Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines: Medical Benefit Drugs
Lamzede® (velmanase alfa-tycv)

Effective: July 1, 2025

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

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

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

Alpha-mannosidosis (AM) is an ultra-rare, progressive lysosomal storage disorder characterized by a deficiency of the enzyme alpha-mannosidase. Approval of Lamzede was based on a 52-week, placebo-controlled trial of 25 patients. After 12 months of treatment, Lamzede was numerically favored over placebo for the following efficacy endpoints: 3-minute stair climbing test, 6-minute walking test, and forced vital capacity. Results were supported by a significant reduction in serum oligosaccharide concentration in Lamzede-treated patients. Results from a Phase 2 trial of five patients <6 years of age also showed a reduction in serum oligosaccharide concentration at 24 months.

Food and Drug Administration (FDA) Approved Indications:

Lamzede (velmanase alfa-tycv) is a recombinant human lysosomal alpha-mannosidase indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients.

Clinical Guideline Coverage Criteria

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

1. Documented diagnosis of alpha-mannosidosis confirmed by enzyme assay demonstrating alpha-mannosidase activity less than 10% of normal activity

AND

2. Documentation the patient has non-central nervous system manifestations

AND

3. Prescribed by or in consultation with a specialist familiar with the treatment of lysosomal storage disorders

Limitations

None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0217	Injection, velmanase alfa-tycv, 1 mg

References:

1. Harmatz P, et al. Enzyme replacement therapy with velmanase alfa (human recombinant alpha-mannosidase): novel global treatment response model and outcomes in patients with alpha-mannosidosis. Mol Genet Metab. 2018;124(2):152–160.
2. Borgwardt L, et al. Efficacy and safety of velmanase alfa in the treatment of patients with alpha-mannosidosis: results from the core and extension phase analysis of a phase III multicentre, double-blind, randomised, placebo-controlled trial. J Inherit Metab Dis. 2018;41(6):1215–1223.
3. Lamzede (velmanase alfa-tycv) [prescribing information]. Parma, Italy; Chiesi Farmaceutici S.p.A.: 2023 Feb.
4. Lund AM, et al. Comprehensive long-term efficacy and safety of recombinant human alpha-mannosidase (velmanase alfa) treatment in patients with alpha-mannosidosis. J Inherit Metab Dis. 2018;41(6):1225–1233.

Approval And Revision History

May 17, 2023: Reviewed by the Medical Policy Approval Committee (MPAC).

June 13, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T), effective July 1, 2023.

Subsequent endorsement date(s) and changes made:

- 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.
- May 14, 2024: Minor wording updates. Removed the Limitation Coverage will not be provided in the following circumstances: a. Member has a history of a HSCT or bone marrow transplant, or b. Member is wheelchair bound due to their illness. Administrative update to add HCPCS code J0217 (eff 7/1/24).
- June 10, 2025: No changes. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template (eff 7/1/25)
- June 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 7/1/25).

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.