (standard), Namenda XR step
09/12/2019	• Updated Limited Distribution List
08/26/2019	• Updated Spravato, Lucemyra
08/07/2019	• Updated CGRP (added line about botulinum toxins)
08/01/2019	• Added: generic insulin lispro, Atripla step, Skyrizi, generic Proventil HFA, Inbrija • Updated: Harvoni, Mayzent, Cosentyx, Humira, Otezla, Siliq, Simponi, Simponi Aria, Stelara, Taltz, Xeljanz • Removed Tekturna step
07/17/2019	• Removed MCA from cost max section, Correct Lenalidomide spelling
07/03/2019	• Added Reconsiderations
07/01/2019	• Updated: Nucynta ER, Zyvox, Dexcom, Incretin mimetics (removed Adlyxin from list of preferred), Lucemyra, Cequa, Fertility Agents, Akynzeo, Alimta, MS, Bavencio, Emend, Empliciti, Fabrazyme, Faslodex, Galafold, Gilenya, growth hormone, Halaven, Imfinzi, Infugem, Kadcyla, Kanuma, Kyprolis, Kytril, Leuprolide, Prolia, Rubraca, Serostim, Thyrogen, Samsca, Xenazine, Xtandi, Zejula, Abiraterone, Abraxane, Adcetris, Aldurazyme, Alpha-1 proteinase inhibitor, Alunbrig, Aranesp, Arzerra, Avastin, Beleodaq, Bendamustine, Benlysta, Bortezomib, Botox, Cometriq, Cabometyx, Cholbam, Crysvita, Cyramza, Doptelet, Dupixent, Dysport, Elaprase, Erbitux, Faslodex, Fusilev, Gazyva, Gemzar, Gilotrif, Granix, Herceptin, Ibrance, Imbruvica, Imlygic, Intron-A, IVIG, Ixempra, Jetrea, Jevtana, Kadcyla, Keytruda, Khapzory, Lartruvo, Leukine, Lonsurf, Lorbrena, Mepsevii, Mircera, Neupogen, Nivestym, Oncaspar, Onivyde, Opdivo, Pegintron, Pegasys, Perjeta, Praluent, Procrit, Promacta, Repatha, Retacrit, Retisert, Ribavirin, Rituxan Hycela, Rydapt, Sandostatin LAR, Soliris, Sustol, Tagrisso, Talzenna, Tarceva, Tavalisse, Tecentriq, Torisel, Tykerb, Tymlos, Vectibix, Velcade, Venclexta, Vidaza, Vitrakvi, Xalkori, Xeloda, Xeomin, Yervoy, Yondelis, Zarxio, Zorbtive, Zykadia, Hemlibra, Feiba, AlphaNine SD, Alprolix, Bebulin, Benefix, Idelvion, Ixinity, Mononine, Profilnine, Rebinyn, Rixubis, Novoseven RT, Advate, Adynovate, Afstyla, Eloctate, Hemofil M, Koate DVI, Kogenate FS, Kovaltry, Monoclate-P, Novoeight, Nuwiq, Obizur, Recombinate, Xyntha, Jivi, Esperoct, Coagadex, Corifact, Tretten, Wilate, Vonvendi, Epclusa, Harvoni, Mavyret, Sovaldi, Vosevi, Zepatier, CGRP antagonists, Kevzara, Enbrel,

Date	Issues/Updates
	Tremfya, Infliximab products, Rituxan, Orencia, Olumiant, Cimzia, Kineret, HP Acthar, Adagen, Ampyra, Aubagio, Avonex, Betaseron, Blincyto, Cinvanti, Darzalex, Erleada, Extavia, Fulphila, Libtayo, Lumizyme, Mulpleta, Naglazyme, Plegridy, Medical exceptions, Precision formulary Exception process • Added: Qmiiz, Doxycycline DR 80mg, Entereg, Rocklatan, brand Xalatan, Motegrity, Penicillamine agents, Diacomit, Actimmune, Boniva IV, Spravato, Balversa, Firdapse, Asparlas, Elzonris, Evenity, Herceptin Hylecta, Hicon, Metastron, Quadramet, Ultomiris, Zilretta, Iluvien, Portrazza, Zofran IV, Aloxi IV, bevacizumab ophthalmic, Brineura, Ozurdex, Vimizim • Removed: Semprex D
05/07/2019	• Added generic Acticlate, updated Xeomin, Myobloc, Botox (Dysport step), updated LDD link, added MN fully funded step therapy
04/19/2019	• Updated: Seysara, Apokyn, Orilissa. Tier exception • Added: Oxervate, DAW penalty override/Member pay difference
04/01/2019	• Added: Nalfon, Symjepi, Ragwitek, Monodox, Nuzyra, Seysara, Sympazan, Tolsura, Arakoda, Pimecrolimus, Dermatologics: steroids (Bryhali, Lexette, Halog, Topicort spray), azelaic acid gel, Noritate excluded for precision, Yupelri, Ztlido, Nocdurna, Inveltys, Cequa, Qbrexza, Rayos excluded precision formulary, Dipentum step, Copiktra, Daurismo, Lorbrena, Talzenna, Tegsedi, Udenyca, Vitrakvi, Vizimpro, Xospata, Elitek, Gamifant, Infugem, Khapzory, Libtayo, Lumoxiti, Revcovi, Yutiq, Zevalin, Arranon, Besponsa, Mepsevii, Qutenza, Unituxin, Adagen, Aliqopa, Eloxatin, Erwinaze, Lartruvo, levonorgestrel-releasing intrauterine systems, Mylotarg, Navelbine, Oncaspar, Taxol, Taxotere, Arikayce, Yescarta, Epidiolex, Abilify MyCite, Depo-SubQ Provera 104, Rituxan Hycela, Obizur • Updated: Qualaquin, triptans (added table for precision excluded items), Albenza, Fanapt, Geodon, Invega, Ajovy, dermatologics: topical antibiotics, Aczone brand, Nexium susp, Prilosec susp, Protonix susp, Farxiga and Xigduo