Xenpozyme *(olipudase alfa-rpcp)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Xenpozyme for injection is a hydrolytic lysosomal sphingomyelin-specific enzyme indicated for treatment of non–central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.
Exclusion Criteria	Patient must not have ASMD Type A.
Required Medical Information	Must provide medical records supporting the request and patient's current weight and height. For initial coverage, must also provide the following: 1. Documentation of a diagnosis of acid sphingomyelinase deficiency (ASMD) Type A/B or Type B. 2. Confirmation of ASMD by enzyme assay demonstrating low ASM enzyme activity (<10% of controls). 3. Clinical symptoms of ASMD including low diffusion capacity of the lungs for carbon monoxide (DLCO) and splenomegaly. 4. Baseline DLCO. For reauthorization: Documentation of a clinical response to therapy compared to pretreatment baseline in one or more of the following: reduction in spleen or liver volume, improvement in lung function (e.g., DLCO) or improvement in symptoms (shortness of breath, fatigue, etc.).
Age Restriction	None.
Prescriber Restrictions	Must be prescribed by, or in consultation with, a specialist familiar with the treatment of 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.
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
J0218	Xenpozyme (olipudase alfa-rpcp)	**Billing unit: 1 mg** 20mg 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