Clinical Policy: Venetoclax (Venclexta)

Reference Number: CP.PHAR.129
Effective Date: 07.17.18
Last Review Date: 11.26
Line of Business: Commercial, HIM/ICHRA, Medicaid Revision Log

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

Description

Venetoclax (Venclexta®) is a B-cell lymphoma 2 protein (BCL-2) inhibitor.

FDA Approved Indication(s)

Venclexta is indicated:

- For the treatment of patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
- In combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy

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 Venclexta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (must meet all)**:**

1. Diagnosis of CLL or SLL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. For brand Venclexta requests, member must use generic venetoclax, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. Request meets one of the following (a, b, or c):*
   a. Prescribed as first-line therapy in one of the following ways (i, ii, iii, or iv):
      i. In combination with Gazyva®;
      ii. In combination with Imbruvica®;
      iii. In combination with Calquence®, with or without Gazyva;
      iv. In combination with Brukinsa®;
   b. Prescribed as subsequent therapy as a single agent or in combination with either rituximab, Gazyva, Imbruvica, Calquence, or Brukinsa (*see Appendix B for examples of prior therapy*);
   c. Prescribed for histologic (Richter) transformation to diffuse large B-cell lymphoma in one of the following ways (i, ii, or iii):
      i. As initial therapy and a component of a RCHOP regimen;

ii. In combination with Tecentriq® and Gazyva;
iii. In combination with Jaypirca® and Gazyva;
**Prior authorization may be required.*

6. Request meets one of the following (a or b):*
   a. Dose does not exceed both of the following (i and ii):
      i. 400 mg per day;
      ii. 4 tablets per day;
   b. 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: 12 months

B. Myeloid Leukemias (must meet all)**:**

1. Diagnosis of one of the following myeloid leukemias (a or b):
   a. AML;
   b. Blastic plasmacytoid dendritic cell neoplasm (BPDCN);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. For brand Venclexta requests, member must use generic venetoclax, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. If diagnosis is AML, one of the following (a or b):
   a. Venclexta is prescribed for induction, post-induction, or consolidation therapy, and one of the following (i or ii):
      i. Age ≥ 75 years and disease is newly diagnosed;
      ii. Member is not a candidate for or declines use of intensive induction chemotherapy (*see Appendix B for examples*);
   b. Disease is relapsed/refractory (*see Appendix B for examples*);*
      **Prior authorization may be required.*
6. If diagnosis is BPDCN, one of the following (a or b):
   a. Venclexta is prescribed for treatment induction;
   b. Disease is relapsed/refractory;
7. Prescribed in combination with one of the following (a, b, or c):
   a. Azacitidine, decitabine, or low-dose (20 mg/m^2) cytarabine;*
   b. For relapsed/refractory disease, therapy-related AML,^ and poor-risk AML: One of the following regimens (i or ii):
      i. Fludarabine and cytarabine, with or without idarubicin;*
      ii. Cladribine, idarubicin, and cytarabine;*
   c. Inqovi®, and one of the following (i or ii):*
      i. Age ≥ 75 years and disease is newly diagnosed;
      ii. Member is not a candidate for or declines use of intensive induction chemotherapy (*see Appendix B for examples*);

**Prior authorization may be required.*
^Therapy-related AML other than core-binding factor (CBF)-AML, antecedent MDS/CMML, or cytogenetic or molecular changes consistent with MDS (previously classified as AML-MRC)

8. Request meets one of the following (a, b, or c):*
   a. In combination with azacitidine or decitabine: Dose does not exceed both of the following (i and ii):

i. 400 mg per day;
ii. 4 tablets per day;

b. In combination with low-dose cytarabine: Dose does not exceed both of the following (i and ii):
i. 600 mg per day;
ii. 6 tablets per day;

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: 12 months

C. Mantle Cell Lymphoma (off-label) (must meet all)**:**

1. Diagnosis of mantle cell lymphoma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. For brand Venclexta requests, member must use generic venetoclax, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. Venclexta is prescribed as one of the following regimens (a, b, or c):
   a. Single agent as subsequent therapy;
   b. In combination with rituximab or Imbruvica as subsequent therapy;*
   c. In combination with Gazyva and Brukinsa, and both of the following (i and ii):*
      i. Disease is positive for TP53 mutation;
      ii. A clinical trial is not available (*a clinical trial is strongly recommended*);

