# Lunsumio (mosunetuzumab-axgb)
## PAM – 073

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| **Iowa Medicaid Program** | Prior Authorization | **Effective Date** | 07/01/2023 |
| **Revision Number** | 2 | **Last Reviewed** | 04/18/2025 |
| **Reviewed By** | Medicaid Medical Director | **Next Review** | 04/17/2026 |
| **Approved By** | Medicaid Clinical Advisory Committee | **Approved Date** | 04/19/2024 |

## Overview

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|---|---|
| Medication: [1] | mosunetuzumab-axgb |
| Brand Name: | Lunsumio® |
| Pharmacologic Category: | bispecific CD20-directed CD3 T-cell engager |
| FDA-Approved Indication(s): | Treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.<br>▶ Accelerated Approval: 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(s). |
| How Supplied: | Single-dose vial containing 1 mg/mL or 30 mg/30 mL |
| Dosage and Administration: | See table below |
| Benefit Category: | Medical |

| Recommended Dose and Schedule (21-Day Treatment Cycles) | | | |
|---|---|---|---|
| Day of Treatment | | Dose | Rate of Intravenous Infusion |
| Cycle 1 | Day 1 | 1 mg | Administer over a minimum of 4 hours |
| | Day 8 | 2 mg | |
| | Day 15 | 60 mg | |
| Cycle 2 | Day 1 | 60 mg | Administer over 2 hours if infusions from Cycle 1 were well-tolerated |
| Cycles 3+ | Day 1 | 30 mg | |

- Should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as cytokine release syndrome and neurologic toxicity.
- Administer for 8 cycles, unless patient experiences unacceptable toxicity or disease progression.
  - For patients who achieve a complete response, no further treatment beyond 8 cycles is required.
  - For patients who achieve a partial response or have stable disease in response to treatment with Lunsumio® after 8 cycles, an additional 9 cycles of treatment (17 cycles total) should be administered, unless a patient experiences unacceptable toxicity or disease progression.

**BOXED WARNING: CYTOKINE RELEASE SYNDROME**

Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving Lunsumio®. Initiate treatment with the Lunsumio® step-up dosing schedule to reduce the risk of CRS. Withhold Lunsumio® until CRS resolves or permanently discontinue based on severity.

## Descriptive Narrative

Follicular lymphoma (FL) is the second most common subtype of non-Hodgkin's lymphoma (NHL) and is the most common of the clinically indolent NHLs (defined as those lymphomas in which survival of the untreated patient is measured in years). The vast majority of patients treated for FL will have an initial response to therapy, with 40 to 80 percent demonstrating a complete response, depending on the initial regimen used. However, conventional therapy for FL is not curative and most of these patients will ultimately develop progressive disease. In addition, less than 10 percent of patients treated with initial chemoimmunotherapy will have refractory disease.[2]

In the United States as a whole, the estimated incidence of FL is 3.18 cases per 100,000 people. The incidence is stable over time but varies with the incidence in White populations being more than twice that in African and Asian populations. The incidence increases with age; FL most frequently presents in middle-aged individuals and the elderly; the median age at diagnosis is 65 years. Rarely, FL arises in children or adolescents.[3]

## Guidelines

The National Comprehensive Cancer Network (NCCN) publishes guidelines for the prevention, diagnosis, and management of malignancies across the continuum of care. The NCCN Guidelines® are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States. The guidelines are developed and updated by 61 individual panels, comprising over 1,700 clinicians and oncology researchers from the 33 NCCN Member Institutions.

Guidelines are reviewed and updated on a continual basis to ensure that the recommendations take into account the most current evidence. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.[4,5]

The information referenced at the time of this policy writing/revision is from the NCCN Guidelines® for (note version number and effective date):[6]

- B-Cell Lymphomas (v.2.2025 – February 10, 2025)

| **NCCN Guidelines® Recommendation(s)** |
|---|
| (1) Classic follicular lymphoma, third-line and subsequent therapy<br>A. Mosunetuzumab-axgb: Category 2A, Preferred Regimen<br>(2) Diffuse large B-cell lymphoma, second-line therapy (relapsed disease < 12 months or primary refractory disease)<br>A. Non-Candidates for CAR T-Cell Therapy<br>i. Polatuzumab vedotin-piiq + mosunetuzumab-axgb: Category 2A, Preferred Regimen<br>(3) Diffuse large B-cell lymphoma, second-line therapy (relapsed disease > 12 months)<br>A. No intention to proceed to transplant<br>i. Polatuzumab vedotin-piiq + mosunetuzumab-axgb: Category 2A, Preferred Regimen |

| **NCCN Categories of Evidence and Consensus** (all recommendations are category 2A unless otherwise indicated) | |
|---|---|
| Category 1 | Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate. |
| Category 2A | Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate. |
| Category 2B | Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate. |
| Category 3 | Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate. |

| **NCCN Categories of Preference** (all recommendations are considered appropriate) | |
|---|---|
| Preferred intervention | Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability. |
| Other recommended intervention | Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes. |
| Useful in certain circumstances | Other interventions that may be used for select patient populations (defined with recommendation). |

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## Criteria

Prior authorization is required.

