HIGHMARK WHOLECARE

Updated:10/2024
PARP Approved:10/2024

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.

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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 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? ☐ Yes ☐ 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 (*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)

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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		
Prescribing Provider Signature	Date	