   **Prior authorization may be required.*
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: 12 months

D. Multiple Myeloma (off-label) (must meet all)**:**

1. Diagnosis of multiple myeloma with t(11;14) translocation;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. For brand Venclexta requests, member must use generic venetoclax, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. One of the following (a or b):
   a. Member has central nervous system (CNS) disease with no other options available;
   b. Member has received ≥ 1 prior therapy (*see Appendix B for examples*) and Venclexta is prescribed in combination with dexamethasone;*

   **Prior authorization may be required.*
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: 12 months

E. Additional NCCN Recommended Uses (off-label) (must meet all)**:**
1. Diagnosis of one of the following (a-g):
   a. Chronic myelomonocytic leukemia (CMML)-2, with Venclexta prescribed in combination with a hypomethylating agent (e.g., azacitidine or decitabine);*
   b. Myelodysplastic syndrome (MDS) that is higher-risk (i.e., IPSS-R [intermediate, high, or very high]), with Venclexta prescribed in combination with either azacitadine, decitabine, or Inqovi);*
   c. Hairy cell leukemia that is relapsed/refractory;
   d. Myeloproliferative neoplasm, with Venclexta prescribed in combination with hypomethylating agents;*
   e. Acute lymphoblastic leukemia (ALL) of one of the following types (i, ii, iii, or iv):
      i. Pediatric acute lymphoblastic leukemia (ALL) that is relapsed/refractory;
      ii. T-cell ALL that is relapsed/refractory;
      iii. Philadelphia chromosome negative B-cell ALL and one of the following (1, 2, or 3):
         1) Age ≥ 18 years and member has substantial comorbidities;
         2) Age ≥ 65 years;
         3) Disease is relapsed or refractory;
      iv. Philadelphia chromosome-positive B-cell ALL, that is refractory to tyrosine kinase inhibitor therapy (e.g., bosutinib, dasatinib, imatinib, Iclusig®, Scemblix®);
   f. Systemic light chain amyloidosis and both of the following (i and ii):
      i. Disease is relapsed/refractory;
      ii. With t(11;14) translocation;
   g. Waldenström macroglobulinemia/ lymphoplasmacytic lymphoma, with Venclexta prescribed as a single agent;

   **Prior authorization may be required.*
2. Prescribed by or in consultation with an oncologist or hematologist;
3. For all indications except pediatric ALL: Age ≥ 18 years;
4. For brand Venclexta requests, member must use generic venetoclax, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. For hairy cell leukemia, pediatric ALL, systemic light chain amyloidosis, and Waldenström macroglobulinemia/ lymphoplasmacytic lymphoma: Member has received ≥ 1 prior therapy (*see Appendix B for examples*);*

   **Prior authorization may be required.*
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: 12 months

F. 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/ICHRA) 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/ICHRA, and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) 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/ICHRA, 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/ICHRA, 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 Venclexta for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For brand Venclexta requests, member must use generic venetoclax, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. For AML, prescribed as combination therapy;
5. If request is for a dose increase, request meets one of the following (a, b, or c):
   a. CLL, SLL, or in combination with azacitidine or decitabine for AML: New dose does not exceed both of the following (i and ii):
      i. 400 mg per day;
      ii. 4 tablets per day;
   b. In combination with low-dose cytarabine for AML: New dose does not exceed both of the following (i and ii):
      i. 600 mg per day;
      ii. 6 tablets per day;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

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/ICHRA) 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/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) 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/ICHRA, 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/ICHRA, 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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALL: acute lymphoblastic leukemia
AML: acute myeloid leukemia
BCL-2: B-cell lymphoma 2 protein
BPDCN: blastic plasmacytoid dendritic cell neoplasm
CBF: core-binding factor
CLL: chronic lymphocytic leukemia
CMML: chronic myelomonocytic leukemia
CNS: central nervous system
FDA: Food and Drug Administration
IPSS-R: revised International Prognostic Scoring System
MDS: myelodysplastic syndrome
NCCN: National Comprehensive Cancer Network
RCHOP: rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone
SLL: small lymphocytic lymphoma

