Pharmacy Drug Policy & Procedure

Policy Name:	Xenpozyme (olipudase alfa)	Policy#:	3188P

Purpose of the Policy

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

Statement of the Policy

Health Alliance Medical Plans will approve the use of Xenpozyme (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) ≤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	
HCPCS Codes	
J0218	Injection, olipudase alfa-rpcp, 1 mg

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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