

Clinical Policy: Mosunetuzumab-axgb (Lunsumio)

Reference Number: PA.CP.PHAR.618

Effective Date: 08/2023

Last Review Date: 01/2026

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. B-Cell Lymphoma (off-label) (must meet all):

1. Diagnosis of one of the following B-cell lymphomas (a-e):
 - a. Diffuse large b-cell lymphoma;
 - b. High-grade b-cell lymphomas;
 - c. HIV-related b-cell lymphomas;
 - d. Post-transplant lymphoproliferative disorders;
 - e. Mantle cell lymphoma (MCL);
2. Request is for one of the following (a-e):
 - a. Second-line and subsequent therapy;
 - b. After completion of first-line therapy or primary refractory disease in non-candidates for CAR T-cell therapy or if no intention to proceed to transplant;
 - c. For MCL: as additional therapy if no response or progressive disease following second-line therapy with noncovalent (ncBTKi) or other continuous treatment regimens;
 - d. For MCL: as additional therapy if partial response, no response or progressive disease following second-line therapy with CAR T-cell therapy or fixed-duration regimens;
 - e. Alternative systemic therapy (if not previously used) for relapsed or refractory disease;
3. Prescribed in combination with Polivy[®];
4. Dose is within FDA maximum limit for any FDA-approved indication or 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)

C. 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. All Indications in Section I (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.PHARM.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.PHARM.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 and may require prior authorization.

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|----------------|--------------------------|
| <p><i>Examples of first-line, second-line and subsequent therapies:</i></p> <ul style="list-style-type: none"> • bendamustine + (Gazyva[®] (obinutuzumab) or rituximab) • CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) ± (Gazyva[®] (obinutuzumab) or rituximab) • CVP (cyclophosphamide, vincristine, prednisone) + (Gazyva[®] (obinutuzumab) or rituximab) <p><i>Single-agent examples:</i> rituximab; Leukeran[®] (chlorambucil) ± rituximab; cyclophosphamide ± rituximab; Revlimid[®] (lenalidomide) ± (Gazyva[®] (obinutuzumab) or rituximab); Aliqopa[®] (copanlisib); Gazyva[®] (obinutuzumab), Tazverik[™] (tazemetostat)</p> | 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

V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---------------------|---|---------------------------------|
| Follicular Lymphoma | <p>Cycle 1*:</p> <ul style="list-style-type: none"> • Day 1: 1 mg • Day 8: 2 mg • Day 15: 60 mg <p>Cycle 2: Day 1: 60 mg Cycles 3+: Day 1: 30 mg</p> | 60 mg/dose intravenous infusion |

** 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.; November 2024. Available at: www.lunsumio.com. Accessed October 13, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 4, 2025.

3. National Comprehensive Cancer Network. B-Cell Lymphomas Version 3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed November 4, 2025.
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, 2025.
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 |
| 1Q 2025 annual review: no significant changes; updated Appendix B with additional therapeutic options per NCCN guidelines; references reviewed and updated. | 01/2025 |
| 1Q 2026 annual review: per NCCN Compendium added off-label use in additional B-cell lymphomas subtypes; references reviewed and updated. | 01/2026 |