

Medical Drug Clinical Criteria

Subject: Lunsumio (mosunetuzumab-axgb)

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Overview

This document addresses the use of Lunsumio (mosunetu~~m~~umab-axgb). Lunsumio is a T-cell engaging bispecific antibody which binds to CD3 receptors on T-cells and CD20 receptors on B-cells. This activates the T-cells to release proinflammatory cytokines, inducing cell death of cancerous lymphoma cells. It is used as a single agent to treat relapsed or refractory follicular lymphoma.

Lunsumio is indicated to treat adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. The National Comprehensive Cancer Network® (NCCN) guidelines for B-Cell Lymphomas provide suggested treatment regimens as third-line and subsequent therapy for follicular lymphoma, but they have not been updated to include a recommendation for the use of Lunsumio to date.

Lunsumio has a black box warning for cytokine release syndrome (CRS). CRS, including serious or life-threatening reactions, can occur. Lunsumio should be initiated using step-up dosing schedule to reduce the incidence of CRS. The drug should be withheld or discontinued permanently based on severity of CRS.

Definitions and Measures

Complete Response or Complete Remission (CR): The disappearance of all signs of cancer as a result of treatment; also called complete remission; does not indicate the cancer has been cured.

Disease Progression: Cancer that continues to grow or spread.

Follicular Lymphoma: A type of B-cell non-Hodgkin lymphoma, a cancer of the immune system that is usually indolent (slow-growing). The tumor cells grow as groups to form nodules. There are several subtypes of follicular lymphoma.

Partial response (PR): A decrease in the size of a tumor, or in the amount of cancer in the body, resulting from treatment; also called partial remission.

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

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

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.

Lunsumio (mosunetuzumab-axgb)

Requests for Lunsumio (mosunetuzumab-axgb) may be approved if the following criteria are met:

- I. Individual has a diagnosis of relapsed, ~~or~~ refractory, or progressive follicular lymphoma; **AND**
- II. Individual has received two or more lines of systemic therapy; **AND**

III. Individual is using Lunsumio as a single agent.

Requests for Lunsumio (mosunetuzumab-axgb) 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

J9350 Injection, mosunetuzumab-axgb, 1 mg [Lunsumio]

ICD-10 Diagnosis

C82.00-C82.99 Follicular lymphoma

Document History

Revised: 02/23/2024

Document History:

- 02/23/2024 – Annual Review: Include progressive disease per NCCN. Coding Reviewed: No changes.
- 02/24/2023 – Annual Review: Create new clinical criteria document for Lunsumio. Coding Reviewed: Added HCPCS J3490, J3590, J9999, C9399. All diagnoses pend. Effective 7/1/2023 Added HCPCS J9350. Deleted J3490, J3590, C9399. Added ICD-10-CM C82.00-C82.99.

References

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3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; 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 January 8, 2024.
 - a. B-Cell Lymphomas. V6.2023. Revised October 10, 2023.

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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