



**Part B Prior Authorization Guidelines
ASMD (Neimann-Pick Disease)
Xenozyme (olipudase alfa-rpcp) J0218
Prior Authorization Request
Medicare Part B Form**

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Self-administered Provider-administered Home Infusion

Chart notes attached. **Other important information:** _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

- Documentation of a diagnosis of acid sphingomyelinase deficiency (ASMD) Type A/B or Type B
- Confirmation of ASMD by enzyme assay demonstrating low ASM enzyme activity (<10% of controls)
- Clinical symptoms of ASMD including low diffusion capacity of the lungs for carbon monoxide (DLCO) and splenomegaly
- Prescribed by, or in consultation with, specialist familiar with treatment of lysosomal storage disorders

If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)

- Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

Part B Prior Authorization Guidelines

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Acid Sphingomyelinase Deficiency PA

Drug Name(s):
XENPOZYME

OLIPUDASE ALFA-RPCP

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Xenpozyme

- Acid sphingomyelinase deficiency

Off-Label Uses:

N/A

Age Restrictions:

N/A

Other Clinical Considerations:

Black Box Warning: (IV; powder for solution)

Patients treated with olipudase alfa-rpcp have experienced hypersensitivity reactions, including anaphylaxis. Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available during olipudase alfa-rpcp administration. If a severe hypersensitivity reaction (eg, anaphylaxis) occurs, olipudase alfa-rpcp should be discontinued immediately and appropriate medical treatment should be initiated. In patients with severe hypersensitivity reaction, a desensitization procedure to olipudase alfa-rpcp may be considered

Resources:

<https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?navitem=headerLogout>