Clinical Policy: Carfilzomib (Kyprolis)

Reference Number: LA.PHAR.309
Effective Date: 02.03.24
Last Review Date: 01.15.25
Line of Business: Medicaid

Coding Implications
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

Carfilzomib (Kyprolis®) is a proteasome inhibitor.

FDA Approved Indication(s)

Kyprolis is indicated

- For the treatment of adult patients with relapsed or refractory multiple myeloma (MM) who have received one to three lines of therapy in combination with:
  - Lenalidomide and dexamethasone or
  - Dexamethasone or
  - Daratumumab and dexamethasone or
  - Daratumumab and hyaluronidase-fihj and dexamethasone or
  - Isatuximab and dexamethasone
- As a single agent for the treatment of adult patients with relapsed or refractory MM who have received one or more lines of therapy.

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 Louisiana Healthcare Connections that Kyprolis is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all)**:**

1. Diagnosis of MM;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. For relapsed or refractory disease, one of the following (a or b):
   a. Member has measurable disease as evidenced by one of the following assessed within the last 30 days (i, ii, or iii):
      i. Serum M-protein ≥ 0.5 g/dL;
      ii. Urine M-protein ≥ 200 mg/24 h;
      iii. Serum free light chain (FLC) assay: involved FLC level ≥ 10 mg/dL (100 mg/L) provided serum FLC ratio is abnormal;

b. Member has progressive disease, as defined by the IMWG response criteria (see *Appendix D*), assessed within 60 days following the last dose of the last anti-myeloma drug regimen received;

5. For primary therapy, Kyprolis is prescribed in one of the following ways (a, b, or c):*
   a. In combination with dexamethasone and lenalidomide;
   b. In combination with dexamethasone and cyclophosphamide;
   c. In combination with dexamethasone, lenalidomide, and Darzalex® (daratumumab);

   **Prior authorization may be required.*
6. For maintenance therapy, Kyprolis is prescribed in combination with lenalidomide;
7. For previously treated multiple myeloma for relapsed or refractory disease, Kyprolis is prescribed in one of the following ways (a - i):*
   a. In combination with dexamethasone or with lenalidomide plus dexamethasone in patients who have received one to three lines of therapy *(see Appendix B for examples of prior therapy)*;
   b. As a single agent in patients who have received one or more lines of therapy;
   c. In combination with Darzalex (daratumumab) or Darzalex Faspro® (daratumumab/hyaluronidase-fihj) and dexamethasone in patients who have received one to three lines of therapy;
   d. In combination with Sarclisa (isatuximab-irfc) and dexamethasone in patients who have received one to three lines of therapy;
   e. In combination with Xpovio (selinexor) and dexamethasone in patients who have received one to three lines of therapy;
   f. In combination with dexamethasone and cyclophosphamide, with or without thalidomide, in patients who have received one to three lines of therapy;
   g. In combination with pomalidomide and dexamethasone in patients who have received one to three lines of therapy;
   h. In combination with venetoclax and dexamethasone in patients with t(11:14) translocations who received one to three lines of therapy;
   i. In combination with bendamustine and dexamethasone for patients with late relapse or progressive disease who have failed at least three prior therapies;

