CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Empliciti Utilization Management Medical Policy
- Empliciti® (elotuzumab intravenous infusion – Bristol-Myers Squibb)

REVIEW DATE: 04/15/2026

OVERVIEW

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

- In combination with lenalidomide and dexamethasone in adults who have received one to three prior therapies.
- In combination with pomalidomide and dexamethasone in adults who have received at least two prior therapies (including lenalidomide and a proteasome inhibitor).

Guidelines

The National Comprehensive Cancer Network (NCCN) Multiple Myeloma clinical practice guidelines (version 5.2026 – January 9, 2026) recommend Empliciti in treatment regimens for patient with relapsed or refractory disease after one to three prior therapies.[3] In this population, Empliciti/pomalidomide/dexamethasone is recommended after two prior therapies including lenalidomide and a proteasome inhibitor for anti-CD-38 refractory, bortezomib-refractory, and lenalidomide-refractory patients as a "Preferred" regimen (category 2A). Empliciti/lenalidomide/dexamethasone (category 1) and Empliciti/bortezomib/dexamethasone (category 2A) are listed under "Other Recommended Regimens".

Dosing Information

When Empliciti is used in combination with lenalidomide and dexamethasone, the dosing is 10 mg/kg administered intravenously every week for the first two cycles and every 2 weeks thereafter until disease progression or unacceptable toxicity.[1] When Empliciti is used in combination with pomalidomide and dexamethasone, the dosing is 10 mg/kg administered intravenously every week for the first two cycles and 20 mg/kg every 4 weeks thereafter until disease progression or unacceptable toxicity. Each cycle is 28-days. 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, the decision to administer Empliciti is based 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 pomalidomide.
   - **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 eight doses 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. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 9, 2026. Search term: elotuzumab.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 5.2026 – January 9, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 9, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	04/24/2024
Annual Revision	No criteria changes.	04/09/2025
Annual Revision	**Multiple myeloma**: The option for approval for dosing was changed from : "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" to "the dose is 10 mg/kg intravenously administered once weekly for up to eight doses followed by subsequent 10 mg/kg infusions with doses separated by at least 2 weeks"	04/15/2026