Clinical Policy: Elotuzumab (Empliciti)

Reference Number: ERX.SPA.280
Effective Date: 12.01.18
Last Review Date: 11.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 Velcade®;*
   **Prior authorization may be required for Pomalyst, Revlimid, and Velcade.*
6. 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*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, 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: 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration: 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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 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 Revlimjd and dexamethasone: Regimens vary.	Varies
Pomalyst (pomalidomide)	Empliciti in combination with Pomalyst and dexamethasone: Regimens vary.	Varies
Kyprolis (carfilzomib), Velcade® (bortezomib), Revlimid (lenalidomide),	Examples of primary therapy • Bortezomib/lenalidomide/dexamethasone • Bortezomib/cyclophosphamide/dexamethasone • Carfilzomib/lenalidomide/dexamethasone • Daratumumab/lenalidomide/dexamethasone • Daratumumab/lenalidomide/bortezomib/dexamethasone	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cyclophosphamide, dexamethasone	• Carfilzomib/cyclophosphamide/dexamethasone • Carfilzomib/lenalidomide/dexamethasone	
Kyprolis (carfilzomib), Velcade® (bortezomib), Revlimid (lenalidomide), Darzalex® (daratumumab), Ninlaro® (ixazomib), Pomalyst (pomalidomide), Empliciti® (elotuzumab), Farydak (panobinostat), Thalomid® (thalidomide), bendamustine, cyclophosphamide, dexamethasone	Examples of therapy for previously treated for relapsed or refractory disease: • Bendamustine • Bortezomib/dexamethasone • Carfilzomib/lenalidomide/dexamethasone • Daratumumab/bortezomib/dexamethasone • Daratumumab/carfilzomib/dexamethasone • Daratumumab/lenalidomide/dexamethasone • Ixazomib/lenalidomide/dexamethasone • Pomalidomide/bortezomib/dexamethasone • Elotuzumab/lenalidomide/dexamethasone • Panobinostat/bortezomib/dexamethasone • Carfilzomib/cyclophosphamide/dexamethasone • Carfilzomib/dexamethasone • Pomalidomide/carfilzomib/dexamethasone • Carfilzomib/cyclophosphamide/thalidomide/dexamethasone • Panobinostat/carfilzomib	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

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), • 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: ○ With lenalidomide: 10 mg/kg IV once every 2 weeks (on days 1 and 15) ○ 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 • 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	20 mg/kg

VI. Product Availability

Single-dose vial: 300 mg, 400 mg

VII. References

1. Empliciti Prescribing Information. Princeton, NJ: Bristol-Myers Squibb; October 2019. Available at: https://www.empliciti.com/. Accessed August 11, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 11, 2021.
3. National Comprehensive Cancer Network. Multiple Myeloma Version 7.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed August 11, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	08.07.18	11.18
4Q 2019 annual review: added new FDA approved use with pomalidomide; FDA/NCCN dosing requirement added; references reviewed and updated.	08.20.19	11.19
4Q 2020 annual review: no significant changes; references reviewed and updated.	08.11.20	11.20
4Q 2021 annual review: no significant changes; updated Appendix B Therapeutic Alternatives; references reviewed and updated.	08.11.21	11.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.