# Medical Policy

**Healthcare Services Department**

| Policy Name | Policy Number | Scope |
|---|---|---|
| **Elotuzumab (Empliciti®)** | MP-RX-FP-26-23 | ☒ MMM MA ☒ MMM Multihealth |

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

## Service Description

This document addresses the use of *Elotuzumab (Empliciti®),* a SLAMF7-directed immunostimulatory antibody approved by the Food and Drug Administration (FDA) for the treatment of certain patients with multiple myeloma.

**Background Information**

Empliciti is a humanized IgG1 monoclonal antibody that targets the signaling lymphocytic active molecule (SLAM) family member F7 (SLAMF7) protein expressed on myeloma and natural killer cells. Empliciti activates natural killer cells mediating the killing of myeloma cells through antibody-dependent cellular cytotoxicity. Empliciti is used to treat multiple myeloma.

The FDA-approved indications for Empliciti include use in combination with lenalidomide and dexamethasone for the treatment of multiple myeloma in individuals who have received one to three prior therapies. It is also FDA-approved in combination with pomalidomide and dexamethasone, in individuals who have received at least two prior therapies including lenalidomide and a proteasome inhibitor. The trials used to approve these two indications included patients with relapsed, refractory, or progressive disease. The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for use in combination with bortezomib and dexamethasone for previously treated myeloma for relapsed or progressive disease.

Definitions and Measures

- Multiple myeloma: A type of cancer that begins in plasma cells (white blood cells that produce antibodies).
- Plasma cell leukemia: A rare and aggressive form of multiple myeloma characterized by high levels of plasma cells in the peripheral blood.
- Progressive disease: For cancer, disease that is growing (e.g. growth in size of tumor), spreading, or worsening.
- Proteasome inhibitors: A class of drugs used to treat multiple myeloma that work by blocking the action of proteasomes which are cellular complexes that break down proteins. Examples include bortezomib, carfilzomib and ixazomib.
- Refractory disease: Illness or disease that does not respond to treatment.
- Relapse: After a period of improvement, the return of signs and symptoms of cancer.

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**Approved Indications**

Elotuzumab (Empliciti®) is indicated:

- In combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received one to three prior therapies.
- In combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

**Other Uses**

None

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| HCPCS | Description |
|---|---|
| J9176 | Injection, elotuzumab, 1 mg [Empliciti] |

| ICD-10 | Description |
|---|---|
| C90.00-C90.32 | Multiple myeloma and malignant plasma cell neoplasms |
| Z85.79 | Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues |

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## Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

## Elotuzumab (Empliciti®)

**A. Criteria For Initial Approval** (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual has a diagnosis of relapsed, progressive, or refractory multiple myeloma, including plasma-cell leukemia; **AND**

ii. Disease is relapsed, progressive, or refractory following at least one prior therapy; **AND**

iii. Individual is using in combination with one of the following:

A. Lenalidomide and dexamethasone; **OR**

B. Bortezomib and dexamethasone (NCCN 2A); **OR**

C. Pomalidomide and dexamethasone (in individuals who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

**B. Criteria For Continuation of Therapy**

i. MMM considers continuation of Elotuzumab (Empliciti®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of an unacceptable toxicity or disease progression while on the current regimen. The following information should be submitted for reauthorization:

A. A current oncology note documenting the patient's response to treatment showing no progression of disease.

B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results

**C. Authorization Duration**

i. Initial Approval Duration: Per cycle

ii. Reauthorization Approval Duration: Up to 6 months

**D. Conditions Not Covered**

*Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):*

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i. Requests for Empliciti (elotuzumab) may not be approved when the above criteria (Section A: Criteria for Initial Approval) are not met and for all other indications.

## Limits or Restrictions

A. Therapeutic Alternatives

*The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.*

i. N/A

B. Quantity Limitations

*Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.*

| Recommended Treatment | Dosing Recommendations[a] | Recommended Duration |
|---|---|---|
| Used in combination with Lenalidomide and Dexamethasone | Cycles 1 and 2 (28-days cycle): 10 mg/kg weekly (on Days 1, 8, 15, and 22)<br><br>Cycle 3 and following cycles (28-days cycle): 10 mg/kg every 2 weeks | Until disease progression or unacceptable toxicity |
| Used in Combination with Pomalidomide and Dexamethasone | Cycles 1 and 2 (28-days cycle): 10 mg/kg weekly (on Days 1, 8, 15, and 22)<br><br>Cycle 3 and following cycles (28-days cycle): 20 mg/kg every 4 weeks | Until disease progression or unacceptable toxicity |
| **Exceptions** | | |
| None | | |

[a] Premedication must include dexamethasone, diphenhydramine, ranitidine and acetaminophen

## Reference Information

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 20, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.

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4. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 20, 2023.
    a. Multiple Myeloma. V3.2023. Revised December 8, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.



## Policy History

| Revision Type | Summary of Changes | P&T Approval Date | MPCC Approval Date |
|---|---|---|---|
| Annual Review 6/2/2025 | Minimal changes; Word formatting. No coding updates. | 6/9/2025 | 6/19/2025 |
| Annual Review 6/25/2024 | Clarify line of therapy to require at least one prior treatment per label/NCCN. Add therapeutic alternatives section and federal statement. Wording and formatting changes. Coding Reviewed: No changes. | 2/18/2025 | 3/6/2025 |
| Select Review 2/15/2024 | Update statement for criteria for initial approval: Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met all approval criteria. | 3/25/2024 | 5/9/2024 |
| Policy Inception 6/11/2023 | Elevance Health's Medical Policy adoption. | N/A | 11/30/2023 |