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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.

**Effective Date: 02/08/2024**

### **Empliciti<sup>®</sup> (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.

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

- 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 2.2024). 2023 Nov 1. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/myeloma.pdf](https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf). Accessed on December 27, 2023.

Policy History												
#	Date	Change Description										
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 <table border="1" data-bbox="574 942 1308 1188" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>Yes</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>No</td> </tr> <tr> <td>BCNA</td> <td>No</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
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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										
1.4	Effective Date: 02/01/2019	UM medical management system update for MAPPO and BCNA <table border="1" data-bbox="574 1465 1308 1711" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>No</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>Yes</td> </tr> <tr> <td>BCNA</td> <td>Yes</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	Yes	BCNA	Yes
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1.3	Effective Date: 11/01/2018	Updated criteria per oncology vendor										

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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	<p>New Policy</p> <table border="1"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>No</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>No</td> </tr> <tr> <td>BCNA</td> <td>No</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	No	BCNA	No
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\* 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 <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.