Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2022**
Policy Number: PA.CP.PHAR.308	**Effective Date: 01/2018** **Revision Date: 10/2022**
Policy Name: Elotuzumab (Empliciti)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

4Q 2022 annual review: no significant changes; updated Appendix B per NCCN MM guidelines for primary therapy and therapy for previously treated MM; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Elotuzumab (Empliciti)

Reference Number: PA.CP.PHAR.308
Effective Date: 01/2018
Last Review Date: 10/2022

Coding Implications
Revision Log

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
It is the policy of PA Health & 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 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®, Revlimid® or bortezomib;
   **Prior authorization may be required for Pomalyst, Revlimid, 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 pomalidomide, 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*).

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 PA Health & 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, 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 pomalidomide, 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*).

Approval duration: 12 months

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

1. Currently receiving medication via PA Health & 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.	

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Pomalyst (pomalidomide)	Empliciti in combination with Pomalyst and dexamethasone: Regimens vary.	
Kyprolis (carfilzomib), Velcade® (bortezomib), Revlimid (lenalidomide), cyclophosphamide, dexamethasone	Examples of primary therapy 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 Lenalidomide/low-dose dexamethasone	Varies
Kyprolis (carfilzomib), Velcade® (bortezomib), Revlimid (lenalidomide), Darzalex® (daratumumab), Ninlaro® (ixazomib), Pomalyst (pomalidomide),	Examples of therapy for previously treated for relapsed or refractory disease: • Bendamustine • Bendamustine/bortezomib/dexamethasone • Bendamustine/lenalidomide/dexamethasone • Bortezomib/dexamethasone • Bortezomib/lenalidomide/dexamethasone • Bortezomib/liposomal doxorubicin/dexamethasone • Bortezomib/cyclophosphamide/dexamethasone • Carfilzomib/cyclophosphamide/dexamethasone • Carfilzomib/dexamethasone • Carfilzomib/lenalidomide/dexamethasone	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Empliciti® (elotuzumab), Farydak (panobinostat), Thalomid® (thalidomide), bendamustine, cyclophosphamide, dexamethasone, Sarclisa® (istatuximab-irfc), Xpovio® (selinexor)	• Carfilzomib/cyclophosphamide/dexamethasone • Carfilzomib/dexamethasone • Carfilzomib/cyclophosphamide/thalidomide/ dexamethasone • Daratumumab/bortezomib/dexamethasone • Daratumumab/carfilzomib/dexamethasone • Daratumumab/cyclophosphamide/bortezomib/ dexamethasone • Daratumumab/lenalidomide/dexamethasone • Daratumumab/pomalidomide/dexamethasone • 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/dexamethasone • Panobinostat/carfilzomib • Pomalidomide/bortezomib/dexamethasone • Pomalidomide/carfilzomib/dexamethasone • Pomalidomide/cyclophosphamide/dexamethasone Selinexor/bortezomib/dexamethasone	

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	With lenalidomide: 10 mg/kg With pomalidomide: 20 mg/kg

Indication	Dosing Regimen	Maximum Dose
	OR • Pomalidomide: 4 mg PO QD x 21 days of a 28-day cycle <u>Cycles three and beyond:</u> • 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	

V. Product Availability

Single-dose vials: 300 mg, 400 mg

VI. References

1. Empliciti Prescribing Information. Princeton, NJ: Bristol-Myers Squibb; March2022. 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. 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. 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.

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.	08/2018	
2Q 2019: added newly FDA-approved use with pomalidomide for MM; references reviewed and updated.	04/2019	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019	
4Q 2020 annual review: added age limit; references reviewed and updated.	10/2020	
4Q 2021 annual review: updated Appendix B Therapeutic Alternatives; references reviewed and updated.	10/2021	
4Q 2022 annual review: no significant changes; updated Appendix B per NCCN MM guidelines for primary therapy and therapy for previously treated MM; references reviewed and updated.	10/2022	