eGFR, Bendamustine, Ampyra, Caprelsa, Farydak, Firmagon, Forteo, Halaven, Imfinzi, Lumizyme, Marqibo, Myalept, Perjeta, Sensipar, Zorbtive, Abraxane, Adcetris, Afinitor, Aldurazyme, Alimta, Aubagio, Avastin, bavencio, Beleodaq, Berinert, Braftovi, Calquence, Camptosar, Cayston, Cinqair, Cinryze, Cotellic, Cyramza, Doxorubicin, Elaprase, Empliciti, Entyvio, Erbitux, Erivedge, Esbriet, Ofev, Eylea, Fabrazyme, Faslodex, Firazyr, Foltyn, Sublocade, screening questions Immunomodulators, Gazyva, Gilenya, Gleevec, Haegarda, Herceptin, Hetlioz, Hexalen, Hycamtin, Istodax, Immune globulins, Jakafi, Kadcyla, Kalbitor, Keveyis, Keytruda, Kymriah, Kyprolis, Lemtrada, Lenvima, Libtayo, Lucentis, Lynparza, Macugen, Makena, Mekinist, Mektovi, Mozobil, Naglazyme, Natpara, Ninlaro, Nplate, Ocrevus, Opdivo, PAH meds, Pomalyst, Proleukin, Promacta, Pulmozyme, Ravicti, Rebif, Revlimid, Ruconest, Serostim, Soliris, Stivarga, Sylatron, Symdeko, Synribo, Tafinlar, Takhzyro, Tecentriq, Temodar, Thalomid, Tobramycin solutions, Tysabri, Vectibix, Velcade, Venclexta, Xiaflex, Xolair, Xyrem, Yervoy, Zaltrap, Zelboraf, Daklinza, Epclusa, Harvoni, Sovaldi, Technivie, Viekira, Vosevi, Zepatier, Coagadex, Sprycel, Zarxio, Granix, Arcapta, Striverdi, Dulera, Airduo, Botox, Myobloc, Dysport, Xeomin, Hemlibra, Category groupings: inclusion/exclusion • Removed: Vascepa
03/08/2019	• Added generic Albuterol HFA
02/15/2019	• Multiple sclerosis (Betaseron moved to preferred, Zinbryta removed)
02/07/2019	• Added clarification to weight loss agents for which category each falls under in CRM • Updated Onfi/clobazam tabs to have initiative of MNC instead of SPC
01/16/2019	• Updated Hypoglycemics: Incretin mimetics, medical exceptions and precision exclusion processes

Date	Issues/Updates
01/14/2019	• Updated: Zypitamag, Dipentum, Tagrisso, Onfi, Blincyto, Darzalex, Vivitrol, Renewal approval length Humira for UC changed to 12 months instead of 12 weeks, renewal length Rituxan RA changed to 1 month, approval length added for Rituxan CLL and ITP • Added: Empliciti, Exondys51, Radicava, Spinraza, Yondelis, Nucynta IR, Xepi
01/01/2019	• Updated: Abilify Maintena, Abraxane, Absorica, Actemra, Adcetris, Aimovig, Akynzeo, Alimta, Amitiza, Arcalyst, Avastin, Basaglar, Bavencio, Belbuca, Beleodaq, Bendeka, Bevespi Aerosphere, Bortezomib, Butrans, Cimzia, Clindagel, Dupixent, Entyvio, Glyxambi, Halaven, Herceptin, Hetlioz, Hycamtin, Ibrance, Ilaris, Imbruvica, Imfinzi, Inflectra, Infliximab, Intron A, Invega Sustenna, Jublia, Kalydeco, Kerydin, Kevzara, Keytruda, Kineret, Kisqali, Lenvima, Lotronex, Lunesta, Luzu, Minocycline ER tablets, Movantik, Neulasta, Olumiant, Opdivo, Orencia, Orkambi, Otezla, Ozempic, Relistor Injection, Relistor tablets, Remicade, Renflexis, Rituxan Hycela, Ryzodeg, Seebri Neohaler, Segluromet, Signifor LAR, Siliq, Simponi, Simponi Aria, Somatuline, Sprix, Steglatro, Steglujan, Stelara, Supprelin LA, Symproic, Synarel, Taltz, Tecentriq, Testopel, Treanda, Tremfya, Tresiba, Trulance, Utibron, Vectibix, Velcade, Verzenio, Vraylar, Xeljanz, Xeljanz XR, Xeomin, Xtandi, Xultophy, Yervoy, Zarxio, Zypitamag, Glatopa removed from preferencing • Analgesics: Buprenorphine Products for Opiate Addiction – Clarified internal note concerning fully insured vs self insured plans; Androgens – Precision criteria exclusions; Autoimmune (Immunomodulators) medications – Complete Reformatting, with criteria and Step Med changes; Growth Hormones – updated diagnoses; Medical Exceptions – Modified exclusion criteria; Plan Summary – MRx general Commercial phone & fax numbers added; • Added: Ajovy, Albendazole, Alosetron, Aristada Initio, Azedra, Braftovi, BromSite, Crotan, Dacogen, Emgality, Galafold, Glatopa, Hydroxyprogesterone caproate, Ilevro, Jivi, Luliconazole, Mektovi, Mulpleta, Nevanac, Nivestym, Onpattro, Orilissa, Osmolex ER, Palynziq, Perseris, Poteligeo, Praziquantel, Sublocade, Takhzyro, Tibsovo, Tiglutik, Triptodur, Vigadrone • Removed: Veltassa, Flolipid
12/06/2018	• Updated Yonsa
11/06/2018	• Updated Olumiant, Mircera, Revlimid, Olumiant, Plan summary – Indiana Law
