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. 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):

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.

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Limits or Restrictions

A. 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) 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) 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.
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.

Policy History

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Elotuzumab (Empliciti®)	MP-RX-FP-26-23	☒ MMM MA ☒ MMM Multihealth

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023
Select Review	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

Revised: 11/11/2023