BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.21.200

Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Antineoplastic Agents	**Original Policy Date:**	January 20, 2023
Subject:	Lunsumio	**Page:**	1 of 4

Last Review Date: March 6, 2026

Lunsumio

Description

Lunsumio (mosunetuzumab-axgb)

Lunsumio Velo (mosunetuzumab-axgb)

Background
Lunsumio and Lunsumio Velo are T-cell engaging bispecific antibodies that bind to the CD3 receptor expressed on the surface of T-cells and CD20 expressed on the surface of lymphoma cells and some healthy B-lineage cells. In vitro, Lunsumio and Lunsumio Velo activated T-cells, caused the release of proinflammatory cytokines, and induced lysis of B-cells (1-2).

Regulatory Status
FDA-approved indication: Lunsumio and Lunsumio Velo are bispecific CD20-directed CD3 T-cell engagers indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy (1-2).

Lunsumio and Lunsumio Velo carry a boxed warning regarding cytokine release syndrome (CRS). Treatment should be initiated with a step-up dosing schedule to reduce the risk of CRS. Lunsumio or Lunsumio Velo should be withheld until CRS resolves or permanently discontinue based on severity (1-2).

Lunsumio and Lunsumio Velo can cause serious side effects, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), serious or fatal infections, hemophagocytic lymphohistiocytosis (HLH), cytopenias, and tumor flare reactions. Patients should be monitored for signs and symptoms of neurologic toxicity and HLH during treatment. Infections, including

opportunistic infections should be monitored and treated as needed. A complete blood cell count should be evaluated throughout treatment. Prophylactic granulocyte colony-stimulating factor should be administrated as needed. Patients with bulky tumors or disease located in close proximity to airways or a vital organ should be monitored closely during initial therapy (1-2).

Lunsumio and Lunsumio Velo may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment and for 3 months after the last dose (1-2).

The safety and effectiveness of Lunsumio and Lunsumio Velo in patients less than 18 years of age have not been established (1-2).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lunsumio and Lunsumio Velo may be considered **medically necessary** if the conditions indicated below are met.

Lunsumio and Lunsumio Velo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory follicular lymphoma

AND ALL of the following:

1. Patient has received two or more prior systemic therapies
2. Prescriber agrees to monitor for signs and symptoms of cytokine release syndrome (CRS)

3. Prescriber agrees to discontinue treatment after 8 cycles if patient achieves a complete response to therapy
4. Females of reproductive potential **only**: patient will be advised to use effective contraception during therapy and for 3 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory follicular lymphoma

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicity
2. Requests for > 8 cycles of treatment **ONLY**:
    a. Patient has achieved a partial response **OR** has stable disease in response to treatment
    b. Prescriber agrees patient will receive no more than an additional 9 cycles of treatment (17 cycles of treatment total)
3. Prescriber agrees to monitor for signs and symptoms of cytokine release syndrome (CRS)
4. Females of reproductive potential **only**: patient will be advised to use effective contraception during therapy and for 3 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Lunsumio and Lunsumio Velo are indicated for the treatment of relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. Lunsumio and Lunsumio Velo carry a boxed warning regarding cytokine release syndrome (CRS). Lunsumio and Lunsumio Velo can cause severe reactions including neurologic toxicity, hemophagocytic lymphohistiocytosis, cytopenias, and tumor flare. Lunsumio and Lunsumio Velo can also cause serious or fatal infections and should be treated as needed. Female patients of reproductive potential should be advised to use effective contraception during therapy and 3 months after the last dose of treatment. The safety and efficacy of Lunsumio and Lunsumio Velo in patients less than 18 years of age have not been established (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Lunsumio and Lunsumio Velo while maintaining optimal therapeutic outcomes.

References

1. Lunsumio [package insert]. South San Francisco, CA: Genentech, Inc.; December 2025.
2. Lunsumio Velo [package insert]. South San Francisco, CA: Genentech, Inc.; December 2025.
3. NCCN Drugs & Biologics Compendium® Mosunetuzumab-axgb 2026. National Comprehensive Cancer Network, Inc. Accessed on January 29, 2026.

Policy History

Date	Action
January 2023	Addition to PA
March 2023	Annual review and reference update
June 2023	Annual review and reference update
March 2024	Annual review and reference update
March 2025	Annual editorial review and reference update
February 2026	Added Lunsumio Velo to policy
March 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.