

## **Clinical Policy: Bendamustine (Belrapzo, Bendeka, Treanda, Vivimusta)**

Reference Number: CP.PHAR.307

Effective Date: 02.01.17

Last Review Date: 11.25

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**

Bendamustine hydrochloride (Belrapzo<sup>®</sup>, Bendeka<sup>®</sup>, Treanda<sup>®</sup>, Vivimusta<sup>®</sup>) is an alkylating drug.

### **FDA Approved Indication(s)**

Belrapzo, Bendeka, Treanda, and Vivimusta are indicated for the treatment of patients with:

- Chronic lymphocytic leukemia (CLL). Efficacy relative to first line therapies other than chlorambucil has not been established.
- Indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes and 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<sup>®</sup> that Belrapzo, Bendeka, Treanda, Vivimusta, and bendamustine are **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 small lymphocytic lymphoma (SLL);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age  $\geq$  18 years;
4. Prescribed in combination with rituximab or Gazyva<sup>®</sup>;
5. Request meets one of the following (a or b):\*
  - a. Dose does not exceed 100 mg/m<sup>2</sup> on Days 1 and 2 of a 28-day cycle for up to 6 cycles;
  - 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** – 6 months or to the member's renewal date, whichever is longer

**B. Non-Hodgkin B-Cell Lymphomas (must meet all):**

1. Diagnosis of one of the following (a-h):
  - a. Indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen;
  - b. Classic follicular lymphoma;
  - c. Marginal zone lymphoma (MZL) (i, ii, or iii):
    - i. Splenic MZL;
    - ii. Nodal MZL;
    - iii. Extranodal mucosa-associated lymphoid tissues (MALT) (1 or 2):
      - 1) Gastric MALT lymphoma;
      - 2) Nongastric MALT lymphoma;
  - d. Mantle cell lymphoma;
  - e. Diffuse large B-cell lymphoma (DLBCL) with no intention to proceed to transplant, as subsequent therapy;\*
  - f. HIV-related B-cell lymphoma, as subsequent therapy;\*
  - g. Monomorphic post-transplant lymphoproliferative disorder (PTLD) (B-cell type), as subsequent therapy;\*
  - h. High-grade B-cell lymphomas with no intention to proceed to transplant, as subsequent therapy;\*
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age  $\geq$  18 years;
4. For classic follicular lymphoma, MZL: Prescribed in combination with rituximab or Gazyva;\*
5. For mantle cell lymphoma: Prescribed in combination with rituximab;
6. For indolent B-cell non-Hodgkin lymphoma, DLBCL, HIV-related B-cell lymphoma, PTLD, high-grade B-cell lymphomas: Prescribed in combination with Polivy<sup>®</sup> with or without rituximab;
7. Request meets one of the following (a or b):\*
  - a. Dose does not exceed 120 mg/m<sup>2</sup> on Days 1 and 2 of a 21-day cycle for up to 8 cycles;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*\*See Appendix B for examples - prior authorization may be required for prior therapies*

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

**Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – 6 months or to the member's renewal date, whichever is longer

**C. NCCN Recommended Uses (off-label) (must meet all):**

1. Diagnosis of one of the following (a-g):
  - a. Hodgkin lymphoma (HL) that is relapsed or refractory, as subsequent therapy;\*
  - b. Pediatric HL that is relapsed or refractory, as re-induction or subsequent therapy;\*
  - c. Hematopoietic cell transplantation for NHL without central nervous system (CNS) disease or for HL;
  - d. Multiple myeloma (MM) that is relapsed or refractory, as subsequent therapy after 3 prior therapies;\*
  - e. One of the following T-cell lymphomas (i-v):

