Reference number(s)
5787-A

Specialty Guideline Management
Lamzede

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lamzede	velmanase alfa-tycv

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Lamzede is indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial Requests

- Alpha-mannosidase enzyme assay or genetic testing results supporting the diagnosis.

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- Medical records (e.g., chart notes) documenting baseline age-appropriate values for at least ONE of the following: 3-minute stair climbing test [3MSCT], 6-minute walking test [6MWT], or forced vital capacity [FVC, % predicted].
- Medical records (e.g., chart notes, lab results) documenting baseline serum or urine oligosaccharide concentration.

Continuation Requests

- Medical records (e.g., chart notes, lab results) documenting a response to therapy (e.g., improvement in 3-minute stair climbing test [3MSCT] from baseline, improvement in 6-minute walking test [6MWT] from baseline, improvement in forced vital capacity [FVC, % predicted] from baseline, reduction in serum or urine oligosaccharide concentration from baseline).

Prescriber Specialties

This medication must be prescribed by or in consultation with a physician who specializes in the treatment of enzyme or metabolic disorders.

Coverage Criteria

Alpha-Mannosidosis[1-2]

Authorization of 12 months may be granted for treatment of non-central nervous system manifestations of alpha-mannosidosis when the following criteria are met:

- Diagnosis is confirmed by either of the following:
  - A documented deficiency of alpha-mannosidase activity as measured in blood leukocytes or fibroblasts, or
  - Genetic testing results documenting pathogenic variant(s) in the MAN2B1 gene.
- Member has completed a 3-minute stair climbing test [3MSCT], 6-minute walking test [6MWT], or forced vital capacity [FVC, % predicted] test to establish baseline age-appropriate values.
- Member has undergone baseline serum or urine oligosaccharide concentration testing.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section who are responding to therapy (e.g., improvement in 3-minute stair climbing test [3MSCT] from baseline, improvement in 6-minute walking

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test [6MWT] from baseline, improvement in forced vital capacity [FVC, % predicted] from baseline, reduction in serum or urine oligosaccharide concentration from baseline).

References

1. Lamzede [package insert]. Cary, NC: Chiesi USA Inc.; February 2023.
2. Malm D, Nilssen O. Alpha-Mannosidosis. In: GeneReviews. https://www.ncbi.nlm.nih.gov/books/NBK1396/ (Accessed on November 17, 2025).

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