SPECIALTY GUIDELINE MANAGEMENT

EMPLICITI (elotuzumab)

POLICY

I. 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.

A. FDA-Approved Indications

- 1. 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.
- 2. 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.

B. Compendial Uses

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

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

II. CRITERIA FOR INITIAL APPROVAL

Multiple Myeloma

Authorization of 12 months may be granted for the treatment of multiple myeloma when all of the following criteria are met:

- A. The disease is relapsed or progressive
- B. The requested medication will be used in any of the following regimens:
 - 1. In combination with lenalidomide and dexamethasone in members who have received one to three prior therapies
 - 2. In combination with bortezomib and dexamethasone in members who have received at least one prior therapy
 - 3. In combination with pomalidomide and dexamethasone in members who have received at least two prior therapies, including an immunomodulatory agent and a proteasome inhibitor

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Empliciti [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; October 2019.

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Reference number(s)

2330-A

- 2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed September 30, 2020.
- 3. The NCCN Clinical Practice Guidelines in Oncology Multiple Myeloma (Version 2.2021) 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed September 30, 2020.

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