Clinical Policy: Atezolizumab (Tecentriq), Atezolizumab-Hyaluronidase (Tecentriq Hybreza)

Reference Number: CP.PHAR.235
Effective Date: 06.01.16
Last Review Date: 02.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

- Atezolizumab (Tecentriq®) is a programmed death-ligand 1 (PD-L1) blocking antibody.
- Atezolizumab and hyaluronidase-tqjs (Tecentriq Hybreza™) is a combination of atezolizumab and hyaluronidase, and endoglycosidase.

FDA Approved Indication(s)

Tecentriq and Tecentriq Hybreza are indicated:

- **Non-small cell lung cancer (NSCLC)**
  - As adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage II to IIIA NSCLC whose tumors have PD-L1 expression on ≥ 1% of tumor cells, as determined by an FDA-approved test.
  - For the first-line treatment of adult patients with metastatic NSCLC whose tumors have high PD-L1 expression (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, with no EGFR or ALK genomic tumor aberrations.
  - In combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
  - In combination with paclitaxel protein-bound and carboplatin for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
  - For the treatment of adult patients with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations prior to receiving Tecentriq or Tecentriq Hybreza.
- **Small cell lung cancer (SCLC)**
  - In combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).
- **Heptatocellular carcinoma (HCC)**
  - In combination with bevacizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy.

- **Melanoma**
  - In combination with cobimetinib and vemurafenib for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma as determined by FDA-approved test.
- **Alveolar soft part sarcoma (ASPS)**
  - Tecentriq is used for the treatment of adult and pediatric patients 2 years of age and older with unresectable or metastatic ASPS.
  - Tecentriq Hybreza is only used for the treatment of adult patients with unresectable or metastatic ASPS.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Tecentriq and Tecentriq Hybreza are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a, b, c, d, or e):
   a. For stage II to III NSCLC, prescribed as a single agent and meets one of the following (i or ii):
      i. Member has had previous resection;
      ii. Member has all the following (1, 2 and 3):
         1) High-risk stage IIA or stage IIIB NSCLC (*see Appendix D*);
         2) PD-L1 expression ≥ 1%;
         3) Previously received platinum-containing chemotherapy *(see Appendix B)*;
   b. For member with both a negative or unknown EGFR or ALK mutation status AND recurrent, advanced, or metastatic NSCLC: Member meets one of the following (i, ii, or iii):
      i. Request is for use as a single agent as first-line therapy for tumors that have high PD-L1 expression (PD-L1 ≥ 50% [TC ≥ 50%] or tumor-infiltrating IC covering ≥ 10% of the tumor area [IC ≥ 10%]) and continued as a single agent for maintenance therapy;
      ii. Member has previously received platinum-containing chemotherapy *(see Appendix B)*;
      iii. If no prior progression on a PD-1/PD-L1 inhibitor (i.e., Tecentriq as well as nivolumab, pembrolizumab, durvalumab), request is for single agent as subsequent therapy;
   c. For member with a positive EGFR or ALK mutation status AND recurrent, advanced, or metastatic NSCLC: Member has a history of disease progression during or following an NCCN-recommended therapy for the specific mutation *(see Appendix B)*;

d. For member with non-squamous cell histology AND disease is recurrent, advanced, or metastatic: Request for use is in combination with one of the following (i or ii):
   i. Bevacizumab, paclitaxel, and carboplatin and continued in combination with bevacizumab for maintenance therapy;
   ii. Paclitaxel protein-bound (Abraxane®) and carboplatin and continued as a single agent for maintenance therapy;
e. For member with a performance score of 3, request is for use as a single agent;

5. Request meets one of the following (a, b, or c):*
   a. For Tecentriq: Dose does not exceed 1,680 mg every 4 weeks;
   b. For Tecentriq Hybreza: Dose does not exceed 1,875 mg/30,000 units every 3 weeks;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

B. Small Cell Lung Cancer (must meet all)**:**
1. Diagnosis of extensive-stage SCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with carboplatin and etoposide and continued as a single agent for maintenance therapy;
5. Request meets one of the following (a, b, or c):*
   a. For Tecentriq: Dose does not exceed 1,680 mg every 4 weeks;
   b. For Tecentriq Hybreza: Dose does not exceed 1,875 mg/30,000 units every 3 weeks;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

