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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 02/13/2025

Empliciti[®] (elotuzumab)

HCPCS: J9176

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. Prescribed by or in consultation with an oncologist or hematologist
 - b. Diagnosis of multiple myeloma
 - c. Used in combination with lenalidomide and dexamethasone after treatment failure with one to three prior lines of therapy; OR
 - d. Used in combination with pomalidomide and dexamethasone after treatment failure with two prior therapies, including lenalidomide and a proteasome inhibitor
 - e. Should not be used if prior treatment failure to Empliciti or another anti-SLAMF7 monoclonal antibody
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
 - c. Renewal Criteria: Treatment may be continued until treatment failure, disease progression or until unacceptable toxicity occurs

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Empliciti is an intravenous monoclonal antibody indicated in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma (MM) who have received one to three prior therapies or in combination with pomalidomide and dexamethasone for the treatment of adult patients with MM who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.
- There are no studies and NCCN guidelines do not support use of Empliciti following failure in a previous line of therapy or after failure of another anti-SLAMF7 monoclonal antibody.

References:

- 1. Empliciti [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2022.
- 2. Lonial S, Dimopoulos M, Palumbo A, et al. Elotuzumab therapy for relapsed or refractory multiple myeloma. NEJM. 2015; 373: 621 31.
- 3. Meletios A, Dimopoulos MD, et al. Elotuzumab plus pomalidomide and dexamethasone for multiple myeloma. NEJM. 2018; 379: 1811 22.
- 4. National Comprehensive Cancer Network. Multiple myeloma (Version 1.2025). 2024 Sept 17. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed on December 10, 2024.

| Policy | History | | | | | | |
|--------|----------------------------|---|------------------|---|--|--|--|
| # | Date | Change Description | | | | | |
| 2.2 | Effective Date: 02/13/2025 | Annual review of criteria was performed, no changes were made | | | | | |
| 2.1 | Effective Date: 02/08/2024 | Annual review of criteria was performed, no changes were made | | | | | |
| 2.0 | Effective Date: 02/02/2023 | Updated approval length to allow for FDA recommended dosing for at least 60 days and up to 6 months at a time | | | | | |
| 1.9 | Effective Date: 02/10/2022 | Annual review of criteria was performed, no changes were made | | | | | |
| 1.8 | Effective Date: 12/01/2021 | UM medical management system update for BCBS | | | | | |
| | | | Line of Business | PA Required in Medical Management System (Yes/No) | | | |
| | | | BCBS | Yes | | | |
| | | | BCN | Yes | | | |
| | | | MAPPO | No | | | |
| | | | BCNA | No | | | |
| 1.7 | Effective Date: 02/04/2021 | Annual review of criteria was performed, no changes were made | | | | | |
| 1.6 | Effective Date: 02/06/2020 | Annual review of criteria was performed, no changes were made | | | | | |
| 1.5 | Effective Date: 02/14/2019 | Updated criteria for additional indication for use with pomalidomide | | | | | |

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| 1.4 | Effective Date: 02/01/2019 | UM medical management system update for MAPPO and BCNA | | | | | |
|-----|-------------------------------|---|------------------|---|--|--|--|
| | | | Line of Business | PA Required in Medical Management System (Yes/No) | | | |
| | | | BCBS | No | | | |
| | | | BCN | Yes | | | |
| | | | MAPPO | Yes | | | |
| | | | BCNA | Yes | | | |
| 1.3 | Effective Date: 11/01/2018 | Updated criteria per oncology vendor | | | | | |
| 1.2 | Effective Date: 08/09/2018 | Annual review of criteria was performed, no changes were made | | | | | |
| 1.1 | Effective Date: 08/10/2017 | Annual review of criteria was performed, no changes were made | | | | | |
| 1.0 | Effective Date: 08/11/2016 | New Policy | | | | | |
| | | | Line of Business | PA Required in Medical Management System (Yes/No) | | | |
| | | | BCBS | No | | | |
| | | | BCN | Yes | | | |
| | | | MAPPO | No | | | |
| | | | BCNA | No | | | |

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <u>http://dailymed.nlm.nih.gov/dailymed/index.cfm</u>.

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