Olipudase alfa-rpcp (Xenpozyme™)	Place of Service Outpatient Facility Administration Infusion Center Administration Home Infusion Administration HCPCS: J0218 per 1 mg

Condition(s) listed in policy (*see criteria for details*)

- Acid Sphingomyelinase deficiency (ASMD)

AHFS therapeutic class: Genetic or Enzyme Disorder: Replacement, Modifiers, Treatment

Mechanism of action: hydrolytic lysosomal sphingomyelin-specific enzyme

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Xenpozyme™ (olipudase-alfa-rpcp) based must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Acid sphingomyelinase deficiency (ASMD)

1. Documentation of SMPD1 gene mutation, AND
2. Being used for treatment of non-central nervous system manifestations (e.g. hepatosplenomegaly, thrombocytopenia, interstitial lung disease, hyperlipidemia, short stature)

Covered Doses

Dose escalation phase

	Pediatric (0-17 years)	Adult (18 years and older)
1st dose (Day 1/week 0)	0.03 mg/kg	0.1 mg/kg
2nd dose (week 2)	0.1 mg/kg	0.3 mg/kg
3rd dose (week 4)	0.3 mg/kg	0.3 mg/kg
4th dose (week 6)	0.3 mg/kg	0.6 mg/kg
5th dose (week 8)	0.6 mg/kg	0.6 mg/kg
6th dose (week 10)	0.6 mg/kg	1 mg/kg
7th dose (week 12)	1 mg/kg	2 mg/kg
8th dose (week 14)	2 mg/kg	3 mg/kg*
9th dose (week 16)	3 mg/kg*	---

Maintenance phase:
*Up to 3 mg/kg IV every 2 weeks

Coverage Period

Initial approval: 6 months
Reauthorization if meets criteria below: 1 year

1. Provider attestation of clinical response (e.g. improvement in spleen volume, liver volume, pulmonary function or platelet count)

ICD-10:

E75.249, E75.244, E75.241

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Olipudase alfa-rpcp (Xenpozyme™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT COVERED for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied: 4 mg, 20 mg (single-dose vial)

(6) References

- Xenpozyme™ (olipudase alfa-rpcp) [Prescribing information]. Cambridge, MA: Genzyme Corporation; 7/2023.
- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

(7) Policy Update

Date of last revision: 3Q2023
Date of next review: 1Q2024
Changes from previous policy version:

- No clinical change to policy following revision

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee