

PA Criteria	Criteria Details						
Covered Uses (FDA approved indication)	Lamzede is indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients.						
Exclusion Criteria	Lamzede is not covered for patients with CNS disease manifestations or rapidly progressive disease, patients who cannot walk without support, and/or patients with a history of a HSCT or bone marrow transplant.						
Required Medical Information	Medical records supporting the request must be provided. For alpha-mannosidosis, documentation of the diagnosis confirmed by one of the following must also be provided: <ul style="list-style-type: none"> • biallelic pathogenic variants in MAN2B1 gene OR • enzyme assay demonstrating alpha-mannosidase activity <10% of normal activity. 						
Age Restriction	None.						
Prescriber Restrictions	Must be prescribed by or in consultation with a physician who specializes in the management of patients with alphanmannosidosis, or in the administration of other enzyme replacement therapies for lysosomal storage disorders.						
Coverage Duration	Initial coverage and reauthorization: one year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. For reauthorization: Must have documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (e.g. motor function, FVC, rate of infections, serum oligosaccharides, etc.) compared to the predicted natural history trajectory of disease; AND the patient continues to have an absence of exclusion criteria.						
Other Criteria/Information	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. <table border="1" data-bbox="496 1289 1511 1434"> <thead> <tr> <th>HCPSCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J0217</td> <td>Lamzede (velmanase alfa)</td> <td>Billing unit: 1 mg 10 mg SD Kit</td> </tr> </tbody> </table>	HCPSCS	Description	Billing Units/How Supplied	J0217	Lamzede (velmanase alfa)	Billing unit: 1 mg 10 mg SD Kit
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	5/15/2025	Pharmacy & Therapeutics (P&T) Committee	5/15/2025