

Clinical Policy: Elotuzumab (Empliciti)

Reference Number: CP.PHAR.308

Effective Date: 02.01.17

Last Review Date: 11.19

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
- 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.

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 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 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): CP.PMN.53 for Medicaid and HIM-Medical Benefit.

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 (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 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): CP.PMN.53 for Medicaid and HIM-Medical Benefit.

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 – CP.PMN.53 for Medicaid and HIM-Medical Benefit 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> <ul style="list-style-type: none"> Regimens vary. Per NCCN, the SC rather than IV bortezomib formulation is preferred. <i>An SC generic formulation is not available.</i> 	Varies
Revlimid (lenalidomide)	<u>Empliciti in combination with Revlimid and dexamethasone:</u> <ul style="list-style-type: none"> Regimens vary. 	
Pomalyst (pomalidomide)	<u>Empliciti in combination with Pomalyst and dexamethasone:</u> 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), 	20 mg/kg

Indication	Dosing Regimen	Maximum Dose
	<ul style="list-style-type: none"> • 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 <p>OR</p> <ul style="list-style-type: none"> • Pomalidomide: 4 mg PO QD x 21 days of a 28-day cycle <p><u>Cycles three and beyond:</u></p> <ul style="list-style-type: none"> • Empliciti: <ul style="list-style-type: none"> ○ 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 <p>OR</p> <ul style="list-style-type: none"> • Pomalidomide: 4 mg PO QD x 21 days of a 28-day 	

VI. Product Availability

Single-dose vial: 300 mg, 400 mg

VII. References

1. Empliciti Prescribing Information. Princeton, NJ: Bristol-Myers Squibb; November 2018. Available at: <https://www.empliciti.com/>. Accessed July 22, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 22, 2019.
3. National Comprehensive Cancer Network. Multiple Myeloma Version 3.2019. Available at: <http://www.nccn.org>. Accessed July 22, 2019.

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	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
RT4: added newly FDA-approved use with pomalidomide for MM; references reviewed and updated.	11.27.18	02.19
4Q 2019 annual review: FDA/NCCN dosing requirement added; references reviewed and updated.	08.20.19	11.19

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or

regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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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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