

PA Criteria	Criteria Details						
Covered Uses (FDA approved indication)	Lumizyme is a hydrolytic lysosomal glycogen-specific enzyme indicated for patients with Pompe disease [acid α -glucosidase (GAA) deficiency].						
Exclusion Criteria	Must not be used in combination with another ERT (e.g., Nexviazyme, Pombiliti).						
Required Medical Information	Medical records supporting the request must be provided, including the following: <ul style="list-style-type: none"> • Patient's current weight. • For initial coverage: Confirmation of diagnosis by enzyme assay or genetic testing. 						
Age Restriction	None.						
Prescriber Restrictions	Must be prescribed by or in consultation with a specialist for the condition (such as genetic and metabolic specialists, neurologist, cardiologist, pediatrician).						
Coverage Duration	One year initial; two years reauthorization. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice. For reauthorization, must have documented response to therapy evidenced by improvement or stabilization in condition (such as improved or stable muscle strength, motor function, cardiac involvement, FVC, and/or 6MWT).						
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 1098 1511 1241"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J0221</td> <td>Lumizyme (alglucosidase alfa)</td> <td>Billing unit: 10 mg 50 mg SDV</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J0221	Lumizyme (alglucosidase alfa)	Billing unit: 10 mg 50 mg SDV
HCPCS	Description	Billing Units/How Supplied					
J0221	Lumizyme (alglucosidase alfa)	Billing unit: 10 mg 50 mg SDV					

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