Elotuzumab (Empliciti®)

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020
Revision Date: n/a
Review Date: 9/21/2020
Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of elotuzumab. Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

Drug Description[1]

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.

FDA Indications[1]

Elotuzumab is FDA indicated for the treatment of multiple myeloma

- Elotuzumab 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.

- Elotuzumab 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.

NCCN Compendium Supported Indications[2]

- Elotuzumab used in combination with bortezomib and dexamethasone after one previous line of therapy

Coverage Determinations[1,2]

Elotuzumab will require prior authorization. This agent is considered medically necessary for the following oncology indications if all criteria below are met:

Multiple Myeloma[1]

- The member has a diagnosis of multiple myeloma **AND**
- The member has experienced a relapse or progressive disease and has received prior therapy **AND**
- Elotuzumab administration will be used in combination with the following regimens:
    - Given in combination with lenalidomide and dexamethasone in members who have received 1 to 3 prior therapies **OR**
    - Given in combination with pomalidomide and dexamethasone in members who have received at least two prior therapies, including an immunomodulatory agent and a protease inhibitor

Recommended dosage:

- In combination with lenalidomide and dexamethasone:
    - Elotuzumab 10 mg/kg intravenously every week for the first two cycles and every 2 weeks thereafter until disease progression or unacceptable toxicity.
- In combination with pomalidomide and dexamethasone:
    - Elotuzumab 10 mg/kg intravenously every week for the first two cycles and 20 mg/kg every 4 weeks thereafter until disease progression or unacceptable toxicity.

Multiple Myeloma[2]

- The member has a diagnosis of multiple myeloma **AND**
- The member has experienced a relapse or progressive disease and has received prior therapy

Recommended dosage:

- In combination with bortezomib and dexamethasone:[5]
    - Elotuzumab 10mg/kg intravenously every week for the first two cycles, then on days 1 and 11 for cycles 3 thru 8 converting to every 2 weeks thereafter. Dosed as in trials.

All indications:

- Elotuzumab will be approved through clinical review for up to a 6-month duration.

Coverage Limitations

Treatment with elotuzumab is not considered medically necessary for members with the following concomitant conditions:

- The member has experienced disease progression on elotuzumab.
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

Contraindications/Warnings/Precautions[1]

- There are no contraindications listed in the US manufacturer's labeling.
- Warnings/precautions:
    - Infusion-Related Reactions
    - Infections
    - Second Primary Malignancies
    - Hepatotoxicity
    - Interference with Determination of Complete Response

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

- Description: inj., elotuzumab 1 mg
    - J9176

Disclaimer

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from Oncology Analytics, Inc.

References

1. Impliciti [package insert]. Bristol-Myers Squibb Company, Princeton, NJ. Available at: https://packageinserts.bms.com/pi/pi_empliciti.pdf

2. Elotuzumab. NCCN Drugs & Biologics Compendium. Available : https://www.nccn.org/professionals/drug_compendium/content/
3. Lonial S, Dimopoulos MA, Palumbo A, et al. Elotuzumab Therapy for Relapsed or Refractory Multiple Myeloma. N Engl J Med 2015 Aug 13;373(7):621-631.
4. Dimopoulos MA, Dytfeld D, Grosicki S, et al. Elotuzumab plus Pomalidomide and Dexamethasone for Multiple Myeloma. N Engl J Med. 2018 Nov8;379(19);1811-1822.
5. Jakubowiak A, Offidani M, Pegourie B, et al. Randomized phase 2 study: elotuzumab plus bortezomib/dexamethasone vs bortezomib/dexamethasone for relapsed/refractory MM. Blood. 2016 Jun 9;127(23):2833-2840.