STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Lunsumio (mosunetuzumab-axgb)
PAM–073

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	07/01/2023
Revision Number:	1	**Last Rev Date:**	04/19/2024
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	04/18/2025
Approved By:	Medicaid Clinical Advisory Committee	**Approved Date:**	04/19/2024

Overview

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. ➢ 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:	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) 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

As new and emerging therapies are rapidly coming to market, oncology treatment recommendations and guidelines are constantly changing. To keep up with these changes, the National Comprehensive Cancer Network (NCCN) publishes guidelines which are developed and updated by 60 individual panels, comprising over 1,660 clinicians and oncology researchers from the 31 NCCN Member Institutions.[4]

The NCCN Clinical Practice Guidelines in Oncology (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 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.

The information referenced at the time of this policy writing/revision is from:

- NCCN Guidelines® for B-Cell Lymphomas (Version 1.2024 – January 18, 2024)[5]

NCCN Guidelines® recommendation(s) for mosunetuzumab-axgb (Lunsumio®)
(1) Classic follicular lymphoma, third-line and subsequent therapy A. mosunetuzumab-axgb (Lunsumio®): 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).

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;
        ii. Cycle 2: Day 1: 60 mg;
        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 following 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	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 this 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 (12/2022). Genentech, Inc.: South San Francisco, CA. Available online at: www.lunsumio-hcp.com. Accessed January 4, 2024.

[2] Freedman AS, Friedberg JW. Treatment of relapsed or refractory follicular lymphoma. Connor RF, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed February 10, 2024.

[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 February 10, 2024.

[4] National Comprehensive Cancer Network (NCCN). Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 11, 2023.

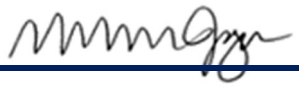
[5] Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas (v.1.2024 – January 18, 2024). Accessed February 10, 2024. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version of the guidelines, go online to NCCN.org.

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
04/19/2024	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee