

Prior Authorization Criteria  
**Xenpozyme (olipudase alfa-rpcp)**

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.

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.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

## 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 Wholecare Pharmacy Services. **FAX:** (888) 245-2049  
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE:** (800) 392-1147 Mon – Fri  
8:30am to 5:00pm

### PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
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:

### 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 ( <i>please provide documentation</i> )	
<input type="checkbox"/> Deficient activity of acid sphingomyelinase in peripheral leucocytes or cultured skin fibroblasts <input type="checkbox"/> A genetic test showing mutations in the SMPD1 gene	

### CURRENT or PREVIOUS THERAPY

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

**XENPOZYME (OLIPUDASE ALFA-RPCP)**  
**PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2**

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**MEMBER INFORMATION**

Member Name:	DOB:	
Member ID:	Member weight:	Height:

**REAUTHORIZATION**

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

**SUPPORTING INFORMATION or CLINICAL RATIONALE**

<b>Prescribing Provider Signature</b>	<b>Date</b>