



Updated: 12/2022
DMMA Approved: 12/2022

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

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

Xenozyme (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. Xenozyme [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 Genet 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>.

**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? <input type="checkbox"/> Yes <input type="checkbox"/> 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:
<p>How was the diagnosis confirmed (<i>please provide documentation</i>)</p> <p><input type="checkbox"/> Deficient activity of acid sphingomyelinase in peripheral leucocytes or cultured skin fibroblasts</p> <p><input type="checkbox"/> A genetic test showing mutations in the SMPD1 gene</p>	

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION	
Has the member experienced an improvement with treatment? <input type="checkbox"/> Yes <input type="checkbox"/> No	
SUPPORTING INFORMATION or CLINICAL RATIONALE	
Prescribing Provider Signature	Date