   **Prior authorization may be required.*
8. Request meets one of the following (a, b, c, d, or e):*
   a. Monotherapy: dose does not exceed 56 mg/m^2 twice weekly each 28-day cycle;
   b. With dexamethasone and lenalidomide: dose does not exceed 27 mg/m^2 twice weekly 3 out of 4 weeks for twelve 28-day cycles, then 27 mg/m^2 twice weekly 2 out of 4 weeks for the next six 28-day cycles for up to a total of 18 cycles;
   c. With dexamethasone ± Darzalex: dose does not exceed (i or ii):
      i. 70 mg/m^2 once weekly each 28-day cycle;
      ii. 56 mg/m^2 twice weekly each 28-day cycle;
   d. With dexamethasone and Sarclisa: 56 mg/m^2 twice weekly each 28-day cycle;
   e. 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. Waldenstrom's Macroglobulinemia (Lymphoplasmacytic Lymphoma) (off-label) (must meet all)**:**
1. Diagnosis of Waldenstrom's macroglobulinemia (i.e., lymphoplasmacytic lymphoma) (WM/LPL);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a component of CaRD (carfilzomib, rituximab*, and dexamethasone) regimen as primary or Kyprolis-relapsed therapy;
   **Prior authorization may be required.*
5. 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. Systemic Light Chain Amyloidosis (off-label) (must meet all)**:**
1. Diagnosis of Systemic Light Chain Amyloidosis;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request is for one of the following (a or b):
   a. Newly diagnosed disease;
   b. Relapsed/refractory as a repeat of initial therapy if relapse-free for several years;
   c. Relapsed/refractory non-cardiac disease;
5. Prescribed in one of the following ways (a or b):
   a. As a single agent;
   b. In combination with dexamethasone;
6. 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

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 for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Therapy

A. Multiple Myeloma (must meet all)**:**
1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Kyprolis for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, c, d, or e):*

a. Monotherapy: new dose does not exceed 56 mg/m^2 twice weekly each 28-day cycle;
b. With dexamethasone and lenalidomide: new dose does not exceed 27 mg/m^2 twice weekly 3 out of 4 weeks for twelve 28-day cycles, then 27 mg/m^2 twice weekly 2 out of 4 weeks for the next six 28-day cycles for up to a total of 18 cycles;
c. With dexamethasone ± Darzalex: new does not exceed (i or ii):
   i. 70 mg/m^2 once weekly each 28-day cycle;
   ii. 56 mg/m^2 twice weekly each 28-day cycle;
d. With dexamethasone and Sarclisa: 56 mg/m^2 twice weekly each 28-day cycle;
e. 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. Waldenstrom's Macroglobulinemia (Lymphoplasmacytic Lymphoma) (off-label) (must meet all)**:**

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Kyprolis for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. 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

C. Systemic Light Chain Amyloidosis (off-label) (must meet all)**:**

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Kyprolis for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. 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

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 for the relevant line of business: LA.PMN.53 for Medicaid.

