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.

**CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION **

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, Medi-Cal, ASO/Shared Advantage/HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.
For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

ADMINISTRATION OF OLIPUDASE-ALFA-RPCP (XENPOZYME™) IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. **Patient is initiating therapy (dose escalation phase up to 6 months) or is re-initiating after at least 6 months off therapy. (***Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.)*

Or

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. **Patient has experienced a previous severe adverse event on olipudase-alfa-rpcp (Xenpozyme™) based on documentation submitted.**

3. **Patient continues to experience moderate to severe adverse events on olipudase-alfa-rpcp (Xenpozyme™) based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**

4. **Patient is clinically unstable based on documentation submitted.**

5. **Patient is physically or cognitively unstable based on documentation submitted.**

(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: 20 mg single-dose vial

(6) References

- Xenpozyme™ (olipudase alfa-rpcp) [Prescribing information]. Cambridge, MA: Genzyme Corporation; 8/2022.
- 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: 2Q2023
Date of next review: 1Q2024
Changes from previous policy version:

- Added new HCPCS code, J0218 per 1 mg, effective 4/1/2023

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