

**POLICY NAME**

Lamzede (velmanase alfa)

**POLICY #**

## Criteria

### Exclusion Criteria – Any of the following prevents coverage

- ☐ **2.1** Previous history of hematopoietic stem cell transplant or bone marrow transplant
- ☐ **2.2** Patient cannot walk without support
- ☐ **2.3** Patient demonstrates majority central nervous system (CNS) symptoms
  - Lamzede does not cross the blood brain barrier and has not been shown to be effective at treating CNS symptoms related to AM
- ☐ **2.4** Patient has severe AM as demonstrated by diagnosis in infancy and rapid disease progression involving the central nervous system
  - Clinical trials did not include adequate representation of patients with severe illness therefore Lamzede has not been proven to show clinical efficacy in this patient population

### Coverage Criteria

- ☐ **1.1** Diagnosis of mild-moderate alpha-mannosidosis (AM) confirmed by enzyme assay demonstrating alpha- mannosidase activity less than 10% of normal activity
- ☐ **1.2** Clinical documentation supports the patient has signs and symptoms consistent with mild - moderate AM (e.g. absence of nerve manifestations, able to move independently)
- ☐ **1.3** Prescribed by or with a specialist familiar with the treatment of this disease
- ☐ **1.4** Age 1 year or older
- ☐ **1.5** Clinical review for coverage is completed by both a pharmacist and medical director