C. Hepatocellular Carcinoma (must meet all):
1. Diagnosis of HCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with bevacizumab as first-line systemic therapy or adjuvant therapy;
5. Request meets one of the following (a, b, or c):*
   a. For Tecentriq: Dose does not exceed 1,680 mg every 4 weeks;
   b. For Tecentriq Hybreza: Dose does not exceed 1,875 mg/30,000 units every 3 weeks;

c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

D. Melanoma (must meet all):
1. Diagnosis of melanoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with cobimetinib and vemurafenib;
5. Member is *BRAF V600* mutation positive;
6. One of the following (a or b):
   a. Disease is unresectable or metastatic;
   b. Request is for use as re-induction therapy;
7. Request meets one of the following (a, b, or c):*
   a. For Tecentriq: Dose does not exceed 1,680 mg every 4 weeks;
   b. For Tecentriq Hybreza: Dose does not exceed 1,875 mg/30,000 units every 3 weeks;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

E. Alveolar Soft Part Sarcoma (must meet all):
1. Diagnosis of ASPS;
2. Disease is unresectable or metastatic;
3. Prescribed by or in consultation with an oncologist;
4. Member meets one of the following (a or b):
   a. Tecentriq: Age ≥ 2 years;
   b. Tecentriq Hybreza: Age ≥ 18 years;
5. Prescribed as a single-agent therapy;
6. Request meets one of the following (a, b, or c):*
   a. For Tecentriq, Dose does not exceed one of the following (i or ii):
      i. For adults: 1,680 mg every 4 weeks;
      ii. For pediatrics: 15 mg/kg (up to a maximum of 1,200 mg) every 3 weeks;
   b. For Tecentriq Hybreza: Dose does not exceed 1,875 mg/30,000 units every 3 weeks;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

F. Mesotheliomas (off-label) (must meet all):
1. Diagnosis of one of the following (a, b, or c):
   a. Peritoneal mesothelioma;
   b. Pericardial mesothelioma;
   c. Tunica vaginalis testis mesothelioma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with bevacizumab as subsequent systemic therapy;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).**

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

G. Urothelial Carcinoma (off-label) (must meet all)**:**
1. Diagnosis of urothelial carcinoma (UC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. One of the following (a or b):
   a. Member is ineligible for cisplatin-containing chemotherapy, and the tumor expresses PD-L1;
   b. Member is ineligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) regardless of PD-L1 status;
5. Prescribed as a single agent;
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).**

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

H. Cervical Cancer (off-label) (must meet all)
1. Diagnosis of small cell neuroendocrine carcinoma of the cervix;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is persistent, recurrent, or metastatic;
5. Prescribed in combination with cisplatin/carboplatin and etoposide and continued as a single agent for maintenance therapy;
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).**

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

I. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Tecentriq or Tecentriq Hybreza for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed one of the following (i or ii):
      i. For pediatric ASPS: 15 mg/kg (up to a maximum of 1,200 mg) every 3 weeks;
      ii. All other indications (1 or 2):
         1) For Tecentriq: 1,680 mg every 4 weeks;
         2) For Tecentriq Hybreza: 1,875 mg/30,000 units every 3 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALK: anaplastic lymphoma kinase
ASPS: alveolar soft part sarcoma
EGFR: epidermal growth factor receptor
ES-SCLC: extensive-stage small cell lung cancer
FDA: Food and Drug Administration
HCC: hepatocellular carcinoma
IC: immune cells
NSCLC: non-small cell lung cancer
PD-L1: programmed death-ligand 1
SCLC: small cell lung cancer
TC: tumor cells
UC: urothelial carcinoma

