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

Reference Number: LA.PHAR.307
Effective Date: 10.02.22
Last Review Date: 01.15.25~~05.20.24~~ Coding Implications
Line of Business: Medicaid Revision Log

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

****Please note: This policy is for medical benefit****

Description
Bendamustine hydrochloride (Belrapzo®, Bendeka®, Treanda®, Vivimusta™~~)~~) 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 Louisiana HealthCare Connections® that Belrapzo, Bendeka, Treanda, ~~and~~ 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 ~~chronic lymphocytic leukemia (~~CLL~~) (i.e.,~~ or small lymphocytic lymphoma ~~[(~~SLL~~]););~~
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Prescribed in combination with rituximab or Gazyva®;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 100 mg/m^2 on Days 1 and 2 of a 28-day cycle, 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: 6 months

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

1. One of the following diagnoses (a~~ through k~~ h):

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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. ~~Follicular~~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):
      ~~c.~~1) Gastric MALT lymphoma;
      ~~d.~~2) Nongastric MALT lymphoma;
~~e. Nodal marginal zone lymphoma;~~
~~f. Splenic marginal zone lymphoma;~~
~~g.~~d. Mantle cell lymphoma;
~~h.~~e. Diffuse large B-cell lymphoma (DLBCL) ~~(~~with no intention to proceed to transplant, as subsequent therapy~~);*;~~*
~~i.~~f. HIV-related B-cell lymphoma~~ (~~, as subsequent therapy~~);*;~~*
~~j.~~g. Monomorphic post-transplant lymphoproliferative disorder (PTLD) (B-cell type~~)~~ ~~(~~), as subsequent therapy~~);*;~~*
~~k.~~h. High-grade B-cell lymphomas~~: not otherwise specified or with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma) (~~ with no intention to proceed to transplant, as subsequent therapy~~);*;~~*

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

2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. For ~~nodal/splenic marginal zone~~classic follicular lymphoma~~ or gastric/nongastric MALT 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® with or without rituximab;
~~6.~~7. Request meets one of the following (a or b):*
   a. Dose does not exceed 120 mg/m^2 on Days 1 and 2 of a 21-day cycle, 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*).

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

Approval duration: 6 months

C. NCCN Recommended Uses (off-label) (must meet all)**:**
1. Diagnosis of one of the following (a~~, b, c, d, e, f, or g~~-h):
   a. ~~Classic or nodular lymphocyte predominant~~ 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~~);*;~~*

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c. Hematopoietic cell transplantation for NHL without central nervous system (CNS) disease or for HL;
~~c.~~d. Multiple myeloma (MM~~);~~) that is relapsed or refractory, as subsequent therapy after 3 prior therapies;*
e. Mycosis fungidoes (MF)/Sezary Syndrome (SS);
~~d.~~f. One of the following T-cell lymphomas (i, ii, iii, or iv):
~~i. Hepatosplenic T-cell lymphoma (HSTCL) (*as subsequent therapy*);*~~
~~ii.~~i. Adult T-cell leukemia/lymphoma (ATLL~~) (~~), as subsequent therapy~~);*;~~*
ii. ~~Peripheral~~Hepatosplenic T-cell lymphoma (~~PTCL) (~~HSTCL), as subsequent therapy~~):* relapsed/refractory ALCL;~~*
iii. Breast implant-associated ALCL, as subsequent therapy;*
iv. One of the following peripheral T-cell lymphoma (PTCL) subtypes, as initial palliative intent therapy or subsequent treatment therapy (1-7):
1) Peripheral T-cell lymphoma not otherwise specified~~, angioimmunoblastic~~ (PTCL-NOS);
2) Angioimmunoblastic T-cell lymphoma~~, enteropathy~~ (AITL);
3) Anaplastic large cell lymphoma (ALCL);
4) Enteropathy-associated T-cell lymphoma~~, monomorphic~~ (EATL);
5) Follicular T-cell (TFH) lymphoma;
6) Monomorphic epitheliotropic intestinal T-cell lymphoma~~, nodal peripheral T-cell lymphoma~~ (MEITL);
~~iii.~~7) Nodal PTCL with ~~T-follicular helper (~~TFH~~)~~ phenotype~~, or follicular T-cell lymphoma;~~;
~~iv. Breast implant-associated ALCL (*as subsequent therapy*);*~~
g. Systemic light chain amyloidosis (SLCA) that is relapsed/refractory;
~~e.~~h. Waldenstrom's macroglobulinemia~~ (i.e., /~~lymphoplasmacytic lymphoma (including management of Bing–Neel syndrome);
~~f. Systemic light chain amyloidosis (SLCA) in combination with dexamethasone (*as subsequent therapy*);*~~
~~g. Hematopoietic cell transplantation in combination with etoposide, cytarabine, and melphalan for NHL without central nervous system (CNS) disease or for HL;~~
**See Appendix B - prior authorization may be required for prior therapies*

