blue california
Promise Health Plan

velmanase alfa-tycv (Lamzede)

Medical Benefit Drug Policy

Place of Service
Home Infusion Administraiton
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Recombinant human lysosomal alpha-mannosidase
HCPCS:
J0217:Injection, velmanase alfa-tycv, 1 mg
How Supplied:
10 mg as a lyophilized powder in a single-dose vial for reconstitution

Condition(s) listed in policy *(see coverage criteria for details)*

- Alpha-mannosidosis (AM)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Alpha-mannosidosis (AM)
Meets medical necessity if all the following are met:
1. Being used for the treatment of non-central nervous system manifestations of AM
2. Patient has a diagnosis of alpha-mannosidosis as confirmed by ONE of the following:
   a. Documentation of MAN2B1 recessive gene mutation
   b. Alpha-mannosidase activity <10% of normal activity in blood leukocytes

Covered Doses:
Up to 1 mg/kg (actual body weight) given intravenously once weekly

Blue Shield of California Promise Health Plan is an independent licensee of the Blue Shield Association

Coverage Period:
Indefinite

ICD-10:
E77.1

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Lamzede (velmanase alfa-tycv) [Prescribing information]. Parma, Italy: Chiesi Farmaceutici S.p.A.; 2/2023.

Review History

Date of Last Annual Review: 2Q2026
Changes from previous policy version:

- No change to policy following routine annual review

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee