Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 26, 2024

LAMZEDE® (velmanase alfa-tycv)

LENGTH OF AUTHORIZATION: 1 year

REVIEW CRITERIA:

- Patient must be diagnosed with alpha-mannosidosis.
- Diagnosis is confirmed by alpha-mannosidosis activity below 10% of normal as measured in fibroblasts or leukocytes **OR** Mannosidase Alpha Class 2B Member 1 (MAN2B1) gene mutation.
- Diagnosis is supported by non-central nervous system manifestations including, but not limited to, myopathy, impaired fine motor control and coordination and/or facial and skeletal abnormalities.
- Baseline oligosaccharides confirmed per lab submission.
- Prescribed by or in consultation with a geneticist or metabolic specialist.

CONTINUATION OF THERAPY

- Patient met initial review criteria.
- Documentation of positive clinical response including but not limited to the following:
    - improvement in motor function
    - improvement in pulmonary function
    - reduction in serum oligosaccharides
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 10 mg of lyophilized powder in single-dose vial for reconstitution