Medical Policy:

Empliciti® (elotuzumab) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.144	March 18, 2024	

Definitions

Empliciti (elotuzumab): Elotuzumab is a humanized IgG1 monoclonal antibody that specifically targets the SLAMF7 (Signaling Lymphocytic Activation Molecule Family member 7) protein. SLAMF7 is expressed on myeloma cells independent of cytogenetic abnormalities. SLAMF7 is also expressed on Natural Killer cells, plasma cells, and at lower levels on specific immune cell subsets of differentiated cells within the hematopoietic lineage.

Elotuzumab directly activates Natural Killer cells through both the SLAMF7 pathway and Fc receptors. Elotuzumab also targets SLAMF7 on myeloma cells and facilitates the interaction with Natural Killer cells to mediate the killing of myeloma cells through antibody-dependent cellular cytotoxicity (ADCC). In preclinical models, the combination of elotuzumab and lenalidomide resulted in enhanced activation of Natural Killer cells that was greater than the effects of either agent alone and increased anti-tumor activity in vitro and in vivo.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time) [Medical Benefit]:

Given in combination with Lenalidomide/Dexamethasone:

- 1200 billable units weekly for the first two 28-day cycles (8 doses), then every two weeks thereafter beginning D1 of cycle 3

Given in combination with Pomalidomide/Dexamethasone:

- 1200 billable units weekly for the first two 28-day cycles (8 doses), then 2300 billable units every four weeks thereafter beginning D1 of cycle 3

Guideline

I. Initial Approval Criteria

Empliciti *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. **Multiple Myeloma**
    A. Patient has a diagnosis of relapsed or progressive disease; **AND**
        i. Used in combination with lenalidomide and dexamethasone after failure of one to three prior therapies; **OR**
        ii. Used in combination with pomalidomide and dexamethasone after failure of at least two prior therapies, including lenalidomide and a proteasome inhibitor.

Limitations/Exclusions

Empliciti is not considered medically necessary for when any of the following selection criteria is met:

1. Members with non-secretory or oligo-secretory or serum free light-chain only myeloma.
2. Members with active plasma cell leukemia.
3. Members with Known Human immunodeficiency virus (HIV) infection or active hepatitis A, B, or C.
4. Disease progression while taking Empliciti (elotuzumab).
5. The maximum dose should not exceed 20 mg/kg.
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. Renewal Criteria

1. Patient continues to meet criteria in INITIAL APPROVAL CRITERIA.
2. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions, infections, second primary malignancies, hepatotoxicity, etc.

Dosage/Administration

Indication	Dose
Multiple Myeloma in combination with lenalidomide and dexamethasone	10 mg/kg administered intravenously every week for the first two cycles and every 2 weeks, thereafter, until disease progression or unacceptable toxicity.
Multiple Myeloma in combination with pomalidomide and dexamethasone	10 mg/kg administered intravenously every week for the first two cycles, then 20mg/kg every 4 weeks thereafter, until disease progression or unacceptable toxicity.

Applicable Procedure Codes

Code	Description
J9176	Injection, elotuzumab, 1 mg, 1 billable unit = 1 mg

Applicable NDCs

Code	Description
00003-2291-xx	Empliciti 300 mg single use vial
00003-4522-xx	Empliciti 400 mg single use vial

ICD-10 Diagnoses

Code	Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma, in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/18/2024	Annual Review: removed C90.10, C90.12, no criteria changes
EmblemHealth & ConnectiCare	07/06/2023	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	04/21/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	07/15/2019	Annual Review

References

1. Empliciti prescribing information. Bristol-Myers Squibb. December 2016.
2. Clinical Pharmacology Elsevier Gold Standard. 2017.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2017.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2017.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists. Bethesda, MD. 2017.