

Clinical Policy: Elotuzumab (Empliciti)

Reference Number: CP.PHAR.308

Effective Date: 02.01.17

Last Review Date: 11.18

Line of Business: Medicaid, HIM-Medical Benefit

[Coding Implications](#)

[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.

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.

It is the policy of health plans affiliated with Centene Corporation® 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 \geq 18 years;
4. Member has received \geq 1 prior therapy (*see Appendix B for examples*);
5. Empliciti is prescribed in combination with dexamethasone, and either Revlimid® or Velcade®;
**Prior authorization may be required for Revlimid and Velcade.*
6. Request meets one of the following (a or b):
 - a. Dose does not exceed 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;
 - 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

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Multiple Myeloma (must meet all):

1. Currently receiving medication via Centene benefit, 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 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;
 - 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 Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

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 policies – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid 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 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> • Regimens vary.	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<ul style="list-style-type: none"> Per NCCN, the SC rather than IV bortezomib formulation is preferred. <i>An SC generic formulation is not available.</i> 	
Revlimid (lenalidomide)	<u>Empliciti in combination with Revlimid and dexamethasone:</u> <ul style="list-style-type: none"> Regimens vary. 	
Darzalex® (daratumumab) Empliciti (elotuzumab) Kyprolis® (carfilzomib) Ninlaro® (ixazomib) Revlimid (lenalidomide) Thalomid® (thalidomide) Velcade (bortezomib)	<u>Examples of primary and subsequent therapy regimens:</u> <ul style="list-style-type: none"> 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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MM	<u>Cycles one and two:</u> <ul style="list-style-type: none"> 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. <u>Cycles three and beyond:</u> <ul style="list-style-type: none"> Empliciti: 10 mg/kg IV once every 2 weeks (on days 1 and 15). 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. 	10 mg/kg

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

VI. Product Availability

Single-dose vial: lyophilized powder for reconstitution for injection: 300 mg, 400 mg

VII. References

1. Empliciti Prescribing Information. Princeton, NJ: Bristol-Myers Squibb; May 2017. Available at: <https://www.empliciti.com/>. Accessed July 16, 2018.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 16, 2018.
3. National Comprehensive Cancer Network. Multiple Myeloma Version 04.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed July 16, 2018.

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

Follow the rules outlined in the attached Revision Log Updating document

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.182 Excellus Oncology.	01.17	02.17
Converted to new template. Added age restriction as safety and effectiveness have not been established in pediatric patients per PI/safety approach. Added max dose criteria for both FDA and off-label NCCN uses. Increased initial/continued approval from 3/6 months to 6/12 months, respectively. Added Appendix B: Examples of Myeloma Therapy per NCCN guidelines for multiple myeloma.	08.30.17	11.17
4Q 2018 annual review: no significant changes; added HIM-Medical, NCCN and FDA-approved uses summarized for improved clarity; specialist involvement in care and continuation of care added; references reviewed and updated.	08.07.18	11.18

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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