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

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CaRD: carfilzomib, rituximab, dexamethasone
FDA: Food and Drug Administration
FLC: free light chain
IMWG: International Myeloma Working Group
MM: multiple myeloma
NCCN: National Comprehensive Cancer Network
WM/LPL: Waldenstrom's macroglobulinemia/lymphoplasmacytic 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Kyprolis (carfilzomib), bortezomib (Velcade®), lenalidomide (Revlimid), cyclophosphamide, dexamethasone	MM: Examples of primary therapy • Bortezomib/dexamethasone • Bortezomib/lenalidomide/dexamethasone • Bortezomib/cyclophosphamide/dexamethasone • Bortezomib/doxorubicin/dexamethasone • Bortezomib/thalidomide/dexamethasone • Carfilzomib/cyclophosphamide/dexamethasone • Carfilzomib/lenalidomide/dexamethasone • Cyclophosphamide/lenalidomide/dexamethasone • Daratumumab/lenalidomide/dexamethasone • Daratumumab/lenalidomide/bortezomib/ dexamethasone • Daratumumab/carfilzomib/lenalidomide/ dexamethasone • Daratumumab/cyclophosphamide/bortezomib/ dexamethasone • Daratumumab/bortezomib/thalidomide/ dexamethasone • Daratumumab/bortezomib/melphalan/prednisone • Dexamethasone/thalidomide/cisplatin/doxorubicin/ cyclophosphamide/etoposide/bortezomib (VTD-PACE) • Ixazomib/cyclophosphamide/dexamethasone • Ixazomib/lenalidomide/dexamethasone	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	• Lenalidomide/low-dose dexamethasone	
Kyprolis (carfilzomib), bortezomib (Velcade), lenalidomide (Revlimid), Darzalex® (daratumumab), Ninlaro® (ixazomib), Pomalyst (pomalidomide), Empliciti® (elotuzumab), Thalomid® (thalidomide), bendamustine, cyclophosphamide, dexamethasone, Sarclisa® (istatuximab-irfc), Xpovio® (selinexor)	<u>MM: Examples of therapy for previously treated for relapsed or refractory disease:</u> • Bendamustine • Bendamustine/bortezomib/dexamethasone • Bendamustine/lenalidomide/dexamethasone • Bendamustine/carfilzomib/dexamethasone • Bortezomib/dexamethasone • Bortezomib/lenalidomide/dexamethasone • Bortezomib/liposomal doxorubicin/dexamethasone • Bortezomib/cyclophosphamide/dexamethasone • Carfilzomib/cyclophosphamide/dexamethasone • Carfilzomib/dexamethasone • Carfilzomib/lenalidomide/dexamethasone • Carfilzomib/cyclophosphamide/dexamethasone • Carfilzomib/cyclophosphamide/thalidomide/ dexamethasone • Cyclophosphamide/lenalidomide/dexamethasone • Cyclophosphamide • Daratumumab • Daratumumab/bortezomib/dexamethasone • Daratumumab/carfilzomib/dexamethasone • Daratumumab/cyclophosphamide/bortezomib/ dexamethasone • Daratumumab/lenalidomide/dexamethasone • Daratumumab/pomalidomide/dexamethasone • Dexamethasone/cyclophosphamide/etoposide/cisplatin • Dexamethasone/thalidomide/cisplatin/doxorubicin/ cyclophosphamide/etoposide/ +/- bortezomib • Elotuzumab/lenalidomide/dexamethasone • Elotuzumab/bortezomib/dexamethasone • Elotuzumab/pomalidomide/dexamethasone • Istatuximab-irfc/carfilzomib/dexamethasone • Ixazomib/cyclophosphamide/dexamethasone • Ixazomib/lenalidomide/dexamethasone • Ixazomib/pomalidomide/desamethasone • Isatuximab-irfc/pomalidomide/dexamethasone	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	• Lenalidomide/dexamethasone Pomalidomide/bortezomib/dexamethasone • Pomalidomide/carfilzomib/dexamethasone • Pomalidomide/cyclophosphamide/dexamethasone • Pomalidomide/dexamethasone • Selinexor/bortezomib/dexamethasone • Selinexor/carfilzomib/dexamethasone • Selinexor/daratumumab/dexamethasone • Selinexor/opomalidomide/dexamthasone • Venetoclax/dexamethasone • Ideocabtagene vicleucel • Ciltacabtagene autoleucel • Teclistamab-cqyv • Benlantamab mafodotin-blmf	
rituximab (Rituxan®), Kyprolis (carfilzomib) dexamethasone	WM/LPL: CaRD (carfilzomib, rituximab, and dexamethasone)	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/Black Box Warnings
None reported

Appendix D: General Information
- The IMWG response criteria for multiple myeloma definition of progressive disease requires only one of the following:
  - Increase of 25% from lowest response value in any of the following:
    - Serum M-component (absolute increase must be ≥ 0.5 g/dL), and/or
    - Urine M-component (absolute increase must be ≥ 200 mg/24 h), and/or
  - Only in patients without measurable serum and urine M-protein levels: the difference between involved and uninvolved FLC levels (absolute increase must be > 10 mg/dL)
  - Only in patients without measurable serum and urine M protein levels and without measurable disease by FLC levels, bone marrow plasma cell percentage irrespective of baseline status (absolute increase must be ≥ 10%)
  - Appearance of a new lesion(s), ≥ 50% increase from nadir in SPD (sum of the products of the maximal perpendicular diameters of measured lesions) of > 1 lesion, or ≥ 50% increase in the longest diameter of a previous lesion >1 cm in short axis;
  - ≥ 50% increase in circulating plasma cells (minimum of 200 cells per μL) if this is the only measure of disease

