Generic Name: velmanase alfa-tyvc

Therapeutic Class or Brand Name: Lamzede®

Preferred: N/A

Non-preferred: N/A

Date of Origin: 10/21/2025

Date Last Reviewed / Revised: 10/21/2025

Prior Authorization Criteria

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of alpha mannosidosis (AM) and must meet ALL criteria listed:
   A. Diagnosis confirmed by both of the following:
      i. Pathogenic *MAN2B1* gene mutation confirmed by genetic testing AND
      ii. Alpha-mannosidase enzyme activity below 10% of normal as measured in blood leukocytes or other nucleated cells.
   B. Presence of non-central nervous system manifestations of AM (eg, motor function disturbances, physical disability, hearing and speech impairment, skeletal abnormality, etc.)
   C. Baseline serum oligosaccharide level within the last 12 months.
   D. For patients of childbearing potential, documentation of a negative pregnancy test prior to treatment initiation and a confirmed contraception plan for the duration of therapy is required.

II. Prescribed by or in consultation with a geneticist, endocrinologist, or metabolic specialist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

Exclusion Criteria

- Pregnancy

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Product is available in 10 mg/1 mL vials.
- Quantity sufficient 1 mg/kg dose once weekly (based on actual body weight).

Approval Length

- **Authorization:** 6 months
- **Re-Authorization:** 1 year, with an updated letter of medical necessity or progress notes showing improvement or maintenance with the medication. Positive clinical response must be demonstrated through improvement in motor function, improvement in pulmonary function, or reduction in serum oligosaccharides of at least 50% from baseline.

Appendix

- N/A

References

1. Chiesi USA, Inc. Lamzede (velmanase alfa-tycv) injection. Prescribing Information. Cary, NC: Chiesi USA, Inc.; 2023. Accessed October 16, 2025. https://resources.chiesiusa.com/Lamzede/LAMZEDE_PI.pdf
2. Borgwardt L, Guffon N, Amraoui Y, 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. doi:10.1007/s10545-018-0185-0