VENTURA COUNTY HEALTH CARE PLAN

Utilization Review Policy

POLICY: Oncology – Empliciti® (elotuzumab injection for intravenous use – Bristol-Myers Squibb)

APPROVAL DATE: 02/20/2019

OVERVIEW

Empliciti is a SLAMF7 (signaling lymphocytic activation molecule family member 7)-directed immunostimulatory antibody.[1] It attaches to SLAMF7 on myeloma cells and Natural Killer (NK) cells; therefore, it acts directly on myeloma cells plus enhances the activity of NK cells to kill the myeloma cells. In multiple myeloma, Empliciti is indicated for the following uses:

1. in combination with Revlimid (lenalidomide capsules) and dexamethasone for the treatment of patients with multiple myeloma who have received one to three prior therapies; AND
2. along with Pomalyst® (pomalidomide) and dexamethasone, to treat adults who have multiple myeloma that has relapsed or become resistant after two or more previous treatments with Revlimid and a proteasome inhibitor, such as Velcade® (bortezomib injection) or Kyprolis® (carfilzomib injection).

If the dose of one drug in the regimen is delayed, interrupted, or discontinued, the treatment with the other drugs may continue as scheduled. However, if dexamethasone is delayed or discontinued, base the decision whether to administer Empliciti on clinical judgment (i.e., risk of hypersensitivity).

Guidelines

The NCCN Multiple Myeloma clinical practice guidelines (version 2.2019 – November 16, 2018) recommend Empliciti in treatment regimens for patients who were previously treated for multiple myeloma.[3] In this population, Empliciti/Revlimid (lenalidomide capsules)/dexamethasone is among the Preferred regimens, whereas Empliciti/Velcade (bortezomib injection)/dexamethasone and Empliciti/Pomalyst/dexamethasone are listed as among the other recommended regimens.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Empliciti. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the criteria and dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Because of the of the specialized skills required for evaluation and diagnosis of patients treated with Empliciti, as well as the monitoring required for adverse events and long-term efficacy, approval requires Empliciti to be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Multiple Myeloma**. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** The patient has tried at least one other regimen for multiple myeloma (e.g., regimens containing one or more of the following agents: Velcade [bortezumab injection], Revlimid [lenalidomide capsules], dexamethasone, cyclophosphamide, Darzalex [daratumumab injection]); AND
   - **B)** Empliciti is used in combination with at least one other agent (e.g., dexamethasone, Revlimid® [lenalidomide capsules], Velcade [bortezomib injection]); AND
   - **C)** Empliciti is prescribed by or in consultation with an oncologist or a hematologist.

   Dosing. Approve the following regimens:
   - **A)** The dose is 10 mg/kg intravenously (IV) administered once weekly up to nine infusions followed by a similar IV dose once every 2 weeks thereafter; OR
   - **B)** The dose is 10 mg/kg IV administered once weekly for up to eight doses followed by a 20 mg/kg dose once every 4 weeks thereafter.

   It is recommended that treatment with Empliciti continue until disease progression or unacceptable toxicity. Therapy is individualized with careful consideration of the risks and benefits of continued treatment.

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. Rationale for non-coverage for these specific conditions is provided below. (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.

REFERENCES

1. Empliciti® [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; May 2017.
2. The NCCN Drugs and Biologics Compendium. © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on October 15, 2018. Search term: elotuzumab.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (Version 2.2019 – November 16, 2018). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on February 8, 2019.

HISTORY

Type of Revision	Summary of Changes*	Approval Date
New policy	--	11/14/2018
Early annual revision	**Multiple Myeloma:** When previous therapy is required, reword criterion to require a previous regimen for multiple myeloma (previous worded as previous therapy).	02/20/2019