blue california
Promise Health Plan

olipudase alfa-rpcp (Xenpozyme)

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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

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

Acid Sphingomyelinase Deficiency (ASMD)
Meets medical necessity if all the following are met:
Initial

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

Reauthorization

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

Covered Doses:
Dose escalation phase

	Pediatric (0-17 years) Does not exceed the following:	**Adult (18 years and older)** Does not exceed the following:
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 intravenously every 2 weeks

Coverage Period:
Initial: 6 months
Reauthorization: Yearly

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. Genzyme Corporation, Cambridge, MA: 12/2024.

Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee