Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Lynozyfic™ (linvoseltamab-gcpt)

Effective: January 1, 2026

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

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☐ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☒ 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

Multiple myeloma (MM) is a progressive, incurable blood cancer that affects plasma cells. Plasma cells are a type of matured B cells found in bone marrow that produce antibodies. When damaged, they rapidly displace normal cells and create tumors in the bone marrow. MM is typically characterized by the neoplastic proliferation of plasma cells producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and can result in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures. Additional disease-related complications include hypercalcemia, kidney impairment, anemia, and infections.

While overall outcomes for patients with MM have improved substantially in recent decades, MM is a heterogeneous disease with some patients progressing rapidly despite treatment and others responding to treatment for many years. There are many approved treatment combinations for patients with relapsed or refractory multiple myeloma (RRMM). Most patients experience serial relapses over time and will ultimately receive most if not all available agents at some point during their disease course. There are no guidelines for sequencing treatment options that can be used in the fifth line setting for RRMM. Providers will consider patient comorbidities, ability to tolerate side effects, ECOG score, prior exposure to agents, and availability of therapies in the specific area.

The accelerated approval was based on response rate and durability of response data from the pivotal, open-label, multicenter, multicohort, ongoing Phase 1/2 LINKER-MM1 trial. Among the efficacy population of 80 patients, the objective response rate was 70%, with 45% of patients achieving a complete response (CR) or stringent CR. The median duration of response (DOR) was not reached. With a median follow-up of 11.3 months among responders, the estimated DOR rate was 89% at 9 months and 72% at 12 months. Continued approval of Lynozyfic for R/R MM may be contingent upon verification of clinical benefit in a confirmatory trial.

Food and Drug Administration - Approved Indications

Lynozyfic is indicated for the treatment of adult patients with relapsed or refractory (R/R) multiple myeloma (MM) who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

Clinical Guideline Coverage Criteria

The plan may authorize Lynozyfic for Members when **ALL** the following criteria is met:

1. Documented diagnosis of relapsed or refractory multiple myeloma
2. Documentation the patient has received at least four (4) prior lines of therapy, that include at least one drug from **ALL** of the following drug classes:
    a. Proteasome inhibitor (e.g., bortezomib, Kyprolis [carfilzomib], Ninlaro [ixazomib]).
    b. Immunomodulatory agent (e.g. thalidomide, lenalidomide or Pomalyst [pomalidomide])
    c. Anti-CD38 monoclonal antibody (e.g., Darzalex [daratumumab], Darzalex Faspro [daratumumab and hyaluronidase fjhi], Sarclisa [isatuximab])
3. Patient is 18 years of age or older
4. The patient has an Eastern Cooperative Oncology Group (ECOG) score of 0 to 1
5. 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
C9307	INJECTION LINVOSELTAMAB-GCPT 1 MG
J9601	Injection, linvoseltamab-gcpt, 1 mg

References:

1. **Lynozyfic** [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; July 2025. https://www.regeneron.com/downloads/Lynozyfic_fPI.pdf. Accessed November 24, 2025.
2. National Comprehensive Cancer Network (NCCN) Guidelines: Multiple Myeloma. Version 3.2023.

Approval And Revision History

December 8, 2025: Reviewed by the Medical Policy Approval Committee (MPAC).
December 9, 2025: Reviewed by Pharmacy and Therapeutics Committee (P&T).
Subsequent updates and endorsement(s):

- January 2026: Administrative update: Added HCPCs code to guideline (eff 1/1/26)
- April 2026: Administrative update to remove Carelink from template. Added HCPCs code J9601 (Lynozyfic), effective 4/1/26.

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: Dr ug 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.