

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



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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
<i>Annual policy review. Update to reauthorization criteria for non-MPC renewals</i>	<i>02/2024</i>
<i>New Policy</i>	<i>09/2023</i>