- i. Adult T-cell leukemia/lymphoma (ATLL), as subsequent therapy;\*
  - ii. Hepatosplenic T-cell lymphoma (HSTCL), as subsequent therapy;\*
  - iii. Breast implant-associated ALCL, as subsequent therapy;\*
  - iv. T-cell prolymphocytic leukemia (T-PLL);
  - v. One of the following peripheral T-cell lymphoma (PTCL) subtypes, as initial palliative intent therapy or subsequent treatment therapy (1-8):
    - 1) Peripheral T-cell lymphoma not otherwise specified (PTCL-NOS);
    - 2) Angioimmunoblastic T-cell lymphoma (AITL);
    - 3) Anaplastic large cell lymphoma (ALCL);
    - 4) Enteropathy-associated T-cell lymphoma (EATL);
    - 5) Follicular T-cell lymphoma (FTCL);
    - 6) Follicular helper T-cell (TFH) lymphoma;
    - 7) Monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL);
    - 8) Nodal PTCL with TFH phenotype;
  - f. Systemic light chain amyloidosis (SLCA) that is relapsed/refractory;
  - g. Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma (including management of Bing-Neel syndrome);
- \*See Appendix B for example therapies - prior authorization may be required for prior therapies*
2. Prescribed by or in consultation with an oncologist or hematologist;
  3. Age  $\geq$  18 years, unless diagnosis is pediatric HL;
  4. For hematopoietic cell transplantation: Prescribed in combination with etoposide, cytarabine, and melphalan;
  5. For T-cell lymphomas: Prescribed as a single agent or in combination with Adcentris<sup>®</sup>;
  6. For SLCA: Prescribed in combination with dexamethasone;
  7. For Waldenstrom's macroglobulinemia: Prescribed as a single agent or in combination with rituximab;
  8. 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** – 6 months or to the member's renewal date, whichever is longer

**D. 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 Belrapzo, Bendeka, Treanda, Vivimusta, or bendamustine 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 (a or b):\*
  - a. New dose does not exceed (i or ii):
    - i. CLL/SLL: 100 mg/m<sup>2</sup> on Days 1 and 2 of a 28-day cycle for up to 6 cycles;
    - ii. Non-Hodgkin indolent B-cell lymphoma: 120 mg/m<sup>2</sup> on Days 1 and 2 of a 21-day cycle for up to 8 cycles;
  - 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 to the member's renewal date, whichever is longer

### 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*

AITL: angioimmunoblastic T-cell lymphoma  
 ALCL: anaplastic large cell lymphoma  
 ATLL: adult T-cell leukemia/lymphoma  
 CLL: chronic lymphocytic leukemia  
 CNS: central nervous system  
 DLBCL: diffuse large B-cell lymphoma  
 EATL: enteropathy-associated T-cell lymphoma  
 FDA: Food and Drug Administration  
 FTCL: follicular T-cell lymphoma  
 HIV: human immunodeficiency virus  
 HL: Hodgkin lymphoma  
 HSTCL: hepatosplenic gamma-delta T-cell lymphoma  
 MALT: mucosa-associated lymphoid tissue

MEITL: monomorphic epitheliotropic intestinal T-cell lymphoma  
 MM: multiple myeloma  
 MCL: marginal zone lymphoma  
 NCCN: National Comprehensive Cancer Network  
 NHL: non-Hodgkin lymphoma  
 PTCL: peripheral T-cell lymphoma  
 PTLN: post-transplant lymphoproliferative disorder  
 PTLN-NOS: post-transplant lymphoproliferative disorder not otherwise specified  
 SLCA: systemic light chain amyloidosis  
 SLL: small lymphocytic lymphoma  
 TFH: T-cell follicular helper

