



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

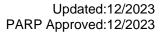
All requests for Xenpozyme (olipudase alfa rpcp) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a <u>diagnosis</u> 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:
  - o Documentation of deficient activity of acid sphingomyelinase in peripheral leucocytes or cultured skin fibroblasts
  - o 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:
  - o 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.

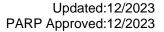




## XENPOZYME (OLIPUDASE ALFA-RPCP) PRIOR AUTHORIZATION FORM

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

	8:30ar	n to 5:00pm					
	PROVIDER	INFORMAT	ION				
Requesting Provider:			Provider NPI:				
Provider Specialty:			Office Contact:				
State license #:			Office NPI:				
Office Address:			Office Phone:				
	Office Fax:						
	MEMBER 1	INFORMAT	ION				
Member Name:		DOB:					
Member ID:	mber ID: Mer		weight:	Height:			
	REQUESTED DI	RUG INFOR	MATION				
Medication:		Strength	:				
Directions:	Directions:		<b>':</b>	Refills:			
Is the member currently received No	ing requested medicat	ion?  Yes	Date Med	lication Initiated:			
	Rilling	Information					
This medication will be billed:			allv				
JCODE:	at a pharmacy o	It meate	arry,				
Place of Service: Hospital	Provider's office	e Membe	r's home	Other			
		vice Informa					
Name:			NPI:				
Address:			Phone:				
ME	EDICAL HISTORY	(Complete for	r ALL regu	uests)			
Diagnosis: ICD Code:							
How was the diagnosis confirm	ned (please provide do	ocumentation)					
☐ Deficient activity of ac	id sphingomvelinase i	n peripheral le	eucocytes o	r cultured skin fibroblasts			
A genetic test showing			,				
	CURRENT or Pl		HERAPY				
Medication Name	Strength/	Dates of		Status (Discontinued &			
	Frequency	Therap	oy	Why/Current)			
			-				





## XENPOZYME (OLIPUDASE ALFA-RPCP) PRIOR AUTHORIZATION FORM (CONTINUED)— PAGE 2 of 2

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

0.000.000	· · · · F							
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							