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cisplatin-, oxaliplatin- (Eloxatin®) or carboplatin-containing chemotherapy	UC: Varies	Varies
cisplatin-, or carboplatin-containing chemotherapy	NSCLC: Varies	Varies
Xalkori® (crizotinib) Alecensa® (alectinib) Zykadia® (ceritinib)	NSCLC with ALK tumor aberration: Varies	Varies
erlotinib (Tarceva®) Gilotrif® (afatinib) gefitinib (Iressa®)	NSCLC with EGFR tumor aberration: Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Tecentriq: None reported
  - Tecentriq Hybreza: Patients with known hypersensitivity to hyaluronidase or any of its excipients
- Boxed warning(s): None reported

Appendix D: General Information

- NSCLC examples of high-risk factors: may include poorly differentiated tumors (including lung neuroendocrine tumors [excluding well-differentiated neuroendocrine tumors]), vascular invasion, wedge resection, visceral pleural involvement, and unknown lymph node status (Nx). These factors independently may or may not be an indication and may be considered when determining treatment with adjuvant chemotherapy.
- SCLC consists of two stages: limited-stage and extensive-stage. Extensive-stage is defined as stage IV (T any, N any M 1a/b) or T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan.
- On December 2, 2022, following consultation with the FDA, Roche withdrew Tecentriq's use for any form of UC. The withdrawal was based on data from the IMVigor130 study, which tested Tecentriq with chemotherapy against chemotherapy alone and failed to meet the co-primary endpoint of overall survival. Patients given Tecentriq chemo combination lived a median of 16 months after treatment, compared with 13.4 months for those receiving just chemo, a difference that wasn't statistically significant.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Adjuvant NSCLC	Following resection and up to 4 cycles of platinum-based chemotherapy: ***Tecentriq***: 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks for up to 1 year ***Tecentriq Hybreza:*** 1,875 mg atezolizumab and 30,000 units hyaluronidase SC every 3 weeks for up to 1 year When administering with chemotherapy with or without bevacizumab, administer Tecentriq or Tecentriq Hybreza prior to chemotherapy and bevavizumab when given on the same day	Tecentriq: 1,680 mg/4 weeks Tecentriq Hybreza; 1,875 mg/3 weeks
Metastatic NSCLC	***Tecentriq:*** 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks	Tecentriq: 1,680 mg/4 weeks

Indication	Dosing Regimen	Maximum Dose
	Tecentriq Hybreza: 1,875 mg atezolizumab and 30,000 units hyaluronidase SC every 3 weeks When administering with chemotherapy with or without bevacizumab, administer Tecentriq or Tecentriq Hybreza prior to chemotherapy and bevavizumab when given on the same day	Tecentriq Hybreza; 1,875 mg/3 weeks
SCLC	***Tecentriq:*** 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks ***Tecentriq Hybreza***: 1,875 mg atezolizumab and 30,000 units hyaluronidase SC every 3 weeks When administering with carboplatin and etoposide, administer Tecentriq or Tecentriq Hybreza prior to chemotherapy when given on the same day.	Tecentriq: 1,680 mg/4 weeks Tecentriq Hybreza; 1,875 mg/3 weeks
HCC	***Tecentriq:*** 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks. ***Tecentriq Hybreza***: 1,875 mg atezolizumab and 30,000 units hyaluronidase SC every 3 weeks Administer Tecentriq or Tecentriq Hybreza prior to bevacizumab when given on the same day. Bevacizumab is administered at 15 mg/kg every 3 weeks.	Tecentriq: 1,680 mg/4 weeks Tecentriq Hybreza; 1,875 mg/3 weeks
Melanoma	Following completion of a 28 day cycle of cobimetinib and vemurafenib, administer Tecentriq or Tecentriq Hybreza in combination with cobimetinib 60 mg PO QD (21 days on/7 days off) and vemurafenib 720 mg PO BID ***Tecentriq:*** 840 mg IV every 2 weeks, 1,200 mg every 3 weeks, or 1680 mg every 4 weeks ***Tecentriq Hybreza***:1,875 mg atezolizumab and 30,000 units hyaluronidase SC every 3 weeks	Tecentriq: 1,680 mg/4 weeks Tecentriq Hybreza; 1,875 mg/3 weeks
ASPS	***Tecentriq:*** • Adults: 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks Pediatrics: 15 mg/kg (up to a maximum of 1,200 mg) every 3 weeks •	Tecentriq: • Adults: 1,680 mg/4 weeks • Pediatrics: 15 mg/kg (up to 1,200 mg)/3 weeks

