Lunsumio, Intravenous (mosunetuzumab-axgb)
PAM – 073

Iowa Medicaid Program	Prior Authorization	**Effective Date**	07/01/2023
Revision Number	3	**Last Reviewed**	10/16/2026
Reviewed By	Medicaid Medical Director	**Next Review**	04/16/2027
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	04/19/2024

Overview

Medication: [1]	mosunetuzumab-axgb for intravenous (IV) infusion
Brand Name:	Lunsumio®
Pharmacologic Category:	Antineoplastic; 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. ▶ 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 12/19/2025: FDA approved Lunsumio Velo, a subcutaneous (SC) form of Lunsumio. *The IV and SC formulations have different dosage and administration instructions and are not interchangeable.*
Dosage and Administration:	See table below

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.

Benefit Category:	Medical

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). It 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, usually years after treatment. Approximately 20 percent of patients will have disease progression within 24 months of initial chemoimmunotherapy, and a small percentage will not respond to initial chemoimmunotherapy (i.e., refractory disease).[2]

In the United States as a whole, FL accounts for approximately 35 percent of NHLs and has an 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) Clinical Practice Guidelines in Oncology document evidence-based, consensus-driven management to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that are most likely to lead to optimal outcomes. The guidelines are developed and updated by 63 individual panels, comprising over 1,900 clinicians and oncology researchers from the 33 NCCN Member Institutions. The categories for recommendations are based on both the level of clinical evidence available and the degree of consensus within the NCCN Guidelines Panel.

The library of NCCN Guidelines® currently apply to more than 97 percent of people living with cancer or anyone at risk for a diagnosis of cancer in the United States. The guidelines incorporate real-time updates in keeping with the rapid advancements in the field of cancer research and management and are intended to assist all individuals who impact decision-making in cancer care, including physicians, nurses, pharmacists, payers, patients and their families, and others.

The NCCN Guidelines® provide recommendations based on the best evidence available at the time they are derived. Because new data are published continuously, it is essential that the NCCN Guidelines also be continuously updated and revised* to reflect new data and clinical information that may add to or alter current clinical practice standards.[4,5]

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

- B-Cell Lymphomas (v.4.2026 – May 26, 2026)

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 Cycle 2: 60 mg Cycles 3+: 30 mg	9 months [or up to 8 treatment cycles (1 cycle = 21 days)]
Subsequent Authorization(s)	30 mg per cycle	12 months (see bullet points for conditions): • If member received 8 initial treatment cycles, an additional 9 cycles may be approved, up to a total of 17 cycles overall • 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 (06/2026). Genentech, Inc.: South San Francisco, CA. Available online: www.lunsumio-hcp.com. Accessed July 31, 2026.

[2] Freedman AS, Salles G. Treatment of relapsed or refractory follicular lymphoma. Connor RF, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed August 3, 2026.

[3] Freedman AS, Aster JC, Salles G. Clinical manifestations, pathologic features, diagnosis, and prognosis of follicular lymphoma. Connor RF, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed August 3, 2026.

[4] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[5] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[6] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are continuously updated and revised to reflect new data and clinical information that may add to or alter current clinical practice standards. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced at the time of this revision (note version number and effective date):

- B-Cell Lymphomas (v.4.2026 – May 20, 2026)

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
10/16/2026	CAC	Annual review. Changed policy name to include “intravenous”, to distinguish Lunsumio (IV) from Lunsumio Velo, which is a subcutaneous injection. Policy format update: Removed current NCCN Guidelines recommendations, as guidelines may change more frequently than the review cadence of this document. Will continue to reference NCCN when writing criteria, and include the specific version referenced at the time of the policy writing/revision.	3
Signature William (Bill) Jagiello, DO			

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 William (Bill) Jagiello, DO			

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

CAC = Medicaid Clinical Advisory Committee