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| POLICY NAME | Lamzede (velmanase alfa) | POLICY # | 3189P |
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Criteria

Coverage Criteria

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

Exclusion Criteria – Any of the following prevents coverage

- ☐ Previous history of hematopoietic stem cell transplant or bone marrow transplant
- ☐ Patient cannot walk without support
- ☐ 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
- ☐ 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