*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.*

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
<b>Examples of primary therapies (NCCN)</b>		
<b>B-cell NHL (e.g., DLBCL, HIV-related B-cell lymphoma, PTCL)</b>		
RCHOP rituximab + (cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies
EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab	Varies	Varies
RCDOP rituximab + (cyclophosphamide, liposomal doxorubicin, vincristine, prednisone)	Varies	Varies
RCEOP rituximab + (cyclophosphamide, etoposide, vincristine, prednisone)	Varies	Varies
RGCVP rituximab + (gemcitabine, cyclophosphamide, vincristine, prednisone)	Varies	Varies
RCEPP rituximab + (cyclophosphamide, etoposide, prednisone, procarbazine)	Varies	Varies
Pola-R-CHP (Polivy [polatuzumab vedotin-piiq], rituximab, cyclophosphamide, doxorubicin, prednisone)	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<b>HL</b>		
ABVD (doxorubicin, bleomycin, vinblastine, dacarbazine) + rituximab	Varies	Varies
RCHOP rituximab + (cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies
CVbp (cyclophosphamide, vinblastine, prednisolone) + rituximab	Varies	Varies
rituximab	Varies	Varies
<b>MM</b>		
bortezomib/lenalidomide/dexamethasone	Varies	Varies
carfilzomib/lenalidomide/dexamethasone	Varies	Varies
daratumumab/lenalidomide/dexamethasone	Varies	Varies
<b>T-cell Lymphomas (e.g., HSTCL, ATLL, ALCL, PTCL)</b>		
ICE (ifosfamide, carboplatin, etoposide)	Varies	Varies
DHAP (dexamethasone, andcisplatin, cytarabine) + platinum (carboplatin, cisplatin, or oxaliplatin)	Varies	Varies
EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab	Varies	Varies
HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone) alternating with high-dose methotrexate and cytarabine	Varies	Varies
CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone)	Varies	Varies
CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies
Polivy (brentuximab vedotin) ± CHP (cyclophosmaide, doxorubicin, prednisone)	Varies	Varies

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

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - Belrapzo, Bendeka: patients with a history of a hypersensitivity reaction to bendamustine, polyethylene glycol 400, propylene glycol, or monothioglycerol
  - Treanda: patients with a history of a hypersensitivity reaction to bendamustine
  - Vivimusta: patients with a history of a hypersensitivity reaction to bendamustine, polyethylene glycol 400, dehydrated alcohol, or monothioglycerol
- Boxed warning(s): none reported



**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
CLL/SLL*	Bendeka: 100 mg/m <sup>2</sup> IV over 10 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles  Belrapzo, Treanda: 100 mg/m <sup>2</sup> IV over 30 minutes on days 1 and 2 of a 28-day cycle, up to 6 cycles  Vivimusta: 100 mg/m <sup>2</sup> IV over 20 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles	See regimen
Indolent B-cell lymphoma*	Bendeka: 120 mg/m <sup>2</sup> IV over 10 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles  Belrapzo, Treanda: 120 mg/m <sup>2</sup> IV over 60 minutes on days 1 and 2 of a 21-day cycle, up to 8 cycles  Vivimusta: 120 mg/m <sup>2</sup> IV over 20 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles	See regimen

\*Non-Hodgkin lymphomas

**VI. Product Availability**

Drug Name	Availability
Bendamustine (Belrapzo, Bendeka, Vivimusta)	Solution (multiple-dose vial): 100 mg/4 mL
Bendamustine (Treanda)	Lyophilized powder (single-dose vial): 25 mg in a 20 mL vial; 100 mg in a 20 mL vial

**VII. References**

1. Belrapzo Prescribing Information. Woodcliff Lake, NJ: Eagle Pharmaceuticals, Inc; January 2024. Available at: [www.belrapzo.com](http://www.belrapzo.com). Accessed July 16, 2025.
2. Bendeka Prescribing Information. Parsippany, NJ: Teva Pharmaceuticals.; January 2024. Available at: [www.bendekahcp.com](http://www.bendekahcp.com). Accessed July 16, 2025.
3. Treanda Prescribing Information. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; October 2022. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/022249s0261bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022249s0261bl.pdf). Accessed July 16, 2025.
4. Vivimusta Prescribing Information. Princeton, NJ: Slayback Pharma; February 2024. Available at: [www.vivimusta.com](http://www.vivimusta.com). Accessed July 16, 2025.
5. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). July 16, 2025.
6. National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version 3.2025. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/cll.pdf](https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf). Accessed July 16, 2025.
7. National Comprehensive Cancer Network. B-cell Lymphomas Version 2.2025. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/b-cell.pdf](https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf). July 16, 2025.

