Clinical Policy: Mosunetuzumab-axgb (Lunsumio)

Reference Number: PA.CP.PHAR.618
Effective Date: 08/2023
Last Review Date: 01/2024

Description
Mosunetuzumab-axgb (Lunsumio™) is a bispecific CD20-directed CD3 T-cell engager antibody.

FDA Approved Indication(s)
Lunsumio is indicated for the 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).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Lunsumio is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Follicular Lymphoma (must meet all)**:**

1. Diagnosis of relapsed or refractory follicular lymphoma characterized as both of the following (a and b):
   a. Grade 1, 2 or 3a (low grade or slow growing);
   b. Presence of at least one bi-dimensionally measurable lesion (≥ 1.5 cm in its largest dimension for nodal lesions, or ≥1.0 cm in its largest dimension for extranodal lesions;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Age ≥ 18 years;
4. Member has received at least two prior lines of systemic therapy including all of the following (a and b);
   a. One anti-CD20-directed therapy (e.g., rituximab, Arzerra®, Gazyva®);
   b. One alkylating agent (e.g., bendamustine, cyclophosphamide);
5. Member does not have a known current or past central nervous system (CNS) lymphoma, or a history of CNS disease (e.g., stroke/transient ischemic attack with residual neurologic deficits; epilepsy with seizures in the past 2 years; CNS vasculitis or neurodegenerative disease);
6. Dose does not exceed one of the following (a or b):
   a. All of the following (i, ii and iii):
      i. Cycle 1:
         a) Day 1: 1 mg;
         b) Day 8: 2 mg;

c) Day 15: 60 mg;
ii. Cycle 2: Day 1: 60 mg;
iii. Cycles 3+: Day 1: 30 mg;
b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 9 months (8 treatment cycles of 21 days each)

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Follicular Lymphoma (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member meets one of the following (a or b):
   a. Received 8 initial treatment cycles and needs further therapy due to incomplete or partial response;
   b. Did not receive 8 initial treatment cycles, and wishes to resume therapy;
3. Member is responding positively to therapy;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. All of the following (i, ii and iii):
      i. Cycle 1:
         a) Day 1: 1 mg;
         b) Day 8: 2 mg;
         c) Day 15: 60 mg;
      ii. Cycle 2: Day 1: 60 mg;
      iii. Cycles 3+: Day 1: 30 mg;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months (*see comments below*)

- **For members who received 8 initial treatment cycles, 9 additional continued therapy cycles will be approved for the total of 17 cycles between the initial and continued therapy.**
- **For members who did not receive 8 initial treatment cycles, but wish to resume therapy, approval will be granted to complete the 8 initial treatment cycles after which re-authorization for continued therapy will be required.**

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CNS: central nervous system
CRS: cytokine release syndrome
FDA: Food and Drug Administration
FL: follicular lymphoma
ICANS: immune effector cell associated neurotoxicity
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of first-line, second-line and subsequent therapies: • bendamustine + rituximab • RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) • RCVP (rituximab, cyclophosphamide, vincristine, prednisone) *Single-agent examples*: rituximab; Leukeran® (chlorambucil) ± rituximab; cyclophosphamide ± rituximab; Revlimid® (lenalidomide) ± rituximab; Aliqopa® (copanlisib)	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): None reported
- Boxed warning(s): Cytokine release syndrome including serious or life-threatening reactions, and neurologic toxicity including immune effector cell associated neurotoxicity

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Follicular Lymphoma	Cycle 1*: • Day 1: 1 mg • Day 8: 2 mg	60 mg/dose intravenous infusion

Indication	Dosing Regimen	Maximum Dose
	• Day 15: 60 mg Cycle 2: Day 1: 60 mg Cycles 3+: Day 1: 30 mg	

** Refer to prescribing information for details on administration duration for each cycle, recommended premedications and dose modifications for adverse reactions.*

VI. Product Availability

Solution for intravenous infusion in a single-dose vial:

- 1 mg/mL (total 1 mL vial volume)
- 30 mg/30 mL (total 30 mL vial volume)

VII. References

1. Lunsumio Prescribing Information. South San Francisco, CA: Genentech, Inc.; December 2022. Available at: www.lunsumio.com. Accessed October 2, 2023.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 4, 2023.
3. National Comprehensive Cancer Network. B-Cell Lymphomas Version 6.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed November 4, 2023.
4. ClinicalTrials.gov. A safety, efficacy and pharmacokinetic study of BTCT4465A (mosunetuzumab) as a single agent and combined with atezolizumab in non-Hodgkin's lymphoma (NHL) and chronic lymphocytic leukemia (CLL). Available at: https://www.clinicaltrials.gov/ct2/show/record/NCT02500407. Accessed November 4, 2023.
5. Budde LE, Assouline S, Sehn LH, *et al*. Single-agent mosunetuzumab shows durable complete responses in patients with relapsed or refractory b-cell lymphomas: phase I dose-escalation study. *J Clin Oncol*. 2022;40(5):481-491.
6. Budde LE, Sehn LH, Matasar M, *et al*. Safety and efficacy of mosunetuzumab, a bispecific antibody, in patients with relapsed or refractory follicular lymphoma: a single-arm, multicentre, phase 2 study. *Lancet Oncol*. 2022;23(8):1055-1065.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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

Reviews, Revisions, and Approvals	Date
Policy created	07/2023
1Q 2024 annual review: added HCPCS code [J9350]; references reviewed and updated.	01/2024