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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
CLL/SLL *Examples of first-line, second-line, and subsequent therapies:* • FCR (fludarabine, cyclophosphamide, rituximab) • HDMP (high-dose methylprenisolone) + rituximab Single-agent examples: Imbruvica® (ibrutinib); Brukinsa® (zanubrutinib), Campath® (alemtuzumab) ± rituximab; Gazyva; Copiktra® (duvelisib); Calquence® (acalabrutinib) ± Gazyva;	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Revlimid® (lenalidomide) ± rituximab; Arzerra® (ofatumumab) ± FC (fludarabine, cyclophosphamide); Leukeran® (chlorambucil) + rituximab; Zydelig® (idelalisib) ± rituximab		
AML Examples of induction therapy: cytarabine with idarubicin or daunorubicin, cytarabine with idarubicin or daunorubicin or mitoxantrone	Varies	Varies
Mantle cell lymphoma Examples of induction/chemoimmuno-therapy: • RDHA (rituximab, dexamethasone, cytarabine) + platinum therapy (e.g., carboplatin, cisplatin, oxaliplatin) • Alternating RCHOP/RDHAP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)/(rituximab, dexamethasone, cytarabine, cisplatin)	Varies	Varies
Multiple myeloma Examples of primary therapy: • Bortezomib/lenalidomide/dexamethasone • Bortezomib/cyclophosphamide or lenalidomide/dexamethasone • Carfilzomib or ixazomib/lenalidomide/ dexamethasone • Daratumumab/lenalidomide/ dexamethasone ± bortezomib • Lenalidomide/dexamethasone • Daratumumab/bortezomib/ mephalan/prednisone • Daratumumab/cyclophosphamide /bortezomib/dexamethasone Examples of maintenance therapy: • Lenalidomide • Bortezomib	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• Bortezomib/lenalidomide		
Pediatric ALL Examples of induction and consolidation therapy: • EsPhALL (cyclophosphamide, mercaptopurine, cytarabine, methotrexate) + imatinib/Sprycel® (dasatinib) • High-dose MTX, vincristine, daunorubicin, cyclophosphamide, pegaspargase/calaspargase, dexamethasone, cytarabine, Sprycel®	Varies	Varies
T-Cell ALL Examples of therapy: • HyperCVAD (hyperfractionated cyclophosphamide, vincristine, doxorubicin, dexamethasone, alternating with methotrexate, cytarabine, ± nelarabine • vincristine+prednisone • POMP (mercaptopurine, methotrexate, prednisone, vincristine)	Varies	Varies
Systemic light chain amyloidosis Examples of primary therapy: • Darzalex Faspro® (daratumumab and hyaluronidase-fihj)/ bortezomib/cyclophosphamide/ dexamethasone, bortezomib ± dexamethasone, bortezomib/ cyclophosphamide/dexamethasone, melphalan/dexamethasone	Varies	Varies
Waldenström macroglobulinemia / lymphoplasmacytic lymphoma Examples of primary therapy: • Brukinsa® (zanubrutinib), Imbruvica® (ibrutinib) ± rituximab, bendamustine/rituximab, / rituximab/cyclophosphamide/ dexamethasone	Varies	Varies
Hairy cell leukemia Examples of BRAF inhibitor therapy:	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Zelboraf® (vemurafenib), Tafinlar® (dabrafenib)		

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): concomitant use of Venclexta with strong inhibitors of CYP3A at initiation and during ramp-up phase in patients with CLL/SLL
- Boxed warning(s): none reported

Appendix D: General Information

Patient or disease state characteristics that may preclude use of intensive induction therapy include but are not limited to the following examples:

- Limited functional status as indicated by an Eastern Cooperative Oncology Group (ECOG) performance status of ≥ 2
- Significant comorbidity (e.g., severe cardiac, pulmonary, or renal disease)
- AML without favorable cytogenetics or molecular markers
- AML secondary to prior antineoplastic therapy
- AML preceded by a hematologic disorder such as MDS

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CLL and SLL	Venclexta 5-week dose ramp-up schedule: 20 mg PO QD for one week followed by 50 mg PO QD for one week, 100 mg PO QD for one week, 200 mg PO QD for one week, then 400 mg PO QD Venclexta in combination with Gazyva: On Cycle 1 Day 22, start Venclexta according to the 5-week ramp-up schedule. Continue Venclexta 400 mg PO QD from Cycle 3 Day 1 until the last day of Cycle 12. Venclexta in combination with rituximab: Administer rituximab after the 5-week ramp-up schedule with Venclexta. Continue Venclexta 400 mg PO QD for 24 months from Cycle 1 Day 1 of rituximab. Venclexta in combination with Calquence for patients with previously untreated CLL/SLL: On Cycle 3 Day 1, start Venclexta according to the 5-week ramp up schedule. Continue Venclexta 400 mg PO QD until the last day of Cycle 14.	400 mg/day

Indication	Dosing Regimen	Maximum Dose
	Venclexta as monotherapy: 400 mg PO QD after the patient has completed the 5-week dose ramp-up schedule until disease progression or unacceptable toxicity	

