

Velmanase alfa-tycv (Lamzede®)

Place of Service

Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

HCPCS: J3490

- Through 12/31/2023: C9399, J3490
- Effective 1/1/2024 and after: J0217 per 1 mg

NDCs:

10122-180-02 (One 10 mg single-dose vial)
10122-180-05 (Five 10 mg single-dose vials)
10122-180-10 (Ten 10 mg single-dose vials)

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

- [Non-neurological effects of alpha-mannosidosis \(AM\)](#)

AHFS therapeutic class: Enzymes

Mechanism of action: Recombinant human lysosomal alpha-mannosidase

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Lamzede® (velmanase alfa-tycv) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Non-neurological effects of alpha-mannosidosis (AM)

1. Being used for the treatment of non-central nervous system manifestations of AM, **AND**
2. Patient has a diagnosis of alpha-mannosidosis as confirmed by one of the following:
 - a. Documentation of MAN2B1 recessive gene mutation, OR
 - b. Alpha-mannosidase activity <10% of normal activity in blood leukocytes

Covered Doses

Up to 1 mg/kg (actual body weight) given by IV once weekly

Coverage Period

Indefinitely

ICD-10:

E77.1

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Lamzede® (velmanase alfa-tycv) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT COVERED for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied: 10 mg as a lyophilized powder in a single-dose vial for reconstitution.

(6) References

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

(7) Policy Update

Date of last revision: 4Q2023

Date of next review: 2Q2024

Changes from previous policy version:

- Added HCPCS J1413 per therapeutic dose, effective 1/1/2024 and after.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*