

Medical Drug Clinical Criteria

Subject:	Empliciti (elotuzumab)		
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Overview

This document addresses the use of Empliciti (elotuzumab). Empliciti is a humanized IgG1 monoclonal antibody that targets the signaling lymphocytic active molecule (SLAM) family member F7 (SLAMF7) protein expressed on myeloma and natural killer cells. Empliciti activates natural killer cells mediating the killing of myeloma cells through antibody-dependent cellular cytotoxicity. Empliciti is used to treat multiple myeloma.

The FDA-approved indications for Empliciti include use in combination with lenalidomide and dexamethasone for the treatment of multiple myeloma in individuals who have received one to three prior therapies. It is also FDA-approved in combination with pomalidomide and dexamethasone, in individuals who have received at least two prior therapies including lenalidomide and a proteasome inhibitor. The supportive clinical trials for these two indications included patients with relapsed, refractory, or progressive disease. The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for use in combination with bortezomib and dexamethasone for previously treated myeloma for relapsed or progressive disease.

Definitions and Measures

Multiple myeloma: A type of cancer that begins in plasma cells (white blood cells that produce antibodies).

Plasma cell leukemia: A rare and aggressive form of multiple myeloma characterized by high levels of plasma cells in the peripheral blood.

Progressive disease: For cancer, disease that is growing (e.g. growth in size of tumor), spreading, or worsening.

Proteasome inhibitors: A class of drugs used to treat multiple myeloma that work by blocking the action of proteasomes which are cellular complexes that break down proteins. Examples include bortezomib, carfilzomib and ixazomib.

Refractory disease: Illness or disease that does not respond to treatment.

Relapse: After a period of improvement, the return of signs and symptoms of cancer.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Empliciti (elotuzumab)

Requests for Empliciti (elotuzumab) may be approved if the following criteria are met:

- I. Individual has a diagnosis of relapsed, progressive, or refractory multiple myeloma, including plasma-cell leukemia; **AND**
- II. Disease is relapsed, progressive, or refractory following at least one prior therapy; **AND**
- III. Individual is using in combination with one of the following:
 - A. Lenalidomide and dexamethasone; **OR**
 - B. Bortezomib and dexamethasone (NCCN 2A); **OR**
 - C. Pomalidomide and dexamethasone (in individuals who have received at least two prior therapies including lenalidomide and a proteasome inhibitor).

Requests for Empliciti (elotuzumab) may not be approved when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9176 Injection, elotuzumab, 1 mg [Empliciti]

ICD-10 Diagnosis

C90.00-C90.32 Multiple myeloma and malignant plasma cell neoplasms

Z85.79 Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Document History

Reviewed: 11/15/2024

Document History:

- 11/15/2024 – Annual Review: No changes. Coding Reviewed: No changes.
- 02/23/2024 – Annual Review: Clarify line of therapy to require at least one prior treatment per label/NCCN. Coding Reviewed: No changes.
- 02/24/2023 – Annual Review: Remove requirement for no prior elotuzumab therapy. Coding Reviewed: No changes.
- 02/25/2022 – Annual Review: Wording and formatting changes. Coding Reviewed: No changes.
- 02/19/2021 – Annual Review: No changes. Coding Reviewed: No changes.
- 02/21/2020 – Annual Review: No changes. Coding Review: No changes.
- 05/17/2019 – Annual Review: First review of Empliciti clinical criteria. Minor wording and formatting updates. Add reference for off label criteria. Coding reviewed: No changes.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 11, 2024.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 11, 2024.
 - a. Multiple Myeloma. V4.2024. Revised April 26, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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