2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years, unless diagnosis is pediatric HL;
4. For hematopoietic cell transplantation, prescribed in combination with etoposide, cytarabine, and melphalan;
5. For MF/SS: prescribed in combination with Adcentris;
6. For T-cell lymphomas: prescribed as a single agent or in combination with Adcentris®;
7. For SLCA: prescribed in combination with dexamethasone;
8. For Waldenstrom's macroglobulinemia: prescribed as a single agent or in combination with rituximab;

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~~4.~~9. 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: 6 months

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 LA.PMN.255
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 LA.PMN.53

II. Continued Therapy
A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Louisiana HealthCare Connections~~Centene~~ benefit, or documentation supports that member is currently receiving Belrapzo, Bendeka, Treanda ~~or ,~~ 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^2 on Days 1 and 2 of a 28-day cycle, up to 6 cycles;
      ii. Non-Hodgkin indolent B-cell lymphoma: 120 mg/m^2 on Days 1 and 2 of a 21-day cycle, 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: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. ~~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 LA.PMN.255
2. 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 LA.PMN.53

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 LA.PMN.53.

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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
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
MF: mycosis fungoides
MM: multiple myeloma
MCL: marginal zone lymphoma
NCCN: National Comprehensive Cancer Network
NHL: non-Hodgkin lymphoma
PTCL: peripheral T-cell lymphoma
PTLD: post-transplant lymphoproliferative disorder
PTLD-NOS: post-transplant lymphoproliferative disorder not otherwise specified
SLCA: systemic light chain amyloidosis
SLL: small lymphocytic lymphoma
SS: Sezary syndrome
TFH: follicular T-cell

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
Examples of primary therapies (NCCN)		
~~DLBCL~~B-cell NHL (e.g., DLBCL, HIV-related B-cell lymphoma, PTCL)		
RCHOP ~~(~~ Rituxan® ~~[~~(rituximab~~],~~) + (cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies
EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + Rituxan® (rituximab)	Varies	Varies
~~**HIV-related B-cell lymphoma**~~		
RCDOP~~EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) +~~ Rituxan® (rituximab) + (cyclophosphamide, liposomal doxorubicin, vincristine, prednisone)	Varies	Varies

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
~~CHOP~~RCEOP Rituxan® (rituximab) + (cyclophosphamide, ~~doxorubicin~~etoposide, vincristine, prednisone) ~~+ Rituxan® (rituximab)~~	Varies	Varies
~~**PTCL**~~RGCVP Rituxan® (rituximab) + (gemcitabine, cyclophosphamide, vincristine, prednisone)	Varies	Varies
RCEPP Rituxan® (rituximab) + (cyclophosphamide, etoposide, prednisone, procarbazine)	Varies	Varies
~~CHOP (~~Pola-R-CHP (Polivy [polatuzumab vedotin-piiq], Rituxan [rituximab], cyclophosphamide, doxorubicin, ~~vincristine,~~ prednisone)	Varies	Varies
~~HL~~		
ABVD (doxorubicin, bleomycin, vinblastine, dacarbazine) + Rituxan (rituximab)	Varies	Varies
~~EPOCH (etoposide, prednisone, vincristine,~~ RCHOP Rituxan (rituximab) + (cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies
CVbp (cyclophosphamide, vinblastine, prednisolone) + Rituxan (rituximab)	Varies	Varies
Rituxan (rituximab)	Varies	Varies
MM		
Bortezomib/lenalidomide/dexamethasone	Varies	Varies
Carfilzomib/lenalidomide/dexamethasone	Varies	Varies
Daratumumab/lenalidomide/dexamethasone	Varies	Varies
~~ATLL~~T-cell Lymphomas (e.g., HSTCL, ATLL, ALCL, PTCL)		
ICE (ifosfamide, carboplatin, etoposide)	Varies	Varies
DHAP (dexamethasone, andcisplatin, cytarabine) + platinum (carboplatin, cisplatin, or oxaliplatin)	Varies	Varies
EPOCH~~CHOP (~~ (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin~~, vincristine, prednisone~~) + Rituxan (rituximab)	Varies	Varies
HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone) alternating with high-dose methotrexate and cytarabine	Varies	Varies
~~HSTCL~~		
~~DHAP (dexamethasone, cisplatin, cytarabine)~~	~~Varies~~	~~Varies~~
~~ICE (ifosfamide, carboplatin, etoposide)~~	~~Varies~~	~~Varies~~
~~MM~~		
~~Bortezomib/liposomal doxorubicin/dexamethasone~~	~~Varies~~	~~Varies~~
~~Carfilzomib/lenalidomide/dexamethasone~~	~~Varies~~	~~Varies~~

