

olipudase alfa-rpcp (Xenpozyme)

Commercial Medical Benefit Drug Policy

Place of Service

Home Infusion Administration

Infusion Center Administration

Outpatient Facility Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT

Mechanism of Action: hydrolytic lysosomal sphingomyelin-specific enzyme

HCPCS:

J0218:Injection, olipudase alfa-rpcp, 1 mg

How Supplied:

4 mg, 20 mg (lyophilized powder in a single-dose vial)

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

- Acid Sphingomyelinase Deficiency (ASMD)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, 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.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG™ Care Guidelines, 19th edition, 2015

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

- 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:

- Patient has experienced a previous severe adverse event on olipudase-alfa-rpcp (Xenpozyme) based on documentation submitted.
- 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.
- Patient is clinically unstable based on documentation submitted.
- Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Acid Sphingomyelinase Deficiency (ASMD)

Meets medical necessity if all the following are met:

- SMPD1 gene mutation
- 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)
1 st dose (Day 1/week 0)	0.03 mg/kg	0.1 mg/kg
2 nd dose (week 2)	0.1 mg/kg	0.3 mg/kg
3 rd dose (week 4)	0.3 mg/kg	0.3 mg/kg
4 th dose (week 6)	0.3 mg/kg	0.6 mg/kg
5 th dose (week 8)	0.6 mg/kg	0.6 mg/kg
6 th dose (week 10)	0.6 mg/kg	1 mg/kg
7 th dose (week 12)	1 mg/kg	2 mg/kg
8 th dose (week 14)	2 mg/kg	3 mg/kg*
9 th dose (week 16)	3 mg/kg*	---

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

Coverage Period:

Initial approval: 6 months

Reauthorization if meets criteria below: 1 year

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

ICD-10:

E75.241, E75.244, E75.249

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Xenpozyme (olipudase alfa-rpcp) [Prescribing information]. Cambridge, MA: Genzyme Corporation; 12/2023.

Review History

Date of Last Annual Review: 4Q2024

Changes from previous policy version:

- No clinical change following revision

Blue Shield of California Medication Policy to Determine Medical Necessity

Reviewed by P&T Committee