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5.21.073

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	December 16, 2015
Subject:	Empliciti	**Page:**	1 of 4

Last Review Date: March 8, 2024

Empliciti

Description

Empliciti (elotuzumab)

Background
Empliciti (elotuzumab) is a monoclonal antibody that specifically targets the SLAMF7 (Signaling Lymphocytic Activation Molecule Family Member 7) protein. Multiple myeloma (MM) is a cancer that forms in a type of white blood cell called plasma cells. SLAMF7 protein is expressed on both myeloma and natural killer cells. Empliciti exerts its anticancer effects by targeting the SLAMF7 protein on myeloma cells directly and by increasing interaction with natural killer cells to mediate the killing of myeloma cells. Empliciti is administered intravenously every week for the first two cycles and then every 2 or 4 weeks thereafter until disease progression or unacceptable toxicity
(1).

Regulatory Status
FDA-approved indications: Empliciti is a SLAMF7-directed immunostimulatory antibody indicated in: (1)

1. combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received one to three prior therapies
2. 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

Empliciti therapy may cause elevations in liver enzymes (aspartate transaminase/alanine transaminase [AST/ALT] greater than 3 times the upper limit, total bilirubin greater than 2 times

the upper limit, and alkaline phosphatase less than 2 times the upper limit) consistent with hepatotoxicity. Liver function should be monitored periodically and therapy stopped upon Grade 3 or higher elevation and continuation of therapy considered after return to baseline values (1).

Safety and effectiveness of Empliciti have not been established in pediatric patients (1).

Related Policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Empliciti may be considered **medically necessary** if the conditions indicated below are met.

Empliciti may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Multiple myeloma (MM)

AND ALL of the following:

1. Patient has **ONE** of the following:
    a. Patient has received at least **ONE** prior multiple myeloma therapy
        i. Used in combination with lenalidomide (Revlimid) and dexamethasone
    b. Patient has received at least **TWO** prior multiple myeloma therapies including lenalidomide (Revlimid) and a proteasome inhibitor
        i. Used in combination with pomalidomide (Pomalyst) and dexamethasone
2. Prescriber agrees to monitor liver functions periodically for signs of hepatotoxicity

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Multiple myeloma (MM)

AND ALL of the following:

1. Used in combination with dexamethasone and **ONE** of the following:
   a. lenalidomide (Revlimid)
   b. pomalidomide (Pomalyst)
2. Prescriber agrees to monitor liver functions periodically for signs of hepatotoxicity
3. **NO** disease progression or unacceptable toxicity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Duration 12 months

Rationale

Summary

Empliciti (elotuzumab) is a monoclonal antibody indicated for the treatment of multiple myeloma (MM). Empliciti has been shown to cause hepatotoxicity and should be stopped if Grade 3 or higher elevation of liver enzymes and therapy continued after return to baseline. Safety and effectiveness of Empliciti have not been established in pediatric patients (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Empliciti while maintaining optimal therapeutic outcomes.

References

1. Empliciti [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; March 2022.
2. NCCN Drugs & Biologics Compendium® Elotuzumab 2024. National Comprehensive Cancer Netowrk, Inc. Accessed on January 31, 2024.

Policy History

Date	Action
December 2015	New Policy
March 2016	Annual review Policy number changed from 5.04.73 to 5.21.73
June 2016	Annual review
September 2016	Annual review
June 2017	Annual editorial review
June 2018	Annual editorial review and reference update
November 2018	Addition of indication of multiple myeloma in combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor
March 2019	Annual review
June 2020	Annual review and reference update
December 2020	Annual review
March 2021	Annual editorial review
March 2022	Annual review and reference update
June 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.21.073
December 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.