Indication	Dosing Regimen	Maximum Dose
	Tecentriq Hybreza (adults only): 1,875 mg atezolizumab and 30,000 units hyaluronidase SC every 3 weeks	Tecentriq Hybreza (adults only): 1,875 mg/3 weeks

VI. Product Availability

Drug Name	Availability
Atezolizumab (Tecentriq)	Single-dose vials: 840 mg/14 mL, 1,200 mg/20 mL
Atezolizumab-hyaluronidase (Tecentriq Hybreza)	Single-dose vial: 1,875 mg atezolizumab/30,000 units hyaluronidase/15 mL

VII. References

1. Tecentriq Hybreza Prescribing Information. South San Francisco, CA: Genentech, Inc.; September 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761347s000lbl.pdf. Accessed November 18, 2024.
2. Tecentriq Prescribing Information. South San Francisco, CA: Genentech, Inc.; May 2023. Available at: https://www.tecentriq.com. Accessed November 18, 2024.
3. Atezolizumab In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: nccn.org. Accessed November 7, 2024.
4. Atezolizumab and hyaluronidase-tqjs In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: nccn.org. Accessed November 18, 2024.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9022	Injection, atezolizumab, 10 mg
J9999	Not otherwise classified, antineoplastic drugs
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: for HCC, unresectable or metastatic removed to accommodate local disease per NCCN; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	10.15.20	02.21
RT4 policy update to remove the indication, previously approved under accelerated approval, for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following any platinum-containing	05.12.21	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy.		
1Q 2022 annual review: RT4: removed breast cancer indication and added NSCLC stage II to IIIA treatment indication per updated label; added criterion for use as single-agent therapy for urothelial carcinoma per NCCN; added criterion for Child-Pugh class A status in HCC per NCCN; references reviewed and updated.	01.18.22	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.07.22	
1Q 2023 annual review: added criterion for malignant peritoneal mesothelioma per NCCN; adjusted dose to not exceed 1,680 mg every 4 weeks for melanoma per PI; section V updated per PI; revised commercial approval duration to the current standard for injectables of"6 months or to member's renewal date, whichever is longer"; references reviewed and updated. RT4: for urothelial carcinoma, removed FDA approved accelerated indication per updated PI and changed to off-label as still supported by NCCN; added ASPS indication per updated PI.	01.09.23	02.23
1Q 2024 annual review: for NSCLC, added option for stage IIIB NSCLC; for HCC, added option for Child-Pugh Class B per NCCN; for melanoma, added option for usage as re-induction therapy per NCCN; for ASPS, added prescribed as single-agent therapy per NCCN; added criterion for cervical cancer per NCCN; updated generic availability for Tarceva and Iressa in Appendix B; references reviewed and updated.	10.16.23	02.24
RT4: added newly approved Hybreza formulation.	11.04.24	
1Q 2025 annual review: for Tecentriq Hybreza, updated dosing to include hyaluronidase component and updated contraindications per PI; for non-squamous NSCLC, removed requirement for negative or unknown EGFR or ALK mutation status per NCCN; for NSCLC, added Tecentriq/Tecentriq Hybreza may be continued for maintenance therapy as a single agent (if given as single agent first line therapy or atezolizumab/carboplatin/albumin-bound paclitaxel combination) or in combination with bevacizumab (if atezolizumab/carboplatin/paclitaxel/bevacizumab given) per NCCN; for SCLC and cervical cancer, added Tecentriq/Tecentriq Hybreza may be continued as a single agent for maintenance therapy per NCCN; for HCC, added option to be prescribed as adjuvant therapy and removed criteria requiring confirmation of Child-Pugh class A or B status requirement per NCCN; for melanoma, revised requirement for member BRAF V600 mutation positive to apply to all circumstances (not just metastatic or unresectable disease) per NCCN; for mesotheliomas, added option for usage originating from the	11.18.24	02.25

Reviews, Revisions, and Approvals	Date	P&T Approval Date
pericardium or the tunica vaginalis per NCCN; references reviewed and updated.		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.