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MM	<u>Kyprolis + Dexamethasone:</u> • Cycles: Kyprolis IV as a 30-minute infusion (28-day cycles). o Cycle 1: administer Kyprolis 20 mg/m^2 on Day 1 and 70 mg/m^2 on Days 8 and 15 o Cycle 2 and later: 70 mg/m^2 on Day 1, 8, and 15 • Dose (once weekly 20/70 mg/m^2 regimen): o Starting dose of Kyprolis 20 mg/m^2 on Cycle 1, Day 1 o If tolerated, escalate Kyprolis to 70 mg/m^2 on Day 8 of Cycle 1. o Dexamethasone: 40 mg PO or IV on Days 1, 8, 15 of all 28-day cycles and on Day 22 of Cycles 1-9. <u>Kyprolis + Dexamethasone, OR **Monotherapy**:</u> • Cycles: Kyprolis IV as a 30-minute infusion (28-day cycles). o Cycle 1: administer Kyprolis 20 mg/m^2 on Days 1 and 2, and 56 mg/m^2 on Day 8, 9, 15, and 16 o Cycle 2 and later: administer Kyprolis 56 mg/m^2 on Days 1, 2, 8, 9, 15 and 16 o For monotherapy: Cycle 13 and later: administer Kyprolis 56 mg/m^2 on Days 1, 2, 15 and 16 • Dose (twice weekly 20/56 mg/m^2 regimen): o Starting dose of Kyprolis 20 mg/m^2 on Cycle 1, Days 1 and 2 o If tolerated, escalate Kyprolis to 56 mg/m^2 on Day 8 of Cycle 1. *<u>Do not include if Monotherapy:</u>* o Dexamethasone: 20 mg PO or IV on Days 1, 2, 8, 9, 15, 16, 22 and 23 of each 28-day cycle. <u>Kyprolis + lenalidomide + Dexamethasone, OR **Monotherapy**:</u> • Cycles: Kyprolis IV as a 10-minute infusion for 28-day cycles. o Cycle 1: administer Kyprolis 20 mg/m^2 on Days 1 and 2, and 27 mg/m^2 on Days 8, 9, 15 and 16 o Cycle 2 to 12: administer Kyprolis 27 mg/m^2 on Days 1, 2, 8, 9, 15 and 16 o Cycle 13 and later, administer Kyprolis 27mg/m^2 on Day 1, 2, 15 and 16 o Discontinue Kyprolis after Cycle 18 and continue lenalidomide and dexamethasone thereafter. • Dose (twice weekly 20/27 mg/m^2 regimen):	70 mg/m^2

Indication	Dosing Regimen	Maximum Dose
	○ Starting dose of Kyprolis: 20 mg/m^2 on Cycle 1, Days 1 and 2 ○ If tolerated, escalate Kyprolis to 27 mg/m^2 on Day 8 of Cycle 1. *Do not include if Monotherapy:* ○ Lenalidomide: 25 mg PO QD on Days 1–21 of each cycle. ○ Dexamethasone: 40 mg PO or IV on Days 1, 8, 15, and 22 of each 28-day cycle. Kyprolis + Darzalex + Dexamethasone: Twice weekly 20/56 mg/m^2 regimen: • Cycles: Kyprolis IV as a 30-minute infusion (28-day cycles). ○ Cycle 1: administer Kyprolis 20 mg/m^2 on Days 1 and 2 and 56 mg/m^2 on Days 8, 9, 15 and 16 ○ Cycle 2 and later: administer Kyprolis 56 mg/m^2 on Days 1, 2, 8, 9, 15 and 16 • Dose: ○ Starting dose of Kyprolis: 20 mg/m^2 on Cycle 1, Days 1 and 2 ○ If tolerated, escalate Kyprolis to 56 mg/m^2 on Day 8 of Cycle 1 ○ See prescribing information for Darzalex, Darzalex Faspro, and dexamethasone dosing. Once weekly 20/70 mg/m^2 regimen: • Cycles: Kyprolis IV as a 30-minute infusion (28-day cycles). ○ Cycle 1: administer Kyprolis 20 mg/m^2 on Day 1 and 70 mg/m^2 on Days 8 and 15 ○ Cycle 2 and later: administer Kyprolis 70 mg/m^2 on Days 1, 8 and 15 • Dose: ○ Starting dose of Kyprolis: 20 mg/m^2 on Cycle 1, Days 1 and 2 ○ If tolerated, escalate Kyprolis to 70 mg/m^2 on Day 8 of Cycle 1 ○ See prescribing information for Darzalex, Darzalex Faspro, and dexamethasone dosing. Kyprolis + Sarclisa + Dexamethasone: Twice weekly 20/56 mg/m^2 regimen: • Cycles: Kyprolis IV as a 30-minute infusion (28-day cycles).	

