HIGHMARK HEALTH OPTIONS

Updated: 09/2024
DMMA Approved: 09/2024

Request for Prior Authorization for Xenpozyme (olipudase alfa-rpcp)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Xenpozyme (olipudase alfa-rpcp) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Xenpozyme (olipudase alfa-rpcp) Prior Authorization Criteria:

Coverage may be provided with a diagnosis of acid sphingomyelinase deficiency (ASMD) with non-central nervous system manifestations and the following criteria is met:

- Confirmation of ASMD diagnosis by one of the following:
  - Documentation of deficient activity of acid sphingomyelinase in peripheral leucocytes or cultured skin fibroblasts
  - A genetic test showing mutations in the SMPD1 gene
- Is age appropriate according to FDA approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Is prescribed by or in consultation with a metabolic disease specialist or geneticists
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**:
  - Documentation of improvement or stabilization in disease
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

References:

1. Xenpozyme [package insert]. Cambridge, MA; Genzyme Corporation; August 2022.
2. Wasserstein M, Dionisi-Vici C, Giugliani R, et al. Recommendations for Clinical Monitoring of Patients with Acid Sphingomyelinase Deficiency (ASMD). *Mol Genert Metab.* February 2019; 126(2): 98-105. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7249497/pdf/nihms-1588212.pdf.

3. McGovern M, Dionisi-Vici C, Giugliani R, et al. Consensus Recommendation for a Diagnostic Guideline for Acid Sphingomyelinase Deficiency. *Genetics in Medicine.* September 2017; 19 (9) 968-974). Retrieved from file:///C:/Users/akeck/Downloads/gim20177.pdf.

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XENPOZYME (OLIPUDASE ALFA-RPCP)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8:00 am to 7:00 pm

PROVIDER INFORMATION	
Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION		
Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION		
Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No		

Billing Information
This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE: _____
Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information	
Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)	
Diagnosis:	ICD Code:

How was the diagnosis confirmed (*please provide documentation)*
- ☐ Deficient activity of acid sphingomyelinase in peripheral leucocytes or cultured skin fibroblasts
- ☐ A genetic test showing mutations in the SMPD1 gene

CURRENT or PREVIOUS THERAPY			
Medication Name	**Strength/ Frequency**	**Dates of Therapy**	**Status (Discontinued & Why/Current)**

REAUTHORIZATION
Has the member experienced an improvement with treatment? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date