

# SPECIALTY GUIDELINE MANAGEMENT

## LAMZEDE (velmanase alfa-tycv)

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

Lamzede is indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients.

All other indications are considered experimental/investigational and not medically necessary.

#### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. Initial requests: alpha-mannosidase enzyme assay or genetic testing results supporting the diagnosis.
- B. Continuation of therapy requests: documentation (e.g., chart notes, lab results) of a response to therapy (e.g., improvement in 3-minute stair climbing test [3MSCT] from baseline, improvement in 6-minute walking test [6MWT] from baseline, improvement in forced vital capacity [FVC, % predicted] from baseline, reduction in serum or urine oligosaccharide concentration from baseline).

#### III. CRITERIA FOR INITIAL APPROVAL

##### **Alpha-mannosidosis**

Authorization of 12 months may be granted for treatment of non-central nervous system manifestations of alpha-mannosidosis when the diagnosis is confirmed by either of the following:

- A. A documented deficiency of alpha-mannosidase activity as measured in blood leukocytes or fibroblasts, or
- B. Genetic testing results documenting a mutation in the *MAN2B1* gene.

#### IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III who are responding to therapy (e.g., improvement in 3-minute stair climbing test [3MSCT] from baseline, improvement in 6-minute walking test [6MWT] from baseline, improvement in forced vital capacity [FVC, % predicted] from baseline, reduction in serum or urine oligosaccharide concentration from baseline).

#### V. REFERENCES

Reference number(s)
5787-A

1. Lamzede [package insert]. Cary, NC: Chiesi USA Inc.; February 2023.
2. Malm D, Nilssen O. Alpha-Mannosidosis. In: GeneReviews. <https://www.ncbi.nlm.nih.gov/books/NBK1396/> (Accessed on February 17, 2023).