Medical Drug Clinical Criteria

Subject:	Lunsumio (mosunetuzumab-axgb)		
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Overview

This document addresses the use of Lunsumio (mosunetuumab-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 which include Lunsumio as a single agent.

NCCN also provides 2A recommendation for use in Diffuse Large B-Cell Lymphoma, High Grade B-Cell Lymphoma, HIV Related B-Cell Lymphomas and Post-Transplant Lymphoproliferative Disorders. The use of Lunsumio in combination with Polivy (polatuzumab vedotin-piiq) in diffuse large b-cell lymphoma and high-grade b-cell lymphoma is supported by the ongoing phase 1b/2 dose expansion study in which 120 individuals with large b-cell lymphoma had an overall response rate of 59%. Progression free and overall survivals were 11.4 and 23.3 months, respectively. An update to the NCCN guidelines for B-Cell Lymphomas is in progress and the recommendations for HIV-related B-cell lymphomas and post-transplant lymphoproliferative disorders have not been referenced.

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 or 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, 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;

OR

IV. Individual has a diagnosis of one of the following B-cell lymphomas (NCCN 2A);
  A. Relapsed or refractory Diffuse Large B-Cell Lymphoma; **OR**
  B. Relapsed or refractory High Grade B-Cell Lymphoma;

AND

V. Individual is not a candidate for CAR-T therapy; **AND**
VI. Individual is not a candidate for transplant; **AND**
VII. Individual is using as second-line and subsequent therapy; **AND**
VIII. Using in combination with polatuzumab-vedotin-piiq (Polivy).

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
C83.30-C83.38	Diffuse large B-cell lymphoma
C83.398	Diffuse large B-cell lymphoma of other extranodal and solid organ sites
C85.10-C85.19	Unspecified B-cell lymphoma

Document History

Revised: 02/21/2025
Document History:

- 02/21/2025 – Annual Review: Add NCCN 2A recommendations for use in Diffuse Large B-Cell Lymphoma and High Grade B-Cell Lymphoma. Coding Reviewed: Added ICD-10-CM C83.30-C83.38, C83.398, C85.10-C85.19
- 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

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 8, 2025.

a. B-Cell Lymphomas. V1.2025. Revised December 20, 2024.

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