10/01/2018	• Updated: Lyrica Cr, Corlanor, Trelegy Ellipta, Trulance, Symproic, Uceris, Saxenda, Praluent, Repatha, Alpha-1 Proteinase inhibitors, Actemra, Akynzeo, Alecensa, Baraclude, Berinert, Bosulif, Botox, Cerdelga, Cerezyme, Cinqair, Darzalex, Dysport, Elelyso, Entyvio, Fasenra, Firazyr, Gilenya, Haegarda, Hepsera, Iclusig, Idhifa, infliximab, Iressa, IVIG, Juxtapid, Kalbitor, Keytruda, Kymriah, Kynamro, Lonsurf, Lutathera, Mekinist, Mircera, Myobloc, Nerlynx, Nexavar, Nucala, Ocrevus, Prolia, Xgeva, Rituxan, Ruconest, Simponi, Sprycel, Stelara, Sutent, Tafinlar, Targretin, Tasigna, Tecentriq, Samsca, Tysabri, Visudyne, Votrient, VPRIV, Vyxeos, Xeljanz, Xeomin, Xofigo, Xolair, Zavesca, Zolinza, Zydelig, Abraxane, Adcetris, Afinitor, Alimta, Arcalyst, Avastin, Bavencio, Beleodaq, Bendeka, Bortezomib, Cyramza, Emend, Enbrel, Erbitux, Faslodex, Fusilev, Gazyva, Halaven, Humira, Imfinzi, Imlygic, Intron A, Jevtana, Kineret, Kyprolis, Leukine, Lupron, Neulasta, Opdivo, PegIntron, Pegasys, Provenge, Rubraca, Rydapt, Sandostatin, Sustol, Sylvant, Tagrisso, Tarceva, Torisel, Treanda, Tykerb, Tymlos, Varubi, Vectibix, Venclexta, Vidaza, Xalkori, Xeloda, Xtandi, Yervoy, Zaltrap, Mavyret, CEM section (removed AMP), precision exception process, Synagis • Added: Bonjesta, Rhopressa, Zypitamag, Lucemyra, Doptelet, Fulphila, Olumiant, Retacrit, Tavalisse, Paraplatin, Injectafer, Jynarque, Crysvita, Ilumya, Trogarzo, Cinvanti, Gemzar, Ixempra, Kanuma, Retisert, medical exception criteria, MRIOA after hours info, Aimovig, GammaCore • Removed: New drugs to market section

Date	Issues/Updates
09/04/2018	• Added drug names to some criteria missing direction since tables removed on last update
08/16/2018	• Removed drug tables, updated Xeljanz
07/23/2018	• Updated Cycloset, ED precision table, Incretin Mimetics, Added exception criteria to Renflexis, Xeloda table • Removed Evzio (excluded on both formularies) • Added step therapy laws
07/01/2018	• Updated: Auvi-Q, tetracycline products, Briviact, Luzu, Latuda, Saphris, Dermatologicals: Topical Immunomodulators, Dexcom, Freestyle Libre, Gastrointestinals: PPIs, Admelog Insulin, Trulance, Bepreve, Elestat, Emadine, Pataday, Patanol, Restasis, Uceris Rectal foam, Uceris tablet, hereditary angioedema, Verzenio, Aranesp, Granix, Lynparza, Procrit, Strensiq, Zoladex, Avastin, Perjeta, Xgeva, Prolia, Botox, Dysport, Myobloc, Xeomin, Nucala, Immune Globulins, Abraxane, Darzalex, ., Adcetris, Alimta, Beleodaq, Velcade, Erbitux, Faslodex, Gazyva, Gilotrif, Inflectra, Kadcyla, Keytruda, Kyprolis, Lucentis, Leuprolide products, Mircera, Neulasta, Opdivo, Remicade, Renflexis, Rituxan IV, Sandostatin LAR, Stelara, Tecentriq, Treanda, Trelstar, Vectibix, Zarxio, Zytiga, Actemra, Hyaluronic Acid Derivatives, Orencia, Ozempic • Narcotic Analgesics: Fentanyl Buccal Products - title changed to Opioid Analgesics: TIRF (Transmucosal Immediate-released Fentanyl) • Added: Coremino, Rayos, Eliquis starter pack, Impoyz, Dexcom, Steglatro, Steglujan, Segluromet, Lonhala, Olopatadine 0.1%, Olopatadine 0.2%, Pazeo 0.7%, Symdeko, Erleada, Noctiva, Bavencio, Bendeka, Bortezomib IV, Fasenra, Cinqair, interleukin-5 antagonist monoclonal antibodies category, Rituxan Sub-Q, Onivyde, Fusilev, Imfinzi, Lutathera, Luxturna, glatiramer acetate, Glatopa, QVAR RediHaler • Removed: Optivar, Entresto, Bonjesta
05/31/2018	• Updated Briviact criteria, Nplate, Soliris, Treanda, Evzio, hyaluronic acid derivatives (added renewal section), off label oncology, Auvi-q • Added fluticasone/salmeterol, Oxaydo, Arnuity Ellipta to Precision table, quantity limit to test strips
04/25/2018	• Removed step criteria for Requip XL
04/19/2018	• Added SPC initiative for androgen and anticonvulsant SPC products, removed remaining tiers and quantity limits in the criteria • Added Lyrica CR
04/10/2018	• Removed Tiers from drug tables, removed quantities from tables
04/01/2018	• Updated: HepC agents- substance abuse requirements, Repatha, Praluent, Tivicay spelling, Bevyxxa, Zortress, Sitavig, Auvi-Q, long acting narcotics, Retin-A, Savaysa, SGLT2 inhibitors, Gocovri, Immunomodulators (added Cosentyx and Xeljanz as preferred, added baseline scoring tool, etc.), Alecensa, Benlysta, Bosulif, Cabozantinib, Cysteamine, Forteo, Imbruvica, Increlex, PAH, Pegasys, Pomalyst, Procrit, Rubraca, Sprycel, Sutent, Synarel, Tasigna, Zelboraf, Zykadia, Harvoni, Elmiron, Remicade (updated header to include all infliximab products) • Added: Gattex renewal criteria, Fiasp, Vyzulta, Ozempic, Qtern, Symlin, Symproic, Dexcom, Freestyle libre, Odactra, Xhance, Trelegy Ellipta, Lastacaft ST added to precision, Verzenio, Calquence, Endari, Prevymis, Hemlibra, Ximino, Arymo, MorphaBond • Removed: Mirapex (step), Aricept (step), Coreg cr (step), Eliquis PA, Lastacaft ST from standard, Voltaren gel/diclofenac gel (step), Trisenox
