Clinical Policy: Elotuzumab (Empliciti)

Reference Number: PA.CP.PHAR.308
Effective Date: 01/18
Last Review Date: 11/17

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness ® clinical policy for elotuzumab (Empliciti™).

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness ® that Empliciti is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all):

1. Diagnosis of multiple myeloma;
2. Member has received ≥ 1 prior therapy;
3. Meets a or b:
   a. FDA approved use:
      i. Empliciti is prescribed in combination with lenalidomide and dexamethasone;
   b. Off-label NCCN recommended use:
      i. Empliciti is prescribed in combination with bortezomib and dexamethasone.

Approval duration: 3 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. Multiple Myeloma (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. No disease progression or unacceptable toxicity.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy**.**

Background
Description/Mechanism of Action:
Elotuzumab is a humanized IgG1 monoclonal antibody that specifically targets the SLAMF7 (Signaling Lymphocytic Activation Molecule Family member 7) protein. SLAMF7 is expressed on myeloma cells independent of cytogenetic abnormalities. SLAMF7 is also expressed on

Natural Killer cells, plasma cells, and at lower levels on specific immune cell subsets of differentiated cells within the hematopoietic lineage. Elotuzumab directly activates Natural Killer cells through both the SLAMF7 pathway and Fc receptors. Elotuzumab also targets SLAMF7 on myeloma cells and facilitates the interaction with Natural Killer cells to mediate the killing of myeloma cells through antibody-dependent cellular cytotoxicity (ADCC). In preclinical models, the combination of elotuzumab and lenalidomide resulted in enhanced activation of Natural Killer cells that was greater than the effects of either agent alone and increased anti-tumor activity in vitro and in vivo.

Formulations:
Empliciti (elotuzumab) is supplied as a lyophilized powder for reconstitution available as follows:

- 300 mg single-dose vial
- 400 mg single-dose vial

FDA Approved Indications:
Emplicity is a SLAMF7-directed immunostimulatory antibody/intravenous formulation indicated

- In combination with lenalidomide and dexamethasone for treatment of patients with multiple myeloma who have received one to three prior therapies.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9176	Injection, elotuzumab, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date

References
1. Empliciti prescribing information. Princeton, NJ: Bristol-Myers Squibb Company; November 2015. Available at http://packageinserts.bms.com/pi/pi_empliciti.pdf. Accessed January 9, 2017.
2. Elotuzumab. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed January 9, 2017.
3. Multiple myeloma (Version 3.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 10, 2017.