Elotuzumab (Empliciti®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

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

- 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

~~Therapy for previously treated multiple myeloma for relapsed or progressive disease in combination with bortezomib and dexamethasone~~

- 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)

All other indications are considered experimental/investigational and not medically necessary.

COVERAGE CRITERIA

Multiple Myeloma

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

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

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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.

EFFECTIVE DATE

ID_CHS_2025