Indication	Dosing Regimen	Maximum Dose
	○ Cycle 1: administer Kyprolis 20 mg/m^2 on Days 1 and 2 and 56 mg/m^2 on Days 8, 9, 15 and 16 ○ Cycle 2 and later: administer Kyprolis 56 mg/m^2 on Days 1, 2, 8, 9, 15 and 16 • Dose: ○ Starting dose of Kyprolis: 20 mg/m^2 on Cycle 1, Days 1 and 2 ○ If tolerated, escalate Kyprolis to 56 mg/m^2 on Day 8 of Cycle 1 ○ See prescribing information for Sarclisa dosing. _____ *Calculate the Kyprolis dose using the patient's actual body surface area at baseline. In patients with a body surface area greater than 2.2 m^2, calculate the dose based upon a body surface area of 2.2 m^2.*	

VI. Product Availability

Single-dose vials: 10 mg, 30 mg, 60 mg

VII. References

1. Kyprolis Prescribing Information. Thousand Oaks: Onyx Pharmaceuticals, Inc.; June 2022. Available at: https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Kyprolis/kyprolis_pi.pdf. Accessed July 15, 2024.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 1, 2024.
3. National Comprehensive Cancer Network. Multiple Myeloma Version 04.2024 Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed August 1, 2024.
4. National Comprehensive Cancer Network. Waldenstrom's macroglobulinemia-lymphoplasmacytic lymphoma Version 02.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/waldenstroms.pdf. Accessed August 1, 2024.
5. National Comprehensive Cancer Network. Systemic Light Chain Amyloidosis Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/amyloidosis.pdf. Accessed August 1, 2024.

Coding Implications

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

HCPCS Codes	Description
J9047	Injection, carfilzomib, 1 mg

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy.	06.15.23	01.03.24
Annual review: updated MM initial approval criteria to include "for maintenance therapy, Kyprolis is prescribed in combination with lenalidomide" and "in combination with bendamustine and dexamethasone for patients with late relapse or progressive disease who have failed at least three prior therapies" to align with current NCCN compendium and MM guidelines; for Appendix B, updated section with current MM primary therapies and previously treated for relapsed or refractory therapies per current MM guidelines version 3.2023 and removed Panobinostat regimens as agent was withdrawn from market; references reviewed and updated.	05.07.24	07.29.24
Annual review: for relapse or refractory multiple myeloma prescribing regimens: added hematologist as prescriber option, added IMWG criterion defining progressive MM disease as MM class alignment, revised verbiage from "one or three lines of therapy" to "one to three lines of therapy", added verbiage "in patients who have received one to three lines of therapy" when used in combination with Xpovio, cyclophosphamide, or pomalidomide; added regimen option in combination with venetoclax and dexamethasone in patients with t(11:14) translocations; for systemic light chain amyloidosis, added option for treatment for newly diagnosed disease or relapsed/refractory disease as a repeat of initial therapy if relapse-free for several years per NCCN; references reviewed and updated.	01.15.25	

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. 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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