

<b>Clinical Policy Title:</b>	elotuzumab
<b>Policy Number:</b>	RxA.365
<b>Drug(s) Applied:</b>	Empliciti®
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	09/14/2020
<b>Line of Business Policy Applies to:</b>	All lines of business

### Background

Elotuzumab (Empliciti®) is a SLAMF7-directed immunostimulatory antibody. Elotuzumab 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

### Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Elotuzumab (Empliciti)	MM	<p>Cycles one and two:</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 once daily x 21 days of a 28-day cycle</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• Pomalidomide: 4 mg PO once daily x 21 days of a 28-day cycle</li> </ul> <p>Cycles three and beyond:</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</li> </ul>	20 mg/kg

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Drug Name	Indication	Dosing Regimen	Maximum Dose
		<ul style="list-style-type: none"> <li>the days Empliciti is not given (days 8 and 22), give 40 mg PO once daily</li> <li>Lenalidomide: 25 mg PO once daily x 21 days of a 28-day cycle</li> </ul> OR <ul style="list-style-type: none"> <li>Pomalidomide: 4 mg PO once daily x 21 days of a 28-day</li> </ul>	

### Dosage Forms

Single-dose vial: 300 mg, 400 mg

### Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

#### I. Initial Approval Criteria

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

- Diagnosis of MM;
  - Prescribed by or in consultation with an oncologist;
  - Age ≥ 18 years;
  - Member has received ≥ 1 prior therapy (see Appendix B for examples);
  - Empliciti is prescribed in combination with dexamethasone, and either Pomalyst®, Revlimid®, or Velcade®;\*
- \*Prior authorization may be required for Pomalyst, Revlimid, and Velcade.
- Request meets one of the following (a or b):\*
    - Dose does not exceed (i or ii):
      - 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;
      - 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;
    - 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

**Commercial:** 6 months

**Medicaid:** 6 months

**HIM-Medical Benefit:** 6 months

#### II. Continued Therapy Approval

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

- Currently receiving medication that has been authorized by RxAdvance or documentation supports that member is currently receiving Empliciti for a covered indication and has received this medication for at least 30 days;
- Member is responding positively to therapy;
- 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**

**Commercial:** 12 months

**Medicaid:** 12 months

**HIM-Medical Benefit:** 12 months

**III. Appendices**

**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> Regimens vary.	
Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose

<p>Darzalex<sup>®</sup> (daratumumab) Empliciti (elotuzumab) Kyprolis<sup>®</sup> (carfilzomib) Ninlaro<sup>®</sup> (ixazomib) Revlimid (lenalidomide) Thalomid<sup>®</sup> (thalidomide) Velcade (bortezomib)</p>	<p><u>Examples of primary and subsequent therapy regimens:</u></p> <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>	<p>Varies</p>
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*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/Boxed Warnings**

- Contraindication(s):
  - None reported
- Boxed warning(s):
  - None reported

**References**

1. Empliciti Prescribing Information. Princeton, NJ: Bristol-Myers Squibb; November 2018. Available at: <https://www.empliciti.com/>. Accessed July 15, 2020.
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 15, 2020.
3. National Comprehensive Cancer Network. Multiple Myeloma Version 5.2020. Available at: <http://www.nccn.org>. Accessed July 15, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed <ol style="list-style-type: none"> <li>1. Policy title table was updated.</li> <li>2. Line of business 'Policy Applies to' was updated to all lines of business.</li> <li>3. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..."</li> <li>4. Reference reviewed and updated</li> </ol>	07/15/2020	09/14/2020