02/20/2018	• Updated Strensiq, Ilaris, CEM section, Precision formulary exclusion process

Date	Issues/Updates
02/08/2018	• Updated Stelara, Tremfya, Test strips
12/29/2017	• Updated: Analgesics-NSAIDs oral, quinolones, tetracycline, Multaq, anti-coagulants, anti-convulsants, antidepressants, antimalarials, anti-migraine, antipsychotics, colony stimulating factor, blood products, Bosulif, Daliresp, Cycloset, topical antibiotics for acne, topical-PDE4, topical retinoids, Forteo, Tymlos, PPIs, Daklinza, Epclusa, Harvoni, Hereditary Angioedema products, Soliqua, Iclusig, Imbruvica, Immunomodulators, Benlysta, Inlyta, Iressa, Kalydeco, Zoladex, Lynparza, Nexavar, Restasis, Xiidra, Gocovri, pulmonary HTN, Remicade, Rituxan, Sprycel, Tasigna, Ulcerative colitis, Votrient, Zydelig, Erythropoiesis Stimulating agents, Baraclude, Tyzeka Hemophilia agents • Added: NSAIDS- topical, Clarinex Syrup, Semprex D, Mydayis, biologic agents- allergenic extract agents, blood pressure supplies, CaroSpir, Cosmetic agents, Crohns disease medications, Cysteamine, dermatologics- vitamin D analogs, Thyrogen, Derm- miscellaneous, derm- topical antibiotics, Clindagel, Durlaza, H. pylori agents, Haegarda, Idhifa, Tremfya, Injectable drugs-benefit builder, Mifeprex, Nerlynx, Horizant, Nucala, nutritional diet supplements, Nityr, skeletal muscle relaxants, Duzallo
11/22/2017	• Updated Androgens, Added Mepron
11/09/2017	• Austedo, Vivlodex header, Somavert, Cotempla XR
10/17/2017	• Updated Exception Request TATs for Precision Formulary
10/12/2017	• Weight loss renewal, Truvada, Harvoni
10/06/2017	• Update HepC agents, Onmel spelling • Added Mavyret, Vosevi • Removed Incivek and Infergen
09/29/2017	• Updated Sitavig, Nucynta ER, Precision Bevespi, Actoplus metformin, Vimovo, Sovaldi, Harvoni, Humira, Enbrel, Procrit, Aranesp, Arcalyst, Cabozantinib, Gilotrif, Growth hormone, Ibrance, Infertility agents, Intron-A, Kineret, Orencia, Peg-intron, Pegasys, Tykerb, Venclexta, Zinbryta, Zytiga, Actemra, Kalydeco, Adempas, Ravicti, Hemophilia, Zykadia, Sensipar, Zorvolex, Teflaro, Zyvox, Sivextro, Factive, Luzu, Ocaliva, Cholbam, Isotretinoin, erectile dysfunction, TZDs, Forteo, Fortamet spelling, Otezla spelling, triptan table • Added generic Acticlate (doxycycline), Rebinyn, Austedo, Ingrezza, Alunbrig, Dupixent, Eylea, Faslodex, Kevzara, Kisqali, Lucentis, Macugen, Renflexis, Rydapt, Tymlos, Zejula, Xatmep, HIV drug criteria, ArmonAir Respiclick, Exjade, Jadenu sprinkles, Syprine, Xadago • Removed Cipro, Avelox, Levaquin, ciclopirox solution, Intrarosa, Osphena criteria
09/12/2017	• Updated Calcium channel blockers step, updated fertility drug initiative, generic Uloric spelling, removed duplicate Promacta criteria
08/22/2017	• Added generic acne products, updated Epogen/Aranesp, Otezla • Removed Nucynta IR criteria
08/14/2017	• Tykerb, Added generic Focalin to CNS table, Restasis, Invokamet, and Synjardy
08/07/2017	• Updated Savella and Eucrisa • Added reminder for occurrences for Hep C agents, generic Lialda
08/03/2017	• Updated Axiron, Eliquis, Restasis, Xiidra
07/26/2017	• Updated: Zileuton, Provenge, Pulmozyme, Relistor, Remicade, Revlimid, Linzess, Rituxan, Epiduo (sp), Aczone, Astagraf, Lyrica, long acting narcotics, Samsca, Rasuvo/Otrexup initiative, Signifor, Soliris, Olysio, Sprycel, Sutent, Sylvant, Synarel, Synribo, Tafinlar, Tagrisso, Tarceva, Targretin, Tasigna, Temodar, Tecentriq, tobramycin, Torisel, Treanda, Tykerb, Vectibix, Myrbetriq, Velcade, Venclexta, Vidaza, Votrient, Vpriv, Xalkori, Xenazine, Xeomin, Xiaflex, Xofigo, Xolair, Xtandi, Vascepa, Xyrem,

Date	Issues/Updates
	Yervoy, Zaltrap, Zavesca, Zolinza, Zorbtive, Zydelig, Zykadia, Zytiga, Viberzi, Gleevec, lipotropics, h.p Acthar, Apokyn, Dysport, erectile dysfunction, vivitrol, buprenorphine, Prolia, Synagis, Trulance • Removed: Simulect, Amevive, vancomycin criteria, Refludan, Pedipirox, ciclopirox nail kit, CNL8, Onsolis, Myozyme, Evista/raloxifene criteria, Venofer criteria, Duavee • Changed ICORE to MRX specialty
