

## Clinical Policy: Elotuzumab (Empliciti)

Reference Number: LA.PHAR.308

Effective Date:

Last Review Date: 06.15.23

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  $\geq$  18 years;
  4. Member has received  $\geq$  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. 10 mg/kg per week for the first two cycles (4 doses per 28-day cycle);
        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. 10 mg/kg every week for the first 2 cycles (4 doses per 28-day cycle);
        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. 10 mg/kg per week for the first two cycles (4 doses per 28-day cycle);
      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. 10 mg/kg every week for the first 2 cycles (4 doses per 28-day cycle);
      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 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)	<u>Empliciti in combination with Velcade and dexamethasone:</u> <ul style="list-style-type: none"> <li>Regimens vary.</li> <li>Per NCCN, the SC rather than IV bortezomib formulation is preferred. <i>An SC generic formulation is not available.</i></li> </ul>	Varies
lenalidomide (Revlimid)	<u>Empliciti in combination with Revlimid and dexamethasone:</u> Regimens vary.	
Pomalyst (pomalidomide)	<u>Empliciti in combination with Pomalyst and dexamethasone:</u> Regimens vary.	
Kyprolis® (carfilzomib), bortezomib (Velcade), lenalidomide (Revlimid), cyclophosphamide, dexamethasone	<u>Examples of primary therapy</u> <ul style="list-style-type: none"> <li>Bortezomib/dexamethasone</li> <li>Bortezomib/lenalidomide/dexamethasone</li> <li>Bortezomib/cyclophosphamide/dexamethasone</li> <li>Bortezomib/doxorubicin/dexamethasone</li> <li>Bortezomib/thalidomide/dexamethasone</li> <li>Carfilzomib/cyclophosphamide/dexamethasone</li> <li>Carfilzomib/lenalidomide/dexamethasone</li> <li>Cyclophosphamide/lenalidomide/dexamethasone</li> <li>Daratumumab/lenalidomide/dexamethasone</li> <li>Daratumumab/lenalidomide/bortezomib/dexamethasone</li> <li>Daratumumab/carfilzomib/lenalidomide/dexamethasone</li> <li>Daratumumab/cyclophosphamide/bortezomib/dexamethasone</li> <li>Daratumumab/bortezomib/thalidomide/dexamethasone</li> <li>Daratumumab/bortezomib/melphalan/prednisone</li> </ul>	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<ul style="list-style-type: none"> <li>• Dexamethasone/thalidomide/cisplatin/doxorubicin/ cyclophosphamide/etoposide/bortezomib (VTD-PACE)</li> <li>• Ixazomib/cyclophosphamide/dexamethasone</li> <li>• Ixazomib/lenalidomide/dexamethasone</li> <li>• Lenalidomide/low-dose dexamethasone</li> </ul>	
<p>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)</p>	<p><u>Examples of therapy for previously treated for relapsed or refractory disease:</u></p> <ul style="list-style-type: none"> <li>• Bendamustine</li> <li>• Bendamustine/bortezomib/dexamethasone</li> <li>• Bendamustine/lenalidomide/dexamethasone</li> <li>• Bortezomib/dexamethasone</li> <li>• Bortezomib/lenalidomide/dexamethasone</li> <li>• Bortezomib/liposomal doxorubicin/dexamethasone</li> <li>• Bortezomib/cyclophosphamide/dexamethasone</li> <li>• Carfilzomib/cyclophosphamide/dexamethasone</li> <li>• Carfilzomib/dexamethasone</li> <li>• Carfilzomib/lenalidomide/dexamethasone</li> <li>• Carfilzomib/cyclophosphamide/dexamethasone</li> <li>• Carfilzomib/dexamethasone</li> <li>• Carfilzomib/cyclophosphamide/thalidomide/dexamethasone</li> <li>• Daratumumab/bortezomib/dexamethasone</li> <li>• Daratumumab/carfilzomib/dexamethasone</li> <li>• Daratumumab/cyclophosphamide/bortezomib/dexamethasone</li> <li>• Daratumumab/lenalidomide/dexamethasone</li> <li>• Daratumumab/pomalidomide/dexamethasone</li> <li>• Elotuzumab/lenalidomide/dexamethasone</li> <li>• Elotuzumab/bortezomib/dexamethasone</li> <li>• Elotuzumab/pomalidomide/dexamethasone</li> <li>• Istatuximab-irfc/carfilzomib/dexamethasone</li> <li>• Ixazomib/cyclophosphamide/dexamethasone</li> <li>• Ixazomib/lenalidomide/dexamethasone</li> <li>• Ixazomib/pomalidomide/dexamethasone</li> <li>• Isatuximab-irfc/pomalidomide/dexamethasone</li> <li>• Panobinostat/bortezomib/dexamethasone</li> <li>• Panobinostat/carfilzomib</li> <li>• Pomalidomide/bortezomib/dexamethasone</li> <li>• Pomalidomide/carfilzomib/dexamethasone</li> </ul>	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<ul style="list-style-type: none"> <li>• Pomalidomide/cyclophosphamide/dexamethasone</li> <li>• Selinexor/bortezomib/dexamethasone</li> </ul>	

*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	<p><u>Cycles one and two:</u></p> <ul style="list-style-type: none"> <li>• Empliciti: 10 mg/kg IV once weekly on cycles 1 and 2 (on days 1, 8, 15, and 22),</li> <li>• Dexamethasone: 28 mg PO between 3 and 24 hours before Empliciti plus 8 mg IV between 45 and 90 minutes before Empliciti</li> <li>• Lenalidomide: 25 mg PO QD x 21 days of a 28-day cycle</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• Pomalidomide: 4 mg PO QD x 21 days of a 28-day cycle</li> </ul> <p><u>Cycles three and beyond:</u></p> <ul style="list-style-type: none"> <li>• Empliciti: <ul style="list-style-type: none"> <li>○ With lenalidomide: 10 mg/kg IV once every 2 weeks (on days 1 and 15)</li> <li>○ With pomalidomide: 20 mg/kg IV once every 4 weeks</li> </ul> </li> <li>• 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</li> <li>• Lenalidomide: 25 mg PO QD x 21 days of a 28-day cycle</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• Pomalidomide: 4 mg PO QD x 21 days of a 28-day</li> </ul>	<p>With lenalidomide: 10 mg/kg</p> <p>With pomalidomide: 20 mg/kg</p>

**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.empliciti.com/>. Accessed July 28, 2022.

2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed July 28, 2022.
3. National Comprehensive Cancer Network. Multiple Myeloma Version 5.2022. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/myeloma.pdf](https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf). Accessed July 28, 2022.

### **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.

<b>HCPCS Codes</b>	<b>Description</b>
J9176	Injection, elotuzumab, 1 mg

<b>Reviews, Revisions, and Approvals</b>	<b>Date</b>	<b>LDH Approval Date</b>
Converted corporate to local policy.	06.15.23	

### **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.

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