MEDICAL MUTUAL®

Drug Policy

Policy:	**201820**	**Initial Effective Date: 08/19/2018**
Code(s):	**HCPCS J9176**	**Annual Review Date: 12/20/2018**
SUBJECT:	**Empliciti® (elotuzumab)**	**Last Revised Date: 12/20/2018**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

Empliciti is a SLAMF7-directed immunostimulatory antibody indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received one to three prior therapies.

POLICY STATEMENT

This policy involves the use of Empliciti. Prior authorization is recommended for medical benefit coverage of Empliciti. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. The requirement that the patient meet the Criteria for coverage of the requested medication applies to the initial authorization only. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Empliciti as well as the monitoring required for AEs and long-term efficacy, initial approval requires Empliciti be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Empliciti is recommended in those who meet the following criteria:

1. Multiple Myeloma

Criteria. *Patient must meet the following criteria (A, B, C, and D)*

A. Patient is 18 years or older; AND

B. Empliciti is prescribed by an oncologist, hematologist, or provider who specializes in multiple myeloma treatment; AND

C. Patient has diagnosis of relapsed or progressive multiple myeloma; AND
D. The patient must meet ONE of the following criteria (i, ii, or iii):
   i. Empliciti will be used in combination with lenalidomide and dexamethasone after failure of one to three prior regimens; OR
   ii. Empliciti will be used in combination with bortezomib and dexamethasone; OR
   iii. Empliciti will be used in combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies, including an immunomodulatory agent and a proteasome inhibitor

Dosing in Multiple Myeloma. *Dosing must meet the following (A, B or C):*

A. In combination with lenalidomide:
10 mg/kg IV every week (D1, D8, D15, & D22) for the first two 28-day cycles (8 doses); then every 2 weeks thereafter (D1 & D15) beginning with cycle 3
Give in conjunction with lenalidomide (25 mg daily Days 1-21) and low-dose dexamethasone (given weekly: 28 mg when elotuzumab is also given & 40 mg on weeks elotuzumab is not given)

B. In combination with bortezomib:
10 mg/kg IV weekly for cycles 1 and 2, on days 1 and 11 for cycles 3 to 8, and then on days 1 and 15 thereafter
Bortezomib (1.3 mg/m^2 IV or subcutaneously) administered on days 1, 4, 8, and 11 for cycles 1 to 8 and then on days 1, 8, and 15 thereafter
Dexamethasone 20 mg administered orally on non-elotuzumab dosing days, and as 8 mg orally plus 8 mg IV on elotuzumab dosing days

C. In combination with pomalidomide and dexamethasone:
Cycles 1 and 2: 10 mg/kg once weekly on days 1, 8, 15, and 22 of a 28-day treatment cycle (in combination with pomalidomide and dexamethasone)
Cycle 3 and beyond: 20 mg/kg once every 4 weeks on day 1 of a 28-day treatment cycle (in combination with pomalidomide and dexamethasone)

Initial Approval/ Extended Approval.
A) *Initial Approval:6 months*
B) *Extended Approval: 6 months and Patient has experienced beneficial response with stabilization of disease and has an absence of unacceptable toxicity from the drug.*

Duration of Therapy in Multiple Myeloma. Continue until disease progression or unacceptable toxicity.

Labs/Diagnostics. Obtain liver function tests periodically.

Other Uses With Supportive Evidence

2. Patient has been Started on Empliciti. Approve if the patient meets the conditions for coverage required for **Dosing**, **Extended Approval**, **Duration of Therapy**, and **Labs/Diagnostics** for an approved use in this *Empliciti Utilization Review* policy.

3. Other Cancer-Related Indications. Forward to the Medical Director for review on a case-by-case basis. An example of other indications supported in *NCCN Compendium* are given a category 1, 2A, and 2B recommendation.

Waste Management for All Indications.

Empliciti single-use vial; Solution Reconstituted, Intravenous:
Empliciti: 300 mg (1 ea); 400 mg (1 ea) [contains mouse (murine) and/or hamster protein, polysorbate 80]

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Empliciti has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

- Empliciti [package insert]. Princeton, NJ; Bristol-Myers Squibb Company; May 2017.
- The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (Version 2.2019). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 18, 2018.
- Jakubowiak A, Offidani M, Pégourie B, et al. Randomized phase 2 study: elotuzumab plus bortezomib/dexamethasone vs bortezomib/dexamethasone for relapsed/refractory MM. Blood. 2016 Jun 9;127(23):2833-40.
- The NCCN Drugs & Biologics Compendium. © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on December 18, 2018. Search term: Empliciti.
- Empliciti Monograph. Lexicomp® Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised 12/17/2018. Accessed on December 20, 2018.

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FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J9176

HCPCS Code(s):	
J9176	Injection, elotuzumab, 1 mg