

Corporate Medical Policy

Elotuzumab (Empliciti[®])

File Name:	elotuzumab_empliciti
Origination:	2/2016
Last CAP Review:	4/2020
Next CAP Review:	4/2021
Last Review:	4/2020

Description of Procedure or Service

Elotuzumab (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, and in combination with pomalidomide and dexamethasone for multiple myeloma in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

Elotuzumab (Empliciti) activates the body's immune system to attack and kill multiple myeloma cells. It is approved in combination with another FDA-approved treatment for multiple myeloma called Revlimid (lenalidomide) and dexamethasone (a type of corticosteroid).

Multiple myeloma is a form of blood cancer that occurs in infection-fighting plasma cells (a type of white blood cell) found in the bone marrow. These cancerous cells multiply, produce an abnormal protein and push out other healthy blood cells from the bone marrow. This disease may result in a weakened immune system, and cause other bone and kidney problems.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Elotuzumab (Empliciti) when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Elotuzumab (Empliciti) is covered

Elotuzumab (Empliciti) is considered medically necessary for the treatment of multiple myeloma in patients (18 years of age or older) who have received:

- At least one prior therapy for multiple myeloma, **AND** will receive elotuzumab in combination with lenalidomide and dexamethasone; **OR**
- At least two prior therapies for multiple myeloma including lenalidomide and a proteasome inhibitor, **AND** will receive elotuzumab in combination with pomalidomide and dexamethasone.

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Use of Elotuzumab (Empliciti) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either:

- In accordance with FDA label (when clinical benefit has been established, see Policy Guidelines); **OR**
- In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached.

When Elotuzumab (Empliciti) is not covered

Elotuzumab (Empliciti) is considered not medically necessary and therefore not covered when above criteria are not met.

Elotuzumab (Empliciti) is considered investigational when used for:

1. Non-cancer indications; **OR**
2. When criteria are not met regarding FDA labeling **OR** strong endorsement/support by nationally recognized compendia, as stated under “When Elotuzumab (Empliciti) is covered.”

Policy Guidelines

Initial approval is for 6 months.

Continued therapy with Elotuzumab (Empliciti) will be reviewed every 12 months and based on treatment response and toxicity.

Recommended dosage with lenalidomide and dexamethasone is 10 mg/kg administered intravenously every week for the first two cycles (28-day cycle) and every 2 weeks thereafter until disease progression or unacceptable toxicity.

Recommended dosage with pomalidomide and dexamethasone is 10 mg/kg administered intravenously every week for the first two cycles (28-day cycle). Beginning at cycle 3, the recommended dosage is 20 mg/kg intravenously every 4 weeks until disease progression or unacceptable toxicity

Pre-medicate with dexamethasone, diphenhydramine, ranitidine and acetaminophen. Stop therapy for Grade 2 or higher infusion reactions and permanently discontinue for severe infusion reactions.

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), “Investigational (Experimental) Services.”

Please refer to CMP “Investigational (Experimental) Services” for a summary of evidence standards from nationally recognized compendia.

Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: J9176, S0353, S0354

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

US Food and Drug Administration (FDA). Center for Biologics Evaluation and Research.

Available at:

<http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm474684.htm>

Accessed February 4, 2016.

US Food and Drug Administration (FDA). Center for Biologics Evaluation and Research.

Available at:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/761035s000lbl.pdf

Accessed February 4, 2016.

Senior Medical Director review 2/2016

Specialty Matched Consultant Advisory Panel review-4/2016

Medical Director review 9/2016

Medical Director review 3/2017

Specialty Matched Consultant Advisory Panel 4/2017

Specialty Matched Consultant Advisory Panel 4/2018

Medical Director review 6/2018

Bristol-Myers Squibb Company. Empliciti (elotuzumab) injection for intravenous use. Highlights of prescribing information. November 2018. Available at:

https://packageinserts.bms.com/pi/pi_empliciti.pdf. Accessed April 2019.

Specialty Matched Consultant Advisory Panel 4/2019

Bristol-Myers Squibb Company. Empliciti (elotuzumab) injection for intravenous use. Highlights of prescribing information. October 2019. Available at:

https://packageinserts.bms.com/pi/pi_empliciti.pdf. Last accessed March 2020.

Specialty Matched Consultant Advisory Panel 4/2020

Policy Implementation/Update Information

2/29/16 New policy issued. Elotuzumab (Empliciti) is considered medically necessary in patients who are 18 years of age or older; and who have received at least one prior therapy for multiple myeloma; and who will receive elotuzumab in combination with lenalidomide and

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- dexamethasone . Notification given 2/29/2016 for effective date 4/29/2016. Senior medical director review 2/2016. (lpr)
- 7/1/16 Specialty Matched Consultant Advisory Panel Review meeting 4/27/16. No change to policy statement. Added HCPCS code C9477 to “Billing/Coding” section for effective date 7/1/16. (lpr)
- 12/30/16 Medical Director review 9/2016. No change to policy statement. Deleted HCPCS codes C9477, C9399, J3490, J3590, J9999 and added HCPCS codes J9176, S0353, S0354 to Billing/Coding section. Notification given 12/30/16 for effective date 4/1/17. (lpr)
- 5/26/17 Added the following statement to “When Covered” section: “Use of Elotuzumab (Empliciti) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either: In accordance with FDA label (when clinical benefit has been established, see Policy Guidelines); OR In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached”. Under “When Not Covered” section, added the statement “Elotuzumab (Empliciti) is considered investigational when used for: 1)Non-cancer indications; **OR** 2) When criteria are not met regarding FDA labeling **OR** strong endorsement/ support by nationally recognized compendia, as stated under “When Elotuzumab (Empliciti) is covered.” Added the following statements under “Policy Guidelines” section: 1)Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy, Investigational (Experimental) Services.” 2) Please refer to CMP “Investigational (Experimental) Services” for a summary of evidence standards from nationally recognized compendia. Medical director review 3/2017. Specialty Matched Consultant Advisory Panel review 4/26/2017. No change to policy statement. (lpr)
- 6/29/18 Specialty Matched Consultant Advisory Panel review 4/25/2018. No change to policy intent. Medical Director review 6/2018. (krc)
- 4/30/19 Added the following indication to “When Covered” section: “At least two prior therapies for multiple myeloma including lenalidomide and a proteasome inhibitor, **AND** will receive elotuzumab in combination with pomalidomide and dexamethasone.” Updated “Description” and “Policy Guidelines” sections to reflect newly added indication. Reformatted “When Covered” section for clarity. References added. Specialty Matched Consultant Advisory Panel review 4/17/2019. (krc)
- 6/9/20 Reference added. Specialty Matched Consultant Advisory Panel review 4/15/2020. No change to policy statements. (krc)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.