Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Mosunetuzumab-axgb (Lunsumio®)	MP-RX-FP-55-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of Mosunetuzumab-axgb (Lunsumio®), a bispecific CD20-directed CD3 T-cell engager approved by the Food and Drug Administration (FDA) for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

Background Information

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 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.

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- 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.

Approved Indications

Lunsumio is approved by the Food and Drug Administration (FDA) for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. It was approved under an accelerated pathway, therefore, continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory tria

Other Uses

None

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

ICD-10	Description
C82.00-C82.99	Follicular lymphoma

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Medical Necessity Guidelines

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.

Mosunetuzumab-axgb (Lunsumio®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual has a diagnosis of relapsed or refractory follicular lymphoma; **AND**
ii. Individual has received two or more lines of systemic therapy; **AND**
iii. Individual is using Lunsumio as a single agent.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Mosunetuzumab-axgb (Lunsumio®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. The following information should be submitted for reauthorization:
    A. A current oncology note documenting the patient's response to treatment showing no progression of disease.
    B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

i. Initial Approval Duration: Up to 6 months
ii. Reauthorization Approval Duration: Up to 6 months

D. **Conditions Not Covered**

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Requests for Lunsumio (mosunetuzumab-axgb) may not be approved when the above criteria are not met and for all other indications.

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Limits or Restrictions

A. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosing Schedule
Mosunetuzumab-axgb (Lunsumio®)	Cycle 1 (21-day treatment cycle): • Day 1: 1 mg • Day 8: 2 mg • Day 15: 60 mg Cycle 2 (21-day treatment cycle): • Day 1: 60 mg Cycles 3 onward (21-day treatment cycle): • Day 1: 30 mg
Exceptions	
• Adjust the dose following a dose delay. Please refer to the product Package Insert for recommendations.	

Reference Information

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 18, 2022.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 18, 2023.
    a. B-Cell Lymphomas. V5.2022. Revised July 12, 2022.

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.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023
Select Review	Update statement for criteria for initial approval: Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met all approval criteria.	3/25/2024	5/9/2024

Revised: 11/19/2023