ATRIO HEALTH PLANS

ASMD (Niemann-Pick Disease)
Xenpozyme (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.*

☐	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 ☐ Self-administered	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐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)

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**

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

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**

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

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

_____

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 Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. **Drug meets the following utilization management criteria:**
    a. Documentation of a diagnosis of acid sphingomyelinase deficiency (ASMD) Type A/B or Type B
    b. Confirmation of ASMD by enzyme assay demonstrating low ASM enzyme activity (<10% of controls)
    c. Clinical symptoms of ASMD including low diffusion capacity of the lungs for carbon monoxide (DLCO)
    d. and splenomegaly
    e. Must be prescribed by, or in consultation with, a specialist familiar with the treatment of lysosomal storage disorders.
3. 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:

- Acid sphingomyelinase deficiency

Off-Label Uses:

Xenpozyme

- N/A

Age Restrictions:

- N/A

Other Clinical Consideration:

- 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

Resouces:

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