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, 2025 |
| **Subsection:** | Antineoplastic Agents | **Original Policy Date:** | January 20, 2023 |
| **Subject:** | Lunsumio | **Page:** | 1 of 4 |

***Last Review Date:*** March 7, 2025

# Lunsumio

## Description

## Lunsumio (mosunetuzumab-axgb)

**Background**
Lunsumio (mosunetuzumab-axgb) is a T-cell engaging bispecific antibody that binds 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 activated T-cells, caused the release of proinflammatory cytokines, and induced lysis of B-cells (1).

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

Lunsumio carries 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 should be withheld until CRS resolves or permanently discontinue based on severity (1).

Lunsumio can cause serious side effects, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), serious or fatal infections, hemophagocytric 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).

Lunsumio 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).

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

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

Lunsumio 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 to Lunsumio **OR** has stable disease in response to Lunsumio 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 (mosunetuzumab-axgb) is indicated for the treatment of relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. Lunsumio carries a boxed warning regarding cytokine release syndrome (CRS). Lunsumio can cause severe reactions including neurologic toxicity, hemophagocytic lymphohistiocytosis, cytopenias, and tumor flare. Lunsumio 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 in patients less than 18 years of age have not been established (1).

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

**References**

1. Lunsumio [package insert]. South San Francisco, CA: Genentech, Inc.; November 2024.
2. NCCN Drugs & Biologics Compendium® Mosunetuzumab-axgb 2025. National Comprehensive Cancer Network, Inc. Accessed on January 15, 2025.

## 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 |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.**