Lunsumio® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of relapsed or refractory follicular lymphoma; **AND**
2. Member has received at least two prior systemic therapies; **AND**
3. Member is 18 years of age or older; **AND**
4. Prescribed by, or in consultation with, an oncologist or hematologist; **AND**
5. Request meets one of the following (a or b):
    a. Does not exceed all of the following (i, ii, and iii):
        i. Cycle 1:
            1. Day 1: 1 mg;
            2. Day 8: 2 mg;
            3. Day 15: 60 mg; and
        ii. Cycle 2: Day 1: 60 mg; and
        iii. Cycles 3+: Day 1 of each cycle: 30 mg; or
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Lunsumio® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile; **AND**
3. Member meets one of the following (a or b):
    a. Received eight (8) initial treatment cycles and needs further therapy due to incomplete or partial response; or,
    b. Did not receive the full eight (8) initial treatment cycles and wishes to resume therapy; **AND**
4. Prescribed by, or in consultation with, an oncologist or hematologist; **AND**
5. Request meets one of the following (a or b):
    a. Regimen meets BOTH of the following (i and ii):
        i. Prescribed dose does not exceed 30 mg on day 1 of each 21-day cycle (for cycles 3 or later); **AND**
        ii. Member has not received a total of 17 cycles of therapy with Lunsumio®; or
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

## Approval Duration and Quantity Limits

| 1 cycle = 21 days | Quantity Limits | Approval Duration |
|---|---|---|
| Initial Authorization | Cycle 1: 63 mg<br>Cycle 2: 60 mg<br>Cycles 3+: 30 mg | 9 months<br>[or up to 8 treatment cycles (1 cycle = 21 days)] |
| Subsequent Authorization(s) | 30 mg per cycle | 12 months (see bullet points for conditions):<br>• If member received 8 initial treatment cycles, an additional 9 cycles may be approved, up to a total of 17 cycles overall<br>• If member did not receive 8 initial treatment cycles, but wishes to resume therapy, may be approved to complete the remaining initial 8 treatment cycles (reauthorization for continued therapy beyond the 8 cycles will then be required) |

## Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

| HCPCS | Description |
|---|---|
| J9350 | Injection, mosunetuzumab-axgb, 1 mg |

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

| NDC (Strength) | Labeler | Dosage | Pkg Size | Pkg Qty | Units/ Pkg |
|---|---|---|---|---|---|
| 50242-0142-01 (30 mg/30 mL) | Genentech, Inc. (50242) | 1 mg | 1 | EA | 30 |
| 50242-0159-01 (1 mg/mL) | Genentech, Inc. (50242) | 1 mg | 1 | EA | 1 |

## Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

## References


[1] Lunsumio® prescribing information (12/2024). Genentech, Inc.: South San Francisco, CA. Available online: www.lunsumio-hcp.com. Accessed March 4, 2025.

[2] Freedman AS, Friedberg JW. Treatment of relapsed or refractory follicular lymphoma. Connor RF, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed March 4, 2025.

[3] Freedman AS, Aster JC. Clinical manifestations, pathologic features, diagnosis, and prognosis of follicular lymphoma. Connor RF, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed March 4, 2025.

[4] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[5] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[6] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced (note version number and effective date):

- B-Cell Lymphomas (v.2.2025 – February 10, 2025)


Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

## Criteria Change History

| Change Date | Changed By | Description of Change | Version |
|---|---|---|---|
| [mm/dd/yyyy] | CAC | | |
| **Signature** | | | |

| Change Date | Changed By | Description of Change | Version |
|---|---|---|---|
| [mm/dd/yyyy] | CAC | | |
| **Signature** | | | |

| Change Date | Changed By | Description of Change | Version |
|---|---|---|---|
| 04/18/2025 | CAC | Annual review. Reviewed and updated NCCN Guidelines. No changes to criteria. | 2 |
| **Signature**<br>William (Bill) Jagiello, DO | |  | |

| Change Date | Changed By | Description of Change | Version |
|---|---|---|---|
| 04/19/2024 | CAC | Criteria implementation. | 1 |
| **Signature**<br>William (Bill) Jagiello, DO | |  | |

CAC = Medicaid Clinical Advisory Committee