

Policy Name:	Xenopozyme (olipudase alfa)	Policy#:	3188P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Xenopozyme (olipudase alfa)

Statement of the Policy

Health Alliance Medical Plans will approve the use of Xenopozyme (olipudase alfa) under the specialty medical or Medicare Part B benefit if the following criteria are met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of acid sphingomyelinase deficiency (ASMD) type B or A/B confirmed by enzyme assay and supported by the following:
 - Diffusion capacity of the lungs for carbon monoxide (DLco) $\leq 70\%$ of predicted normal value
 - Spleen volume ≥ 6 multiples of normal for adults or ≥ 5 multiples of normal for pediatric patients
- 1.2 Prescribed by or in consultation with a specialist familiar with the treatment of this disease
- 1.3 Documentation of baseline liver function tests
- 1.4 Clinical review for coverage is completed by both a pharmacist and medical director

2. Exclusion Criteria

- 2.1 Patient has evidence of progressing nerve or brain abnormalities
- 2.2 Patient requires ventilator support

3. Approval Period

- 3.1 Initial: 12 months
- 3.2 Reauthorization: 12 months with documentation to support clinical benefit from therapy

CPT Codes

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HCPCS Codes

J0218	Injection, olipudase alfa-rpcp, 1 mg
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References

1. Xenopozyme (olipudase alfa) [prescribing information]. Cambridge, MA: Genzyme Corporation; December 2023.
2. Wasserstein M, Lachmann R, Hollak C, et al. A randomized, placebo-controlled clinical trial evaluating olipudase alfa enzyme replacement therapy for chronic acid sphingomyelinase deficiency (ASMD) in adults: one-year results. *Genet Med.* 2022;24(7):1425-1436.

3. Diaz GA, Jones SA, Scarpa M, et al. One-year results of a clinical trial of olipudase alfa enzyme replacement therapy in pediatric patients with acid sphingomyelinase deficiency. *Genet Med.* 2021;23(8):1543-1550.
4. Vanier MT. Niemann-Pick diseases. *Handb Clin Neurol* 2013; 113:1717.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.