

Policy Name:	Lamzede (velmanase alfa)	Policy#:	3189P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Lamzede (velmanase alfa)

Statement of the Policy

Health Alliance Medical Plans will approve the use of Lamzede (velmanase alfa) under the specialty medical benefit if the following criteria are met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of mild-moderate alpha-mannosidosis (AM) confirmed by enzyme assay demonstrating alpha-mannosidase activity less than 10% of normal activity
- 1.2 Clinical documentation supports the patient has signs and symptoms consistent with mild - moderate AM (e.g. absence of nerve manifestations, able to move independently)
- 1.3 Prescribed by or with a specialist familiar with the treatment of this disease
- 1.4 Age 1 year or older
- 1.5 Clinical review for coverage is completed by both a pharmacist and medical director

2. Exclusion Criteria

- 2.1 Previous history of hematopoietic stem cell transplant or bone marrow transplant
- 2.2 Patient cannot walk without support
- 2.3 Patient demonstrates majority central nervous system (CNS) symptoms
 - Lamzede does not cross the blood brain barrier and has not been shown to be effective at treating CNS symptoms related to AM
- 2.4 Patient has severe AM as demonstrated by diagnosis in infancy and rapid disease progression involving the central nervous system
 - Clinical trials did not include adequate representation of patients with severe illness therefore Lamzede has not been proven to show clinical efficacy in this patient population

3. Approval Period

- 3.1 Initial: 12 months
- 3.2 Reauthorization: 12 months with documentation of clinical benefit

CPT Codes

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HCPCS Codes

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References

1. Lamzede (velmanase alfa) [prescribing information]. Cary, NC, Chiesi USA Inc; February 2023.
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 Nov;41(6):1215-1223.
3. Malm D, Riise Stensland HM, Edvardsen N. The natural course and complications of alpha-mannosidosis--a retrospective and descriptive study. *J Inherit Metab Dis*. 2014;37:79–82

Created Date: 06/07/23

Effective Date: 06/07/23

Posted to Website: 06/07/23

Revision Date: 10/01/24

DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.