Clinical Policy: Elotuzumab (Empliciti)

Reference Number: LA.PHAR.308
Effective Date: 02.03.24
Last Review Date: ~~06.15.23~~05.02.24
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
Elotuzumab (Empliciti®) is a SLAMF7-directed immunostimulatory antibody.

FDA Approved Indication(s)
Empliciti is indicated in combination with:
- Lenalidomide and dexamethasone for the treatment of patients with multiple myeloma (MM) who have received one to three prior therapies.
- Pomalidomide and dexamethasone for the treatment of adult patients with MM who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

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 Empliciti 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;
3. Age ≥ 18 years;
4. Member has received ≥ 1 prior therapy *(see Appendix B for examples)*;
5. Empliciti is prescribed in combination with dexamethasone, and either Pomalyst®, lenalidomide, or bortezomib;*
   **Prior authorization may be required for Pomalyst, lenalidomide , and bortezomib.*
6. Request meets one of the following (a or b):*
   a. Dose does not exceed (i or ii):
      i. With lenalidomide, both of the following (1 and 2):
         ~~1.~~1) 10 mg/kg per week for the first two cycles (4 doses per 28-day cycle);
         ~~2.~~2) 10 mg/kg per 2 weeks (2 doses per 28-day cycle) for subsequent cycles;
      ii. With Pomalyst, both of the following (1 and 2):

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~~1.~~1) 10 mg/kg every week for the first 2 cycles (4 doses per 28-day cycle);
~~2.~~2) 20 mg/kg every 4 weeks (1 dose per 28-day cycle) for subsequent 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. 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 Empliciti 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 or b):
   a. New dose does not exceed (i or ii):
      i. With lenalidomide, both of the following (1 and 2):
         ~~1.~~1) 10 mg/kg per week for the first two cycles (4 doses per 28-day cycle);
         ~~2.~~2) 10 mg/kg per 2 weeks (2 doses per 28-day cycle) for subsequent cycles;
      ii. With Pomalyst, both of the following (1 and 2):
         ~~1.~~1) 10 mg/kg every week for the first 2 cycles (4 doses per 28-day cycle);
         ~~2.~~2) 20 mg/kg every 4 weeks (1 dose per 28-day cycle) for subsequent 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. 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

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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

FDA: Food and Drug Administration
MM: multiple myeloma
NCCN: National Comprehensive Cancer Network

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
bortezomib (Velcade)	Empliciti in combination with Velcade and dexamethasone: • Regimens vary. • Per NCCN, the SC rather than IV bortezomib formulation is preferred. *An SC generic formulation is not available.*	Varies
lenalidomide (Revlimid)	Empliciti in combination with Revlimid and dexamethasone: Regimens vary.	
Pomalyst (pomalidomide)	Empliciti in combination with Pomalyst and dexamethasone: Regimens vary.	
Kyprolis® (carfilzomib), bortezomib (Velcade), lenalidomide (Revlimid), cyclophosphamide, dexamethasone	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	Varies

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	• 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 • Lenalidomide/low-dose dexamethasone	
Kyprolis (carfilzomib), bortezomib (Velcade), lenalidomide (Revlimid), Darzalex® (daratumumab), Ninlaro® (ixazomib), Pomalyst (pomalidomide), Empliciti® (elotuzumab), ~~Farydak (panobinostat),~~ Thalomid® (thalidomide), bendamustine, cyclophosphamide, dexamethasone, Sarclisa® (istatuximab-irfc), Xpovio® (selinexor)	Examples of therapy for previously treated for relapsed or refractory disease: • 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/dexamethasone~~ • Carfilzomib/cyclophosphamide/thalidomide/ dexamethasone • Cyclophosphamide/lenalidomide/dexamethasone • Cyclophosphamide • Daratumumab • Daratumumab/bortezomib/dexamethasone • Daratumumab/carfilzomib/dexamethasone • Daratumumab/cyclophosphamide/bortezomib/ dexamethasone • Daratumumab/lenalidomide/dexamethasone	Varies

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	• 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 • ~~Panobinostat/bortezomib~~Lenalidomide/dexamethasone • ~~Panobinostat/carfilzomib~~ • 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	

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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MM	Cycles one and two: • Empliciti: 10 mg/kg IV once weekly on cycles 1 and 2 (on days 1, 8, 15, and 22),	With lenalidomide: 10 mg/kg

Indication	Dosing Regimen	Maximum Dose
	• Dexamethasone: 28 mg PO between 3 and 24 hours before Empliciti plus 8 mg IV between 45 and 90 minutes before Empliciti • Lenalidomide: 25 mg PO QD x 21 days of a 28-day cycle OR • Pomalidomide: 4 mg PO QD x 21 days of a 28-day cycle Cycles three and beyond: • Empliciti: o With lenalidomide: 10 mg/kg IV once every 2 weeks (on days 1 and 15) o With pomalidomide: 20 mg/kg IV once every 4 weeks • Dexamethasone: Administer as for cycles one and two and on the days Empliciti is not given (days 8 and 22), give 40 mg PO QD if 75 years or younger OR 20 mg PO QD if older than 75 years • Lenalidomide: 25 mg PO QD x 21 days of a 28-day cycle OR • Pomalidomide: 4 mg PO QD x 21 days of a 28-day	With pomalidomide: 20 mg/kg

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VI. Product Availability
Single-dose vial: 300 mg, 400 mg

VII. References
1. Empliciti Prescribing Information. Princeton, NJ: Bristol-Myers Squibb; March 2022. Available at: https://~~www.~~packageinserts.bms.com/pi/pi_empliciti.~~com/~~.pdf. Accessed ~~July 28, 2022~~August 5, 2023.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed ~~July 28, 2022~~August 5, 2023.
3. National Comprehensive Cancer Network. Multiple Myeloma Version ~~5.2022~~3.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed ~~July 28, 2022.~~August 5, 2023.

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
J9176	Injection, elotuzumab, 1 mg

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy.	06.15.23	01.03.24
Annual review; updated Appendix B with examples of previously treated regimens per current NCCN Multiple Myeloma guidelines; references reviewed and updated.	05.02.24	

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.