

## Clinical Policy: Elotuzumab (Empliciti)

Reference Number: PA.CP.PHAR.308

Effective Date: 01/18

Last Review Date: 10/30/2019

[Coding Implications](#)

[Revision Log](#)

### Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness<sup>®</sup> clinical policy for elotuzumab (Empliciti<sup>™</sup>).

### 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

It is the policy of Pennsylvania Health and Wellness<sup>®</sup> that Empliciti is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

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

1. Diagnosis of multiple myeloma;
2. Prescribed by or in consultation with an oncologist;
3. Member has received  $\geq 1$  prior therapy (*see Appendix B for examples*);
4. Empliciti is prescribed in combination with dexamethasone, and either Pomalyst<sup>®</sup>, Revlimid<sup>®</sup> or Velcade<sup>®</sup>;  
*\*Prior authorization may be required for Revlimid and Velcade.*
5. Request meets one of the following (a or b):
  - a. Dose does not exceed (i or ii):
    - i. With lenalidomide: 10 mg/kg per week for the first two cycles (4 doses per 28-day cycle) and 10 mg/kg per 2 weeks (2 doses per 28-day cycle) for subsequent cycles;
    - ii. With pomalidomide: 10 mg/kg every week for the first 2 cycles (4 doses per 28-day cycle) and 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*).

**Approval duration: 6 months**

##### B. Other diagnoses/indications: Refer to PA.CP.PMN.53

#### II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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: 10 mg/kg per week for the first two cycles (4 doses per 28-day cycle) and 10 mg/kg per 2 weeks (2 doses per 28-day cycle) for subsequent cycles;
    - ii. With pomalidomide: 10 mg/kg every week for the first 2 cycles (4 doses per 28-day cycle) and 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*).

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

**III. 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
Velcade (bortezomib)	<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
Revlimid (lenalidomide)	<u>Empliciti in combination with Revlimid and dexamethasone:</u> <ul style="list-style-type: none"> <li>Regimens vary.</li> </ul>	
Pomalyst® (pomalidomide)	<u>Empliciti in combination with Pomalyst and dexamethasone:</u>	

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Regimens vary.	
Darzalex <sup>®</sup> (daratumumab) Empliciti (elotuzumab) Kyprolis <sup>®</sup> (carfilzomib) Ninlaro <sup>®</sup> (ixazomib) Revlimid (lenalidomide) Thalomid <sup>®</sup> (thalidomide) Velcade (bortezomib)	<u>Examples of primary and subsequent therapy regimens:</u> <ul style="list-style-type: none"> <li>• Bendamustine</li> <li>• Bortezomib/doxorubicin/dexamethasone</li> <li>• Bortezomib/thalidomide/dexamethasone</li> <li>• Bortezomib/lenalidomide/dexamethasone</li> <li>• Bortezomib/cyclophosphamide/dexamethasone</li> <li>• Carfilzomib/lenalidomide/dexamethasone</li> <li>• Carfilzomib/cyclophosphamide/dexamethasone</li> <li>• Daratumumab/lenalidomide/dexamethasone</li> <li>• Dexamethasone/thalidomide/cisplatin/ doxorubicin/cyclophosphamide/bortezomib</li> <li>• Elotuzumab/lenalidomide/dexamethasone</li> <li>• Ixazomib/lenalidomide/dexamethasone</li> <li>• Lenalidomide/dexamethasone</li> </ul>	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/Black Box Warnings*  
None reported

#### IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MM	<u>Cycles one and two:</u> <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> OR <ul style="list-style-type: none"> <li>• Pomalidomide: 4 mg PO QD x 21 days of a 28-day cycle</li> </ul> <u>Cycles three and beyond:</u> <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> </ul>	20 mg/kg

Indication	Dosing Regimen	Maximum Dose
	<ul style="list-style-type: none"> <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</li> <li>Lenalidomide: 25 mg PO QD x 21 days of a 28-day cycle</li> </ul> OR <ul style="list-style-type: none"> <li>Pomalidomide: 4 mg PO QD x 21 days of a 28-day</li> </ul>	

**V. Product Availability**

Single-dose vials: 300 mg, 400 mg

**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	Approval Date
4Q 2018 annual review: no significant changes; NCCN and FDA-approved uses summarized for improved clarity; specialist involvement in care and continuation of care added; references reviewed and updated.	08/18	
2Q 2019: added newly FDA-approved use with pomalidomide for MM; references reviewed and updated.	04/19	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/30/19	

**References**

1. Empliciti Prescribing Information. Princeton, NJ: Bristol-Myers Squibb; November 2018. Available at: <https://www.empliciti.com/>. Accessed November 27, 2018.
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 November 27, 2018.