**velmanase alfa-tycv (Lamzede)**

**Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

**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

**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: 2Q2025
Changes from previous policy version:

- No clinical change following annual review.

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