06/30/2017	• Updated Abraxane, Adcetris, Sandostatin, Appeals, Alimta, Afinitor, Avastin, CNS stimulants, Prestalia, antivirals topical, Mircera, Farydak, Forteo, Gleevec, Imbruvica, Otezla, PAH, Ravicti, Revlimid, Sylatron, Thalomid, Aranesp, Procrit, Actemra, Orencia, Technivie, Daliresp, Savella, Lyrica, Entresto, Relistor tablets, Epipen, Xtampza ER EX on precision, Soliqua, Elidel, Aldurazyme, Alecensa, Abraxane, Adcetris, Sandostatin LAR, Beleodaq, Blincyto, Botox, Cerdelga, Cerezyme, Cometriq, Cyramza, Darzalex, Targretin gel, Dysport, Egrifta, Elaprase, Elelyso, Erbitux, Entyvio, Firmagon, Foltyn, Gattex, Gazyva, Gilotrif, Growth Hormone, Herceptin, Hycamtin, TZDs, Ilaris, Benlysta, Increlex, Intron-A, Iressa, Istodax, Jakafi, Jevtana, Juxtapid, Kadcyla, Kalydeco, Keytruda, Krystexxa, Kynamro, Kyprolis, Lynparza, Marqibo, Ampyra, Myobloc, Myalept, Naglazyme, Nitroglycerin, Nexavar, Opdivo, Perjeta, Pomalyst, Proleukin, Lumizyme, Xgeva, Promacta, Stivarga, Immunomodulators, Zepatier, Test strips, Xeljanz, Remicade, Soliqua, Xultophy, epinephrine • Added Daxbia, Ryvent, Emflaza, Rubraca, Siliq, Xermelo, anti-alcoholic preps, Rhofade, Eucrisa, Airduo Respiclick, Trulance, Inflectra • Removed PA for Descovy, Lupaneta, Selzentry, Triumeq, Amturnide, Myrbetriq, Byvalson
05/16/2017	• Updated Nexavar, Xtandi, Ibrance, Xeloda, pulmonary hypertension, ED, precision test strip table, Zemplar, mesalamine, alogliptin, levalbuterol, Xalkori • Added Glatopa, Onmel, Diclegis, Bonjesta, Zyflo, Zileuton, Vascepa, Sensipar • Updated step for CNS stimulants, Oxytrol, Gelnique, Myrbetriq, anaphylaxis, androgens, antimalarials, SGLT2 inhibitor, immunomodulators, immunosuppressants, Arcalyst, Aricept, inhaled beta agonists • Removed step drug from wording in Otezla and hyaluronic acid derivatives • Add renewal criteria for HIV antivirals, Entresto, Multaq, anti-platelet, COPD agents, Cytoxan, anti-allergen extracts, cardiovascular agents • Changed initiative for Cayston, Kalydeco, Orkambi, pulmozyme, tobramycin
04/14/2017	• Cost exceeds max, growth hormone, vivitrol, weight loss
04/01/2017	• Added Adlyxin, Intrarosa, Soliqua, Xultophy, Vemlidy, Xtampza, Relistor tablets, HBV screening to all Hep C agents, age edit in antipsychotics, link for sildenafil in ED section to pulmonary hypertension • Updated CNS stimulant table, Lyrica, Growth hormone initiative, Akynzeo, Ampyra, Aubagio, Avonex, Betaseron, Caprelsa, Copaxone, Cotellic, Erivedge, Esbriet, Extavia, Gilenya, Hexalen, Intron-A, Jakafi, Mekinist, Mozobil, Ofev, Peg Intron, Pegasys, Plegridy, Rebif, Ribavirin, Stelara, Tafinlar, Tecfidera, Orkambi, Zelboraf, Aranesp, Enbrel, Granix, Mircera, Neupogen, Procrit, Tarceva, Zarxio, Actemra, Berinert, Cinryze, Firazyr, Ruconest, Marinol, Nucynta ER, Restasis, Vivitrol, Evzio, Potiga, Onfi, Felbatol, Sabril, Namzaric, Biguanides, anti-obesity, spelling on Zegerid, Perjeta, antipsychotics, Requip, anaphylaxis agents, length of authorization on Enbrel, Humira, MS, pulmonary hypertension and Botox. • Removed Brilinta criteria
02/21/2017	• Updated Cost Exceeds Max, Cresemba, and Tobramycin
02/16/2017	• Updated Ocaliva, Imbruvica, Cost exceed max. Added Doryx

Date	Issues/Updates
02/10/2017	• Removed gender from Androgens, Fertility, BPH, weight loss. Updated suboxone, Harvoni, epinephrine, cost exceeds max • Added step therapy for InnoPran XL, Inderal XL, Tetracyclines, Solodyn
02/02/2017	• Updated suboxone, precision sections on DPP4 and incretin mimetics
01/25/2017	• Updated Daytrana, SGLT2 inhibitors, Herceptin, Tafinlar, Sutent, Natpara, Biguanide, androgens, precision formulary exception, antipsychotics, antidepressants
01/01/2017	• Updated: QL for Epipen, MS medications, Zontivity, Tamoxifen, Stelara, Fabrazyme, Cotellic, Erectile dysfunction agents initiative, Chantix initiative, Afinitor, epinephrine excluded, androgens, antipsychotic injectables, Bosulif, cost exceeds max, Cerdelga, Targretin topical and oral, fertility agents, renewal criteria for growth hormones for pediatrics, Aranesp, Mircera, Daklinza, Harvoni, Infergen, Olysio, Sovaldi, Technivie, Viekira, Zepatier, hereditary angioedema section, Iclusig, Inlyta, Iressa, Juxtapid, Kynamro, leuprolide products, lipotropics, Lonsurf, Duavee, Nexavar, Odomzo, Orkambi, Requip XL, Sprycel, Sutent, Tasigna, Votrient, weight loss agents, Zavesca, Zelboraf, Zolinza, Zydelig. Glyxambi • Removed: first-omeprazole, first-lansoprazole, tamoxifen, alpha adrenergic blocking agents section, sections marked as 2016, removed 2017 labels, gender wording in androgens, drug to gender section and BPH section, Vivaglobin • Added: Dificid, Alinia, Xifaxan, Syndros, Epclusa, Viekira XR, Cuvitru, Xiidra, Tecentriq, Darzalex, Byvalson • Updated rejection codes: 2193 code to Age limit, Alzheimer's agents, androgens, anticonvulsants, antifungals, antineoplastics, antipsychotics, antivirals, beta-adrenergic agents, CNS stimulants, dermatologic agents, gastrointestinals: IBS agents, immunomodulators topical, narcotic analgesics long acting, oncology agents, retinoids, sedative hypnotics, pulmonary and respiratory agents. Quantity limit per day exceeded to narcotics: long acting and quantity limit sections
11/09/2016	• Updated: Namenda, Aricept, Kadian, Nucynta ER, Zohydro, corrections in LAN table, updated SAN section, cambia, epi-pen, Eliquis, CNS stimulant table, antipsychotics step criteria, Cardura, Viagra for precision formulary, letrozole no pa required, PPI section, gastrointestinals: pancrelipase, incretin mimetics, insulins, DPP4 inhibitors, sglt2 inhibitors, inhale anticholinergics, Utibron, Amitiza, Movantik, Evzio, Subsys, Gralise, Lastacaft, Requip xl, Mirapex xl, Asacol, Apriso • Added testosterone enanthate, added step: Amturnide, Onzetra, Zembrace, Ulesfia, Eurax, Sklice, Ovide, topical acne • Removed Benicar, Atacand, Diovan, Cozaar, Latuda step, opioid QL in quantity limit section
10/27/2016	• Updated Long acting and Short acting narcotics criteria, added Viekira XR and updated all Hep C tables, updated Rozerem, updated Otezla starter pack quantity • Removed Sanctura
10/07/2016	• Updated Alvesco, Fentanyl and Embeda
10/04/2016	• Updated Natesto, Precose, Starlix, Amturnide, Tekturna, Edarbi, Edarbyclor, Arcapta, Qsymia, Striverdi • Added Evekeo, Natroba
10/01/2016	• Updated: Hepatitis C Fibrosis scores, SGLT2 inhibitors, Cabometyx, Tarceva, Tykerb, Xeloda, Zykadia, Lenvima, Neupogen, Cresemba, Zoladex, Vantas, Supprelin LA, Trelstar, Xarelto, Pradaxa, Adoxa, Metozolv, Micardis HCT, Zetia, Exforge, Simcor, Tribenzor, Twynsta, Nexium, Eliquis, Androxy, Oxandrin, Xolair, Synagis, Trintellix, Qsymia, Bethkis, Leuprolide products

Date	Issues/Updates
	• Added: Albenza, Afstyla, Baraclude, Bevespi, Biltricide, Cayston, Denavir, Descovy, Emverm, Gilotrif, GoNitro, Hepsera, Nuplazid, Ocaliva, Sitavig, Stromectol, Taltz, Testone cik, Tyzeka, Utibron, Venclexta, Xerese, Zinbryta, Zovirax
08/31/2016	• Updated Adempas, Strensiq
08/16/2016	• Updated Cost Exceeds Max
08/09/2016	• Updated Ampyra, Apidra, Cost exceeds max, Octreotide, Added Afrezza
07/28/2016	• Added Cabometyx
07/27/2016	• Updated Afinitor, Lenvima
07/19/2016	• Updated Growth Hormone, Immuno globins, incretin mimetics, multiple sclerosis • Added step Lastacaft
07/01/2016	• Added: Zepatier, Coccygeal, Speedgel, Tranzgel, Lidorx, Briviact, Zurampic, Strensiq, Cotellic, Tagrisso, Ninlaro, Alecensa, Adynovate, Coagadex, Idelvion, Kovaltry, Uptravi, Botox, Dyanavel, Adzenys XR, QuilliChew, Zecuity, Onzetra Xsail, Zembrace, Tresiba, Prestalia, Tolak, Stendra • Updated: Jublia, Kerydin, Invokana, Farxiga, Jardiance, Glyxambi, Invokamet, Xigduo, Jentadueto, Tradjenta, Kazano, Nesina, Oseni, Synjardy, Androgens, immunomodulators, Ravicti, Cosentyx, Cometriq, Farydak, Ibrance, Imbruvica, Gazyva, Xeomin, Revlimid, Sylatron, Temodar, Doxil, Aranesp, Granix, Neulasta, Neupogen, Procrit, Opdivo, Zarxio, Actemra, Cimzia, Arzerra, Avastin, Blincyto, Stelara, Eligard, Lupron depot, Emend, Halaven, Kalydeco, Treximet, Apriso, Asacol, Delzicol, Hysingla LA, Nucynta ER, Zohydro ER, Myrbetriq, Asmanex, Tribenzor, Elidel, Test strips, Daklinza, Cinryze, Trulicity, Seebri • Added Precision formulary • Precision Formulary- Diabetic supplies criteria was updated. Exclude all non-preferred except OneTouch
06/01/2016	• Updated MS medications, updated Belbuca and Xopenex
05/16/2016	• Updated Cytoxan, Evzio, Gilenya, Ibrance, Linzess, Remicade, Repatha, test strips, Tecfidera • Added Daraprim, Call procedure
