Reference number(s)
5788-A

Standard Medicare Part B 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 will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

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-minutes 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).

Coverage Criteria

Alpha-mannosidosis[1-3]

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

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication in the coverage criteria section.
- The member is receiving benefit from 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).

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Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Lamzede.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- Presentation of a diagnostic algorithm from an international working group.
- Alpha-Mannosidosis – Gene Reviews.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Lamzede are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for use of genetic testing to confirm a diagnosis of alpha-mannosidosis can be found in a consensus statement from an international working group of experts. In Molecular Genetics and Metabolism, the diagnostic algorithm indicates that screening for alpha-mannosidosis is done by urine (less frequently serum) analysis of mannose-rich oligosaccharides and is often the first assay in the diagnostic path. Direct demonstration of low activity of acid alpha-mannosidase in blood leukocytes or cultured skin fibroblasts is considered to be the most reliable and diagnostic next step. Genetic analysis of MAN2B1 gene should be used to confirm the enzymatic diagnosis and may be used for prenatal diagnosis and genetic counselling of family members, but it should not replace biochemical testing.

References

1. Lamzede [package insert]. Cary, NC: Chiesi USA Inc.; February 2023.
2. Guffon, N, Tylki-Szymanska, A, Borgwardt, L, et al. Recognition of alpha-mannosidosis in paediatric and adult patients: Presentation of a diagnostic algorithm from an international working group. Mol Genet Metab. 2019; 126:470-474.
3. 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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