

**Clinical Policy: Venetoclax (Venclexta)** 

Reference Number: CP.PHAR.129

Effective Date: 07.17.18 Last Review Date: 11.25

Line of Business: Commercial, HIM, Medicaid Revision Log

See <u>Important Reminder</u> 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  $\geq$  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, or iii):
      - i. In combination with Gazyva<sup>®</sup>;
      - ii. In combination with Imbruvica®;
      - iii. In combination with Calquence®, with or without Gazyva;
    - b. Prescribed as subsequent therapy as a single agent or in combination with either rituximab, Gazyva, or Imbruvica (see Appendix B for examples of prior therapy);
    - c. Prescribed as initial therapy for histologic (Richter) transformation to diffuse large B-cell lymphoma as a component of a RCHOP regimen; \*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:**

**Medicaid/HIM** – 12 months

**Commercial** – 12 months or duration of request, whichever is less

#### 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  $\geq$  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  $\geq$  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. Disease is systemic, and request is for palliative treatment (e.g., member has low performance and/or nutritional status [i.e., serum albumin < 3.2 g/dL; not a candidate for intensive remission therapy or tagraxofusp-erzs]);
  - b. Disease is relapsed/refractory;
- 7. Prescribed in combination with azacitidine, decitabine, or low-dose (20 mg/m²) cytarabine;\*

\*Prior authorization may be required.

- 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:**

**Medicaid/HIM** – 12 months



**Commercial** – 12 months or duration of request, whichever is less

### 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  $\geq$  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 Imbruvica 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);
- 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** – 12 months

**Commercial** – 12 months or duration of request, whichever is less

#### 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  $\geq$  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:**

**Medicaid/HIM** – 12 months

**Commercial** – 12 months or duration of request, whichever is less

#### E. Additional NCCN Recommended Uses (off-label) (must meet all):

- 1. Diagnosis of one of the following (a-f):
  - 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 or decitabine;\*
- 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, or iii):
  - 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 or 2):
    - 1) Age  $\geq$  18 years and member has substantial comorbidities;
    - 2) Age  $\geq$  65 years;
- f. Systemic light chain amyloidosis that is relapsed/refractory;
- 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  $\geq$  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:**

**Medicaid/HIM** – 12 months

**Commercial** – 12 months or duration of request, whichever is less

#### **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) 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 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 in combination with azacitidine, decitabine, or low-dose (20 mg/m²) cytarabine;\*
  - \*Prior authorization may be required.
- 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:**

**Medicaid/HIM** – 12 months

**Commercial** – 12 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 policies – 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 ALL: acute lymphoblastic leukemia AML: acute myeloid leukemia BCL-2: B-cell lymphoma 2 protein BPDCN: blastic plasmacytoid dendritic cell neoplasm CLL: chronic lymphocytic leukemia

leukemia

CNS: central nervous system

CMML: chronic myelomonocytic

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	Varies	Varies
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) $\pm$ rituximab;		
Gazyva; Copiktra® (duvelisib);		
Calquence® (acalabrutinib) ± Gazyva;		
Revlimid® (lenalidomide) $\pm$ rituximab;		
Arzerra <sup>®</sup> (ofatumumab) $\pm$ FC		
(fludarabine, cyclophosphamide);		
Leukeran® (chlorambucil) + rituximab;		
Zydelig® (idelalisib) ± rituximab		
AML	Varies	Varies
Examples of induction therapy:		
cytarabine with idarubicin or		



Drug Name	Dosing Regimen	Dose Limit/ Maximum
		Dose
daunorubicin, cytarabine with		Dosc
idarubicin or daunorubicin or		
mitoxantrone		
Mantle cell lymphoma	Varies	Varies
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)		
Multiple myeloma	Varies	Varies
Examples of primary therapy:		
Bortezomib/lenalidomide/dexameth		
asone		
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     Total 1:1		
Bortezomib/lenalidomide	***	<b>37</b> ·
Pediatric ALL	Varies	Varies
Examples of induction and		
consolidation therapy:		
• EsPhALL (cyclophosphamide,		
mercaptopurine, cytarabine,		



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

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	400 mg/day	
	Venclexta in combination with Gazyva: On Cycle 1 Day 22, start Venclexta according to the 5-week ramp-up schedule. Continue Venclexta 400 mg 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 QD for 24 months from Cycle 1 Day 1 of rituximab.		
	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/day	400 mg/day with azacitidine or decitabine; 600 mg/day with cytarabine	



Indication	Dosing Regimen	<b>Maximum Dose</b>
	<ul> <li>In combination with low-dose cytarabine: 600</li> </ul>	
	mg/day	

#### VI. Product Availability

Tablets: 10 mg, 50 mg, 100 mg

#### VII. References

- 1. Venclexta Prescribing Information. North Chicago, IL: AbbVie Inc.; July 2024. Available at: https://www.rxabbvie.com/pdf/venclexta.pdf. Accessed August 25, 2025.
- 2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug\_compendium. Accessed August 25, 2025.
- 3. National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymophoma Version 3.2025. Available at: https://www.nccn.org/professionals/physician\_gls/pdf/cll.pdf. Accessed August 25, 2025.
- 4. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 2.2025. Available at: https://www.nccn.org/professionals/physician\_gls/pdf/b-cell.pdf. Accessed August 25, 2025.
- 5. National Comprehensive Cancer Network. Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma Version 1.2026. Available at: https://www.nccn.org/professionals/physician\_gls/pdf/waldenstroms.pdf. Accessed August 25, 2025.
- 6. National Comprehensive Cancer Network. Systemic Light Chain Amyloidosis Version 1.2026. Available at: https://www.nccn.org/professionals/physician\_gls/pdf/amyloidosis.pdf. Accessed August 19, 2024.
- 7. National Comprehensive Cancer Network. Multiple Myeloma Version 2.2026. Available at: https://www.nccn.org/professionals/physician\_gls/pdf/myeloma.pdf. Accessed August 25, 2025.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2021 annual review: revised mantle cell lymphoma to require use as a single agent or in combination with rituximab or ibrutinib per NCCN; added off-label coverage for BPDCN and multiple myeloma per NCCN; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	06.28.21	11.21
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less	01.20.22	05.22
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

#### **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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