04/12/2016	• Added oral contraceptive section, updated Rasuvo and Otrexup, update approval lengths for immunomodulators, Xolair, Aubagio, Tecfidera, Ampyra
4/1/2016	• Standard Formulary- To provide guidance to the PA team for requests to override ST rejects for Diabetic Supplies, PA criteria was implemented on 4/1/16
03/30/2016	• Added Preferred Agent(s)/Non-Preferred Agent(s) by Genotype tables to each Hep C drug
03/22/2016	• Updated step therapy for Afinitor, Bosulif, Inlyta, Nexavar, Sutent, Tasigna and Votrient • Added step therapy for Glumetza • Added Vraylar
02/23/2016	• Added Addyi, Aristada, Belbuca, Keveyis, Lonsurf, Nuwiq, Seebri, Utibron, Veltassa, Vivlodex • Removed Victrelis • Olysio; added t/f of Harvoni/Sovaldi for genotype 1 • Daklinza: added nonpreferred status on genotype 1
02/09/2016	• Updated Caprelsa, Cimzia, Hycamtin, Intron-A, Jakafi, Lynparza, Mekinist, Mozobil, Nuedexta, Pradaxa, Sandostatin, Orencia, PEGIntron, Pomalyst, Stelara, Stivarga, Tafinlar and Xyrem
01/29/2016	• Changes to Daklinza, Sovaldi, Olysio, Harvoni, and Technivie; added preferred status.
01/20/2016	• Updated Daklinza, Harvoni, Sovaldi, Technivie, Viekira, Simvastatin, Rituxan, Firazyr

Date	Issues/Updates
01/11/2016	• Removed HepC for Alhambra plan, updated Gleevec
12/29/2015	• Updated Harvoni, Olysio, Sovaldi, Viekira, diabetic supplies
12/22/2015	• Updated Harvoni, Olysio, Sovaldi, Viekira and Xtandi • Added Envarsus XR, Iressa, Odomzo, Ixinity, Novoeight, Zarxio, Daklinza, Technivie, Entresto, Natesto and Proair Respiclick
12/07/2015	• Added Viberzi and Soliris • Updated Praluent/Repatha, Rexulti, Lupron, Prolia, Harvoni and Sovaldi
11/17/2015	• Updated Tanzeum step, Xtandi Step • Added Praluent, Repatha, Rexulti, Orfadin and Aptensio • Added address information
11/10/2015	• Updated Cost Exceeds Max section
11/02/2015	• Added Cholbam, Cresemba, Duopa, Jadenu, Invega Trinza, Lenvima, Orkambi
10/26/2015	• Updated Appeals • Added step therapy: Aerospan, Belsomra, Elidel, Mitigare, Protopic, Stiolto, Toujeo • Added Natpara • Updated term dates on HepC medications
10/09/2015	• Added Drug Shortage information • Update Synagis dates • Update Cost Exceeds Maximum
09/22/2015	• Added step therapy for Pegasys • Updated drugs from Tier 2 to Tier 3
08/31/2015	• Added Resveratrol as compound drug exclusion • Fixed heading (changed Ophthalmics to Dermatologicals)
08/27/2015	• Added Fully-Funded Plans to Plan Summary • Added step therapy to Androgens • Updated Appeals section • Updated Step Criteria for Topical Antibiotics for Acne
07/30/2015	• Updated appeals, updated quantity limit
07/20/2015	• Added step therapy: Jardiance, Proventil, Trulicity, Xigduo XR • Removed step therapy: Bydureon, Victoza • Update androgens- topical administration
07/07/2015	• Added Ibrance • Added Farydak • Added step to the following: growth hormone, Duexis • Update appeals
07/01/2015	• Added Viekira Kit ALHAMBRA custom client criteria
06/29/2015	• Cost Exceeds Max compound PA required for clients who select PA and compounds • Compounds-added quantity criteria
06/16/2015	• Added Cost Exceeds Max: Plan Review Procedures • Added Compounds Cost Exceeds max procedures
06/02/2015	• Added Cosentyx

Date	Issues/Updates
	• Added Savaysa
05/26/2015	• Updated Androgens to include Androgel 1.62%
05/22/2015	• Updated drugs from tier 3 to specialty
05/18/2015	• Update Androgens
04/06/2015	• Removed Step from Tobramycin (Tobi) • Added Kitabis
04/01/2015	• Added Akynzeo • Added Lynparza • Added Opdivo • Added Esbriet • Added Signifor LAR • Added OFEV • Triumeq • Tobramycin step edit • Added Tier exception
02/23/2015	• Added step process to Sovaldi, Olysio, and Harvoni • Added Viekira Pak • Added Viekira Pak to Alhambra • Removed MNC: Cost Exceeds MAX
02/16/2015	• Added COX2, Beta Blocker, Dermatologics: Oral antibiotics agents for acne, Gastrointestinal: Pancrease, Evzio, Parkinson's Drug • Added Step for the following drugs: Adoxa, Metozolv, Rapaflo, Amturnide, Coreg CR, Exforge, Exforge HCT, Tekturna, Tekturna HCT, Twynsta, Tribenzor, Simcor, Namenda XR, Jublia, Apidra, Bydureon, Byetta, Kazano, Kombiglyze, Victoza, Ascensia, Bayer, Fast Take, Freestyle, Precision, Prestige, Prodigy, Trueresult, True Track, Pertzye, Ultresa, Viokace, Treximet, Lastacaft, Vimovo, Ryzolt, Mirapex ER, Requip XL
