Nexviazyme *(avalglucosidase alfangpt)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Nexviazyme 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., Lumizyme, Pombiliti).
Required Medical Information	Medical records supporting the request must be provided, including the following: 1. Patient's current weight. 2. 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 a 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.

HCPCS	Description	Billing Units/How Supplied
J0219	Nexviazyme (avalglucosidase alfa-ngpt)	**Billing unit: 4 mg** 100mg 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