AML	PO QD in combination with azacitidine, decitabine, or low-dose cytarabine:
	• Day 1: 100 mg/day
	• Day 2: 200 mg/day
	• Day 3: 400 mg/day
	• Day 4 and beyond, until disease progression or unacceptable toxicity:
	  ○ In combination with azacitidine or decitabine: 400 mg PO QD
	  ○ In combination with low-dose cytarabine: 600 mg PO QD
		400 mg/day with azacitidine or decitabine; 600 mg/day with cytarabine

VI. Product Availability

Tablets: 10 mg, 50 mg, 100 mg

VII. References

1. Venclexta Prescribing Information. North Chicago, IL: AbbVie Inc.; May 2026. Available at: https://www.rxabbvie.com/pdf/venclexta.pdf. Accessed August 25, 2026.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 25, 2026.
3. National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymophoma Version 1.2027. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed August 25, 2026.
4. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 5.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed August 25, 2026.
5. National Comprehensive Cancer Network. Systemic Light Chain Amyloidosis Version 1.2027. Available at: https://www.nccn.org/professionals/physician_gls/pdf/amyloidosis.pdf. Accessed August 25, 2026.
6. National Comprehensive Cancer Network. Multiple Myeloma Version 5.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed August 25, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2022 annual review: for BPDCN, added option of relapsed/refractory disease per NCCN; added criteria for off-label NCCN-supported indications of systemic light chain amyloidosis and Waldenström macroglobulinemia/lymphoplasmacytic lymphoma; added generic oral oncology agent redirection verbiage;	08.02.22	11.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
references reviewed and updated. Template changes applied to other diagnoses/indications.		
4Q 2023 annual review: for CLL/SLL indication, added option of treatment for relapse in combination with Gazyva if previously used as first-line treatment per NCCN; references reviewed and updated.	08.08.23	11.23
4Q 2024 annual review: for CLL/SLL, added Gazyva as combination therapy option for relapsed/refractory disease per NCCN; for AML, removed medical justification for inability to use intensive induction chemotherapy criterion as NCCN additionally supports member declining or being generally ineligible for intensive induction therapy; for mantle cell lymphoma, added option for combination with Gazyva and Imbruvica scenario per NCCN; added CMML-2, hairy cell leukemia, myeloproliferative neoplasm, and pediatric ALL as off-label recommended indications per NCCN; references reviewed and updated.	07.17.24	11.24
4Q 2025 annual review: revised Medicaid and HIM initial approval durations to 12 months for all indications; for CLL/SLL, removed the requirement for "relapse if previously used as first-line therapy" when used in combination with Gazyva per NCCN, removed requirement for "for relapsed/refractory disease" when used as subsequent therapy per NCCN, added combination therapies recommended per NCCN; for AML, removed the age ≥ 60 years pathway and added the FDA-labeled option for age ≥ 75 years, replaced "disease is newly diagnosed" with "induction, post-induction, or consolidation therapy" per NCCN, and simplified criteria for relapsed/refractory disease; for MM, added option for central nervous system per NCCN; for additional NCCN recommended uses section, added adult ALL supported uses and MDS use per NCCN; references reviewed and updated.	08.25.25	11.25
RT4: updated the conditions under which Venclexta can be used as first-line therapy for CLL/SLL to align with the FDA's recent approval of the addition of the AMPLIFY trial results to the Venclexta PI.	03.18.26	
4Q 2026 annual review: for CLL/SLL, added Brukinsa as first-line therapy option, removed requirement for absence of del(17p)/TP53 mutation, added both Brukinsa and Calquence as subsequent therapy combination options, and added additional treatment options for histologic (Richter) transformation per NCCN; for mantle cell lymphoma that is positive for TP53 mutation, replaced combination therapy Gazyva + Imbruvica with combination therapy Gazyva + Brukinsa per NCCN; for AML, expanded therapy options for inclusion of Inqovi and for relapsed/refractory	07.07.26	11.26

Reviews, Revisions, and Approvals	Date	P&T Approval Date
disease, therapy-related AML, and poor-risk AML per NCCN; for BPDCN, removed option for palliative intent of systemic disease and added option for Venclexta prescribed as treatment induction per NCCN; for systemic light chain amyloidosis, added requirement for t(11;14) translocation per NCCN; for MDS, expanded combination therapy options to include Inqovi per NCCN; for Philadelphia chromosome negative B-cell ALL, added option for relapsed/refractory disease per NCCN; for ALL, added indication option for Philadelphia chromosome-positive B-cell ALL per NCCN; for continued therapy for AML, replaced named combination therapy agents with "combination therapy;" added ICHRA line of business; 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.

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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.

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