

5.21.200

Section:	Prescription Drugs	Effective Date:	April 1, 2024
Subsection:	Antineoplastic Agents	Original Policy Date:	January 20, 2023
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Last Review Date: March 8, 2024

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 discontinued based on severity (1).

Lunsumio can cause serious side effects, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), serious or fatal infections, cytopenias, and tumor flare reactions. Patients should be monitored for signs and symptoms of neurologic toxicity 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 administered as needed. Patients with bulky

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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

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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

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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, 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.; December 2022.
2. NCCN Drugs & Biologics Compendium[®] Mosunetuzumab-axgb 2024. National Comprehensive Cancer Network, Inc. Accessed on January 19, 2024.

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

Keywords

This policy was approved by the FEP[®] Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.