Mass General Brigham
Health Plan

Lamzede (velmanase alfa-tycv)
Effective 09/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

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

Coverage Guidelines
Authorization may be granted for members new to General Brigham Health Plan who are currently receiving treatment with Lamzede excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members meeting ALL the following criteria:

1. Member has a diagnosis of non-CNS manifestations of alpha-mannosidosis
2. Diagnosis is confirmed by ONE of the following:
    a. Medical charts documenting deficiency of alpha-mannosidosis activity measured in blood leukocytes or fibroblasts
    b. Medical charts showing genetic testing documenting a mutation in the MAN2B1 gene

Continuation of Therapy
Authorization of 12 months may be granted when medical records are provided for continued treatment in members requesting reauthorization for an indication listed above 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).

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

References

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).

Review History
07/12/2023 - Reviewed at July P&T, Effective 9/1/23