02/02/2015	• Updated Compound Overrides • Updated Vyvanse indication • Added CII Early Fills
01/28/2015	• Updated Androgens • Updated Cost Exceeds Max
01/23/2015	• Updated Appeals • Added Cost Exceeds Maximum: Plan Review
01/14/2015	• Call Center FAQs • Billing Information • Mail Order Facilities
01/02/2015	• Avonex • Betaseron • Copaxone • Extavia • Rebif • Olysio

Date	Issues/Updates
	• Sovaldi • Enbrel • Actemra • Cimzia • Kineret • Orencia • Simponi • Simponi Aria • Stelara • Plegridy • Aubagio • Tecfidera • Growth Hormones-class • Otezla • Xeljanz • Remicade • Victrelis • Hematopoietic agents
12/23/2014	• Added: • Chemotherapy Off-label indication procedures • Antibiotics-Cephalosporins • Apokyn • Beleodaq • Cerdelga • Foltyn • Healthcare reform coverage of contraceptives • Harvoni-General • Harvoni-Alhambra • Sovaldi-Alhambra • Olysio-Alhambra • Keytruda • No criteria drugs • Northera • Prialt • Sculptra • Selective Estrogen Receptor Modulators • Vidaza • Visudyne • Xofigo • Zemplar • Zontivity • Zydelig

Date	Issues/Updates
	• Sabril to anticonvulsants • Savella • Kytril • Aloxi • Mirvaso • Modified: • Sovaldi-General • Olysio-General • HP Acthar • Abraxane • Alpha-1 Proteinase inhibitor • Analgesics: buprenorphine products for opiate addiction • Analgesics: Narcotics: long acting • Androgens • Angiotensin Receptor Blockers • Antibiotics: gastrointestinal • Antibiotics: oxazolidinones • Antibiotics: quinolones • Antifungals: changed to PA required for Ciclodan, ciclopirox bottle and nail kit, Pedipirox, and CNL nail kit • Antihyperkinesis: Added Step therapy to Adderall, Adderall XR, Dexedrine, Daytrana, Metadate CD, Ritalin (all derivatives), ProCentra, and Concerta and all generic derivatives • Antimigraine medications: Triptans- Added Step therapy • Bisphosphonates- Added Reclast and Zometa to Tier 3, Risedronate, pamidronate and Zoledronic acid to tier 1 • Compounds: Added Ubiquinol, LidoProfen cream, and Vopac KT cream • Cost Exceeds Max: Added Final Plan approval 50084-75 • Cometriq-added off label indication protocol • DMARD: added Rasuvo, Otrexup, Trexall and Otezla • PAH-added sildenafil to PA • QL-added opioid QL • Hematopoietic agents_ added three off label indications • Hypoglycemics-added Step therapy • Immunomodulators-added additional dx • Increlex-added additional renewal criteria • Inhaled beta agonist: Arcapta-added additional criteria; Serevent diskus and Foradil aerolizer; added criteria • Leuprolide-added additional criteria; added Supprelin la, Trelstar, Vantas • Lipotropics: added Liptruzet • Off-label Use: verbiage change • Osteoarthritis agents: change in length of approval from 1 year to 3 weeks • Remicade: criteria change • Vectibix: added criteria

Date	Issues/Updates
	• Velcade: added criteria • Xeljanz: modified criteria • Deletions: • Workarounds
10/21/2014	• Acthar diagnosis deletion of MS, SLE, RA, JRA, Spondylitis Nephrotic syndrome, Keratitis. • Acthar approval is 1 month. • Actonel, Mycobutin, Lunesta, Ortho Evra, Mepron, Androgel, Betimol and Testim 1% gel moved to tier 3 • Cyclophosphamide (Cytoxan), Emend, FBL Cream Kit, Cesamet, Oralair sub, Ragwitek, Sivextro, Vivitrol, Tretten, Zontivity, Grastek is PA required • Cystaran, Ravicti, Famciclovir, Relistor, Otrexup removed from specialty list. • Savella, Tanzeum, ProCentra added to Step therapy • Amitiza, Desoxyn, ProCentra, Zenzedi has age edit
08/29/2014	• Immunomodulators-clinical changes • Wt loss agents. Added Belviq • Updated Accu-check qty • Updated EBMS oral chemotherapy agents • Updated Appeals guidelines
08/07/2014	• Added ICORE Specialty Medication Section • Updated EBMS Appeal Guidelines • Added Cost Exceeds Max Section • Added Stelara to Immunomodulators- injectable Section • Added Rx Date Written Too Old Section
07/17/2014	• Updated Clinical Service Team Escalations section • Updated Analgesics – Buprenorphine Products for Opiate Addiction • Updated Antibiotics – Gastrointestinal • Updated Clinical Criteria for Twice Daily Dosing – QL Override for Gastrointestinals PPIs – Step Therapy • Updated Quantity Limits table
07/08/2014	• Change BIN/PCN for BAI/Glendale • Updated QL: 2641/76 • Updated MNC: Drug Exclusion: 50076/70 • Updated CEM verbiage
07/01/2014	• Initial creation