Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Lunsumio™ (mosunetuzumab-axgb) injection

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Public Plans Products

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Accelerated approval of Lunsumio (mosunetuzumab-axgb) was based on the GO29781 Phase 1/2 trial. Patients received Lunsumio by intravenous infusion in treatment cycles of 30 mg every 3 weeks, following step-up dosing in the initial two cycles. Lunsumio was administered for eight cycles or until progression or unacceptable toxicity. After eight cycles, patients with a complete response discontinued therapy; patients with a partial response or stable disease continued treatment up to 17 cycles unless they experienced progressive disease or unacceptable toxicity. Among the cohort of 90 patients in the GO29781 trial with relapsed or refractor follicular lymphoma who had received two or more prior therapies, the objective response rate was 80% and the duration of response was 22.8 months after a median follow-up of 14.9 months.

Food and Drug Administration (FDA) Approved Indications:

Lunsumio is a bispecific CD20-directed CD3 T-cell engager 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.

Note: Providers and Members enrolled with Harvard Pilgrim Health Care may reference the HPHC/OncoHealth guideline located at https://oncohealth.us/medicalpolicies/harvardpilgrim/

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Lunsumio when all the following criteria is met:

1. Documented diagnosis or relapsed or refractory follicular lymphoma

AND

2. Documentation the patient has received at least two systemic prior therapies

AND

3. The prescribing physician is an oncologist or hematologist

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

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

References:

1. Lunsumio (mosunetuzumab-axgb) injection, for intravenous use. [Prescribing Information]. San Francisco, CA; Genentech, Inc. December 2022.
2. Bartlett NL, et al. Mosunetuzumab monotherapy demonstrates durable efficacy with a manageable safety profile in patients with relapsed/refractory follicular lymphoma who received ≥2 prior therapies: updated results from a pivotal phase II study. Presented at: 2022 ASH Annual Meeting; December 10–13, 2022; New Orleans, LA. Abstract 610.
3. Budde LE, 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. doi:10.1016/S1470-2045(22)00335-7.
4. Budde LE, 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. oi:10.1200/JCO.21.00931
5. Leukemia & Lymphoma Society. Follicular lymphoma (FL). Accessed January 12, 2023. https://www.lls.org/research/follicular-lymphoma-fl.

Approval And Revision History

February 15, 2023: Reviewed by the Medical Policy Approval Committee (MPAC).

March 14, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T).

Subsequent endorsement date(s) and changes made:

- Originally approved March 14, 2023, by P&T and February 15, 2023 by MPAC committees effective April 1, 2023.
- Coding update per HCPCS level II quarterly release. Effective date July 1, 2023, the following HCPCS code has been added: J9350.
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- August 2024: Updated prerequisite systemic therapy requirement to “Documentation the patient has received at least two systemic therapies prior therapies.” Removed “The Member will be treated with Lunsumio as a single agent only”, “The Member has no prior history of allogenic transplant”, and” The Member has no prior history of CNS lymphoma.” Removed the Limitation “The recommended dose of Lunsumio should be administered as an intravenous infusion for 8 cycles unless patients experience 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.” Minor wording updates (eff 10/1/24).
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24).
- December 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.