Clinical Policy: Mosunetuzumab-axgb (Lunsumio)

Reference Number: CP.PHAR.618
Effective Date: 03.01.23
Last Review Date: 02.24
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or documentation supports that member is currently receiving Lunsumio for a covered indication and has received this medication for at least 30 days;
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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

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 • Day 15: 60 mg Cycle 2: Day 1: 60 mg Cycles 3+: Day 1: 30 mg	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.; 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	P&T Approval Date
Policy created	01.19.23	02.23
Added HCPCS code [J9350]	05.24.23	
1Q 2024 annual review: no significant changes; references reviewed and updated.	11.04.23	02.24

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.