POLICY: Oncology (Injectable) – Empliciti Utilization Management Medical Policy

- Empliciti® (elotuzumab intravenous infusion – Bristol-Myers Squibb)

EFFECTIVE DATE: 1/1/2021
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Empliciti, a SLAMF7 (signaling lymphocytic activation molecule family member 7)-directed immunostimulatory antibody, is indicated in **multiple myeloma**, in the following situations:[1]

1. in patients who have received one to three prior therapies, in combination with lenalidomide and dexamethasone.
2. in patients who have received at least two prior therapies (including lenalidomide and a proteasome inhibitor), in combination with Pomalyst® (pomalidomide capsules) and dexamethasone.

Guidelines

The National Comprehensive Cancer Network (NCCN) Multiple Myeloma clinical practice guidelines (version 3.2024 – March 8, 2024) recommend Empliciti in treatment regimens for patients who were previously treated for multiple myeloma.[3] In this population, Empliciti/Pomalyst/dexamethasone is recommended for lenalidomide-refractory patients as a "Preferred" regimen (category 2A). Empliciti/lenalidomide/dexamethasone and Empliciti/bortezomib/dexamethasone are listed under "Other Recommended Regimens" (category 1).

Dosing Information

It is recommended that treatment with Empliciti continue until disease progression or unacceptable toxicity.[1] If the dose of one drug in the regimen is delayed, interrupted, or discontinued, treatment with the other drugs may continue as scheduled. However, if dexamethasone is delayed or discontinued, base the decision whether to administer Empliciti on clinical judgment (i.e., risk of hypersensitivity). Therapy is individualized with careful consideration of the risks and benefits of continued treatment.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Empliciti. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the criteria and dosing. Requests for

doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Empliciti, as well as the monitoring required for adverse events and long-term efficacy, approval requires Empliciti to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Empliciti is recommended in those who meet the following criteria:

FDA-Approved Indication

---

1. Multiple Myeloma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

A) Patient is ≥ 18 years of age; AND

B) Patient has tried at least one other regimen for multiple myeloma; AND
Note: Examples of agents used in other regimens include bortezomib, lenalidomide, cyclophosphamide, Darzalex (daratumumab intravenous infusion).

C) Empliciti is used in combination with at least one other agent; AND
Note: Examples of agents that may be used in combination with Empliciti include lenalidomide, bortezomib, and Pomalyst (pomalidomide capsules).

D) Empliciti is prescribed by or in consultation with an oncologist or a hematologist.

Dosing. Approve ONE of the following regimens (A or B):

A) The dose is 10 mg/kg intravenously administered once weekly for up to nine infusions followed by subsequent 10 mg/kg infusions with doses separated by at least 2 weeks; OR

B) The dose is 10 mg/kg intravenously administered once weekly for up to eight doses followed by subsequent 20 mg/kg infusions with doses separated by at least 4 weeks thereafter.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Empliciti is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Empliciti® [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; March 2022.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 17, 2024. Search term: elotuzumab.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2024 – March 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 17, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	04/12/2023
Annual Revision	No criteria changes	04/24/2024
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024