Harvard Pilgrim Health Care | TUFTS Health Plan

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

Effective: July 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

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 Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☒ 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 owing to mutations in the MAN2B1 gene. When alpha-mannosidase is deficient, intracellular accumulation of mannose rich oligosaccharides occurs, which is thought to contribute to the clinical manifestations of the disease. Clinical manifestations may include mild to moderate intellectual disability, hearing loss, weakened immune system, distinctive facial features (e.g., a large head, prominent forehead, and protruding jaw), skeletal abnormalities, and muscle weakness.

Food and Drug Administration (FDA) Approved Indications:

- Lamzede (velmanase alfa-tycv) is an intravenous (IV) enzyme replacement therapy (ERT), specifically, a recombinant form of human alpha-mannosidase. The drug provides or supplements the patient's natural alpha-mannosidase, an enzyme involved in the degradation of mannose–rich oligosaccharides to prevent their accumulation in various tissues in the body. Lamzede acts the same way as the alpha-mannosidase enzyme in the human body; thus, it aims to restore normal cellular activity in patients.

Clinical Guideline Coverage Criteria

The Plan may cover Lamzede when all the following clinical criteria is met:

1. Diagnosis of AM confirmed by enzyme assay demonstrating alpha-mannosidase activity <10% of normal activity.

AND

2. Provider attests that the patient has non-central nervous system manifestations.

AND

3. Lamzede is being prescribed by, or in consultation with, a specialist familiar with the treatment of lysosomal storage disorders

Limitations

- Coverage will not be provided in the following circumstances:
  a. Member has a history of a HSCT or bone marrow transplant
  b. Member is wheelchair bound due to their illness

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
	None

References:

1. Lamzede (velmanase-alfa-tycv) Aventura, Fl. IPD Analytics 2023
2. Lamzede (velmanase-alfa-tycv) [package insert] US Food and Drug Administration April 2023
3. Lamzede(velmanase-alfa-tycv New York NY Medscape Lamzede (velmanase alfa) dosing, indications, interactions, adverse effects, and more (medscape.com)2023
4. Lamzede(velmanase-alfa-tycv Waltham Ma. UpToDate https://www.uptodate.com/contents/velmanase-alfa-drug-information?search=mannosidosis2023

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

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is 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.