8. National Comprehensive Cancer Network. Hodgkin Lymphoma Version 2.2025. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/hodgkins.pdf](https://www.nccn.org/professionals/physician_gls/pdf/hodgkins.pdf). Accessed July 16, 2025.
9. National Comprehensive Cancer Network. Multiple Myeloma Version 2.2026. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/myeloma.pdf](https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf). Accessed July 16, 2025.
10. National Comprehensive Cancer Network. T-cell Lymphomas Version 2.2025. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/t-cell.pdf](https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf). Accessed July 16, 2025.
11. National Comprehensive Cancer Network. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma Version 1.2026. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/waldenstroms.pdf](https://www.nccn.org/professionals/physician_gls/pdf/waldenstroms.pdf). Accessed July 16, 2025.

**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
J9033	Injection, bendamustine hydrochloride, 1 mg
J9034	Injection, bendamustine HCl (Bendeka), 1 mg
J9036	Injection, bendamustine hydrochloride, (belrapzo/bendamustine), 1 mg
J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2021 annual review: added Belrapzo; per NCCN category 2A recommendations: added requirements for combination use for CLL, MALT lymphoma, and marginal zone lymphoma; clarified types of PTCLs; removed gamma delta requirement from HSTCL; added off-label indications of breast-implant ALCL, nodular lymphocyte-predominant HL, pediatric HL, and high-grade B-cell lymphomas; for off-label indications, revised age requirement to allow bypass if diagnosis is pediatric HL; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	06.28.21	11.21
4Q 2022 annual review: added SLCA and hematopoietic cell transplantation under NCCN recommended use given category 2A recommendation; removed primary cutaneous lymphomas as use is no longer supported by NCCN primary cutaneous lymphoma guideline; references reviewed and updated. Template changes applied to other diagnoses/indications.	06.24.22	11.22
RT4: added new dosage form Vivimusta; removed reference to HIM.PA.103 formulary exception policy for Belrapzo and Bendeka	12.28.22	



Reviews, Revisions, and Approvals	Date	P&T Approval Date
as these brands require PA on at least one HIM state formulary (FL).		
Added HCPCS added codes [J9056, J9058, J9059]	05.24.23	
4Q 2023 annual review: removed combination use with Arzerra for CLL from initial criteria as use is no longer supported by NCCN CLL/SLL guideline; renamed AIDS-related B-cell lymphoma to HIV-related per NCCN naming changes; references reviewed and updated.	08.23.23	11.23
4Q 2024 annual review: removed reference to HIM.PA.103 formulary exception policy for generic bendamustine due to formulary status on at least one HIM state formulary; clarified that policy applies to generic bendamustine; for all indications, revised commercial approval duration to “6 months or to the member’s renewal date, whichever is longer”; for NHL per NCCN, clarified follicular lymphoma is classic, updated formatting for MZL to clarify types; specified DLBL is with no intention to proceed to transplant, revised high-grade B-cell lymphoma criteria to lymphoma with no intention to proceed to transplant, added requirements for combination use for classic follicular lymphoma, MZL, indolent NHL, DLBCL, HIV-related B-cell lymphoma, PTLN, and high-grade B-cell lymphoma per NCCN; for off-label NCCN uses per NCCN, added relapsed or refractory requirements to HL, MM, and SLCA, added as subsequent therapy requirement to MM and PTCL, added initial therapy requirement to PTCL; added off-label indications of MF/SS, EATL, and ALCL, clarified PTCL subtypes, clarified Waldenstrom’s macroglobulinemia includes Bing-Neel syndrome, added requirements for combination use for T-cell lymphomas, MF/SS, and Waldenstrom’s macroglobulinemia; updated Appendix B per NCCN; removed bendamustine 45mg and 180mg vials per product discontinuation; removed inactive HCPCS codes; references reviewed and updated.	08.07.24	11.24
HCPCS codes removed [J9058, J9059] and revised description [J9033].	11.06.24	
4Q 2025 annual review: for all indications, extended initial approval duration for Medicaid and HIM from 6 months to 12 months for this maintenance medication for a chronic condition; for off-label NCCN uses per NCCN, added off-label indications of T-PLL and TFH lymphoma and removed mycosis fungoides/Sezary syndrome; references reviewed and updated.	07.16.25	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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**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.

©2017 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene<sup>®</sup> and Centene Corporation<sup>®</sup> are registered trademarks exclusively owned by Centene Corporation.