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
~~Daratumumab/bortezomib /dexamethasone~~	~~Varies~~	~~Varies~~
~~**Monomorphic PTLD (B-cell type)**~~		
~~RCHOP (Rituxan® [rituximab],~~ CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone)	Varies	Varies
~~RCEPP (Rituxan® [rituximab],~~ CHOP (cyclophosphamide, ~~etoposide~~doxorubicin, vincristine, prednisone~~, procarbazine~~)	Varies	Varies
~~**SLCA**~~		
~~Daratumumab and hyaluronidase-fihj/bortezomib/cyclophosphamide/dexamethasone~~Polivy (brentuximab vedotin) ± CHP (cyclophosmaide, doxorubicin, prednisone)	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):
  - Belrapzo, Bendeka: patients with a history of a hypersensitivity reaction to ~~bendamustine~~Bendamustine, polyethylene glycol 400, propylene glycol, or monothioglycerol
  - Treanda: patients with a history of a hypersensitivity reaction to ~~bendamustine~~Bendamustine
  - Vivimusta: patients with a history of a hypersensitivity reaction to ~~bendamustine~~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^2 IV over 10 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles Belrapzo, Treanda: 100 mg/m^2 IV over 30 minutes on days 1 and 2 of a 28-day cycle, up to 6 cycles Vivimusta: 100 mg/m^2 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^2 IV over 10 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles	See regimen

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Indication	Dosing Regimen	Maximum Dose
	Belrapzo, Treanda: 120 mg/m^2 IV over 60 minutes on days 1 and 2 of a 21-day cycle, up to 8 cycles Vivimusta: 120 mg/m^2 IV over 20 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles	

**Non-Hodgkin lymphomas*

VI. Product Availability

Drug Name	Availability
Bendamustine (Belrapzo, Bendeka, Vivimusta)	Solution (multiple-dose vial): 100 mg/4 mL
Bendamustine (Treanda)	~~Solution (single-dose vial): 45 mg/0.5 mL; 180 mg/2 mL~~ 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; ~~June 2022~~January 2024. Available at: www.belrapzo.com. Accessed August ~~10, 2023~~6, 2024.
2. Bendeka Prescribing Information. ~~North Wales, PA~~Parsippany, NJ: Teva Pharmaceuticals ~~USA, Inc.; October 2021.~~.; January 2024. Available at: ~~http~~https://www.~~bendeka.com/~~.accessdata.fda.gov/drugsatfda_docs/label/2024/208194s026lbl.pdf. Accessed August ~~10, 2023~~6, 2024.
3. Treanda Prescribing Information. ~~North Wales, PA~~Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; October 2022. Available at: https://www.~~treandahcp.com/globalassets/treanda-hcp/pdf/treanda_final_pi~~accessdata.fda.gov/drugsatfda_docs/label/2022/022249s026lbl.pdf. Accessed August ~~10, 2023~~6, 2024.
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5. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. August ~~10, 2023~~6, 2024.
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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 ~~HCl (Treanda),~~hydrochloride, 1 mg
J9034	Injection, bendamustine HCl (Bendeka), 1 mg
J9036	Injection, bendamustine ~~HCl, (Belrapzo~~hydrochloride, (belrapzo/bendamustine), 1 mg
~~C9399~~	~~Unclassified drugs or biologicals (Vivimusta)~~
~~J9999~~	~~Not otherwise classified, antineoplastic drugs (Vivimusta)~~
J9056	Injection, bendamustine hydrochloride (V~~v~~ivimusta), 1 mg
~~J9058~~	~~Injection, bendamustine hydrochloride (apotex), 1 mg~~
~~J9059~~	~~Injection, bendamustine hydrochloride (baxter), 1 mg~~

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy	07.22	10.02.22
Added new dosage form Vivimusta. 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	06.02.23	10.05.23
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	05.20.24	07.29.24

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Reviews, Revisions, and Approvals	Date	LDH Approval Date
NCCN naming changes; references reviewed and updated. Added HCPCS codes [J9056, J9058, J9059].		
Annual review; clarified that policy applies to generic Bendamustine; for all indications, for NHL per NCCN, clarified follicular lymphoma is classic, updated formatting for MZL to clarify types; specified DLBL is with no intention to precede 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, PTLD, 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; HCPCS codes removed [J9058, J9059] and revised description [J9033]; references reviewed and updated.	01.15.25	

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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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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.

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