**RX.PA.088.MPC Lamzede® (velmanase alfa-tycv)**

The purpose of this policy is to define the prior authorization process for Lamzede® (velmanase alfa-tycv) for injection, for intravenous infusion.

Lamzede (velmanase alfa-tycv), is indicated for treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients.

**PROCEDURE**

**A. Initial Authorization Criteria:**

**1. Alpha-Mannosidosis. All requests must meet the following criteria:**

- Must have a documented diagnosis of alpha mannosidosis confirmed by:
  a) Alpha-mannosidase activity < 10% of normal activity in blood leukocytes or fibroblasts OR
  b) Molecular genetic testing revealing biallelic MAN2B1 gene mutation
- Member is at least 3 years of age or older
- Must be using Lamzede for treatment of non-central nervous system (CNS) disease manifestations (skeletal abnormalities, myopathy, motor function disturbances, immunodeficiency, etc.)
  Note: If member has CNS and non-CNS manifestations, must have documentation of at least 2 non-CNS symptoms:
  a) Skeletal abnormalities
  b) Myopathy
  c) Motor function disturbances
  d) Hearing impairment
  e) Immunodeficiency
- Dose does not exceed FDA approved indication
- Provider attests that a negative pregnancy test will be documented for female members (within 30 days of starting therapy)
- Member is able to walk without the use of a support aid
- Prescriber attests that the presence of known chromosomal abnormalities and syndromes, other than alpha-mannosidosis that affect psychomotor development are excluded
- Provider attests that member will have documentation of baseline immunoglobulin E (IgE) < 800 IU/mL and baseline serum oligosaccharides
- Must provide documentation of at least one baseline age appropriate value (within 90 days of request) ~~of starting treatment~~):
  a) 6 minute walk test (6-MWT)
  b) 3 minute stair climb test (3-MSCT)
  c) Pulmonary function tests (forced vital capacity)
  d) Motor function tests (i.e. Bruininks-Oseretsky Test of Motor Proficiency (BOT-2))

- The medication is prescribed by or in consultation with a geneticist, metabolic specialist, endocrinologist, or physician who specializes in the treatment of lysosomal storage disorders
- Member must not have a history of hematopoietic stem cell transplant (HSCT)

**B. Reauthorization Criteria:**

**1. Alpha-Mannosidosis.**

**MPC Renewal:**

- All prior authorization renewals are reviewed on a 1-year interval basis to determine the Medical Necessity for continuation of therapy.
- Documentation of a positive clinical response or stabilization in disease, as determined by a positive change in at least one baseline value:
  - Improvement or stability in motor function (i.e. BOT-2)
  - Improvement or stability in pulmonary function (forced vital capacity test)
  - Reduction or stability in serum oligosaccharides
  - Stabilization or slowing the rate of disease progression or clinical decline
  - Improvement in 6 minute walk test (6-MWT)
  - Improvement in 3 minute stair climb test (3-MSCT)
- The medication is prescribed by or in consultation with a geneticist, metabolic specialist, endocrinologist, or physician who specializes in the treatment of lysosomal storage disorders

**Renewal from Previous Insurer:**

- Members who have received prior approval (from insurer other than MPC) and have been taking Lamzede, or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).
- Provider has a documented clinical response of the member's condition which has improved based or stabilized upon the prescriber's assessment
  - Must provide documentation of at least one baseline value to show stabilization or improvement in clinical response since starting therapy
    - 6 minute walk test (6-MWT)
    - 3 minute stair climb test (3-MSCT)
    - Pulmonary function tests (forced vital capacity)
    - Motor function tests (i.e. Bruininks-Oseretsky Test of Motor Proficiency (BOT-2))

**C. Lamzede will be considered investigational or experimental for any other use and will not be covered.**

**Limitations:**

| Length of Authorization (if above criteria met) | |
|---|---|
| Initial Authorization | • Up to 3 months |
| Reauthorization | • Up to 1 year |

**Codes:**

| Code | Description |
|---|---|
| J3590 | Unclassified biologics |

**REFERENCES**

1. Lamzede [prescribing information]. Cary, NC: Chiesi USA Inc.; February 2023.

## REVIEW HISTORY

| DESCRIPTION OF REVIEW / REVISION | DATE APPROVED |
|---|---|
| *Annual Review* | *02/2026* |
| *Annual Review* | *02/2025* |
| *Annual policy review. Update to reauthorization criteria for non-MPC renewals* | *02/2024* |
| *New Policy* | *09/2023* |