Clinical Policy: Elotuzumab (Empliciti)

Reference Number: PA.CP.PHAR.308
Effective Date: 01/18
Last Review Date: 04/19

Coding Implications
Revision Log

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

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 ® 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 ≥ 1 prior therapy *(see Appendix B for examples)*;
4. Empliciti is prescribed in combination with dexamethasone, and either Pomalyst®, Revlimid® or Velcade®;
   **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)	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
Revlimid (lenalidomide)	Empliciti in combination with Revlimid and dexamethasone: • Regimens vary.	
Pomalyst® (pomalidomide)	Empliciti in combination with Pomalyst and dexamethasone:	

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Regimens vary.	
Darzalex® (daratumumab) Empliciti (elotuzumab) Kyprolis® (carfilzomib) Ninlaro® (ixazomib) Revlimid (lenalidomide) Thalomid® (thalidomide) Velcade (bortezomib)	Examples of primary and subsequent therapy regimens: • Bendamustine • Bortezomib/doxorubicin/dexamethasone • Bortezomib/thalidomide/dexamethasone • Bortezomib/lenalidomide/dexamethasone • Bortezomib/cyclophosphamide/dexamethasone • Carfilzomib/lenalidomide/dexamethasone • Carfilzomib/cyclophosphamide/dexamethasone • Daratumumab/lenalidomide/dexamethasone • Dexamethasone/thalidomide/cisplatin/ doxorubicin/cyclophosphamide/bortezomib • Elotuzumab/lenalidomide/dexamethasone • Ixazomib/lenalidomide/dexamethasone • Lenalidomide/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

IV. 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), • 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	20 mg/kg

Indication	Dosing Regimen	Maximum Dose
	• 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 • 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	

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	

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. Accessed November 27, 2018.