Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Mosunetuzumab-axgb (Lunsumio®, Lunsumio Velo)	**MP-RX-FP-55-23**	☒ **MMM MA** ☒ **MMM MultiHealth**	11/30/2023 **Last Review Date:** 03/24/2026	03/24/2026 **Frequently Revision:** Annual

Service Category:

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

Service Description:

This document addresses the use of ***Mosunetuzumab-axgb (Lunsumio®, Lunsumio Velo™),*** 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 and Lunsumio VELO (mosunetuzumab-axgb) are T-cell engaging bispecific antibodies that bind to CD3 receptors on T-cells and CD20 receptors on B-cells, resulting in T-cell activation and cytokine release leading to targeted cytotoxicity of malignant B cells. Lunsumio is an intravenous (IV) formulation and Lunsumio VELO is a subcutaneous (SC) formulation of mosunetuzumab-axgb. These formulations have different dosing schedules and are not interchangeable.

Lunsumio and Lunsumio Velo are 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 mosunetuzumab-axgb 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.

Lunsumio and Lunsumio Velo have a black box warning for cytokine release syndrome (CRS). CRS, including serious or life- threatening reactions, can occur. A step-up dosing schedule is used per Prescribing Information 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.

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- 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.
- Step-up dosing: A dosing approach in which the medication is administered using lower initial doses followed by planned dose increases (e.g., over the first cycle) to reduce the risk and severity of adverse reactions such as cytokine release syndrome (CRS).

Approved Indications

A. 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 trial.

Other Uses

i. None

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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®, Lunsumio Velo™)

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.)*

Requests for initiation of therapy with mosunetuzumab-axgb (Lunsumio® IV or Lunsumio VELO™ SC) 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 mosunetuzumab-axgb 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; **OR**
   C. Relapsed or refractory HIV-Related B-Cell Lymphomas; **OR**
   D. Relapsed or refractory Post-Transplant Lymphoproliferative Disorders; **AND**
v. Individual is using as second-line and subsequent therapy; **AND**
vi. Using in combination with polatuzumab-vedotin-piiq (Polivy).

* Lunsumio (IV) and Lunsumio VELO (SC) have different dosing/administration instructions and should be administered per the applicable PI for the formulation ordered.

B. Criteria For Continuation of Therapy

Requests for continued use of mosunetuzumab-axgb (Lunsumio® IV or Lunsumio VELO™ SC) may be approved if the following criteria are met:

i. MMM considers continuation of Mosunetuzumab-axgb (Lunsumio®/Lunsumio VELO™) 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.

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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 mosunetuzumab-axgb (Lunsumio® IV or Lunsumio VELO™ SC) may not be approved when the above criteria are not met and for all other indications.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. 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®) for intravenous infusion – 1 mg/ml SDV – 30 mg/30 ml SDV	• Cycle 1 (21-day treatment cycle): – Day 1: 1 mg IV – Day 8: 2 mg IV – Day 15: 60 mg IV • Cycle 2 (21-day treatment cycle): – Day 1: 60 mg IV • Cycles 3 onward (21-day treatment cycle): – Day 1: 30 mg IV
Mosunetuzumab-axgb (Lunsumiob Velo™) for subcutaneous inj. – 5 mg/0.5 ml SDV – 45 mg/ml SDV	• Cycle 1 (21-day treatment cycle): – Day 1: 5 mg SC – Day 8: 45 mg SC – Day 15: 45 mg SC • Cycle 2 onward (21-day treatment cycle): – Day 1: 45 mg SC
Exceptions	
• Adjust the dose following a dose delay. Please refer to the product Package Insert for recommendations. • Lunsumio VELO and Lunsumio are different formulations with different dosing schedules. Requests must specify the formulation being requested (IV vs SC), and dosing should follow the applicable Prescribing Information. • IV: premedication Cycle 1 and Cycle 2 for all patients • VELO: premedication Cycle 1 for all patients; Cycles 2+ only for patients who had CRS with the previous dose	

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Codes Information:

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.

ICD-10 Diagnostic Codes:

Codes	Description
B20	Human immunodeficiency virus [HIV] disease [HIV-related B-cell lymphomas]
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
C83.80-C83.89	Other non-follicular lymphoma
C85.10-C85.19	Unspecified B-cell lymphoma
C85.20-C85.29	Mediastinal (thymic) large B-cell lymphoma
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)

HCPCS Codes:

Codes	Description
J9350	Injection, mosunetuzumab-axgb, 1 mg [Lunsumio®, Lunsumio Velo™]

CPT Codes:

Codes	Description
96401	Chemotherapy administration, subcutaneous or intramuscular; non-terminal anti-neoplastic [Lunsumio Velo]
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug [Lunsumio]
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure) [Lunsumio]

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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.; 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 18, 2023.
    a. B-Cell Lymphomas. V2.2025. Revised February 10, 2024.
5. Genentech, Inc. (n.d.). *Lunsumio (mosunetuzumab-axgb) prescribing information.* Accessed February 10, 2026. https://www.gene.com/download/pdf/lunsumio_prescribing.pdf
6. Genentech, Inc. (n.d.). *Lunsumio VELO (mosunetuzumab-axgb) prescribing information.* Accessed February 10, 2026. https://www.gene.com/download/pdf/lunsumio_velo_prescribing.pdf
7. Genentech, Inc. (n.d.). *Lunsumio billing and coding for third-line follicular lymphoma.* Accessed February 10, 2026. https://www.genentech-access.com/content/dam/gene/accesssolutions/pdfs/coding/LUNSUMIO-Billing-Coding-for-Third-line-Follicular-Lymphoma.pdf
8. Genentech, Inc. (n.d.). *Lunsumio VELO billing and coding for follicular lymphoma.* Accessed February 10, 2026. https://www.genentech-access.com/content/dam/gene/accesssolutions/pdfs/coding/lunsumio-velo-billing-coding-for-follicular-lymphoma.pdf

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:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Focus Review	Updated the Medical Policy to include Lunsumio VELO as a new formulation of mosunetuzumab-axgb, clarified the distinction between the IV (Lunsumio) and SC (Lunsumio VELO) products (including non-interchangeability and formulation-specific dosing schedules), and updated the dosing table to reflect the recommended regimens for both formulations. Added "step-up dosing" to the Definitions and Measures section to support CRS-related policy language. Updated coding/billing references and revised the reference list and template formatting as an administrative update.	3/17/2026	03/24/2026
Annual Review	Add NCCN 2A recommendations for use in R/R HIV Related B-Cell lymphomas and Post-transplant Lymphoproliferative disorders. Removed criteria requirements for CAR-T and transplant non-candidates. 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, B20, C83.80-C83.89, C85.20-C85.29, D47.Z1.	10/31/2025	11/10/2025
Annual Review	Include progressive disease per NCCN. Minor wording and formatting updates. Coding Reviewed: No changes.	2/24/2025	3/6/2025
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
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023