Reference number(s)
4858-A

Standard Medicare Part B Management Empliciti

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Empliciti	elotuzumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

- 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.
- Empliciti is indicated 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.

Compendial Uses[2]

- Relapsed or progressive multiple myeloma
- Polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes (POEMS) syndrome
- Plasma cell-related monoclonal immunoglobulin deposition disease (MIDD)
- Plasma cell-related monoclonal gammopathy of renal significance (MGRS)

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All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Multiple Myeloma[1-3]

Authorization of 12 months may be granted for the treatment of previously treated multiple myeloma when any of the following criteria are met:

- The requested medication will be used in combination with lenalidomide and dexamethasone
- The requested medication will be used in combination with bortezomib and dexamethasone
- The requested medication will be used in combination with pomalidomide and dexamethasone in members who have received at least two prior therapies, including an immunomodulatory agent and a proteasome inhibitor

POEMS, MIDD, and MGRS[2,3]

Authorization of 12 months may be granted for the treatment of POEMS, plasma-cell related MIDD, or plasma cell-related MGRS when any of the following criteria are met:

- The requested medication will be used in combination with lenalidomide and dexamethasone
- The requested medication will be used in combination with bortezomib and dexamethasone
- The requested medication will be used in combination with pomalidomide and dexamethasone in members who have received at least two prior therapies, including an immunomodulatory agent and a proteasome inhibitor

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Empliciti
- Empliciti is being used to treat an indication in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
- No unacceptable toxicity while on the current regimen, AND
- No evidence of disease progression while on the current regimen

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Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Empliciti.
- The available compendium
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Micromedex DrugDex
- American Hospital Formulary Service- Drug Information (AHFS-DI)
- Lexi-Drugs
- Clinical Pharmacology
- NCCN Guideline: Multiple myeloma

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Empliciti are covered in addition to using Empliciti in combination with bortezomib and dexamethasone.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Empliciti in combination with an angiogenesis inhibitor or bortezomib, and dexamethasone to treat multiple myeloma, POEMS, plasma-cell related MIDD, and plasma-cell related MGRS can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Empliciti [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; March 2022.
2. The NCCN Drugs & Biologics Compendium 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 16, 2025.
3. The NCCN Clinical Practice Guidelines in Oncology Multiple Myeloma (Version 2.2026) 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 16, 2025.

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