



**COLORADO**  
Department of Health Care  
Policy & Financing

1570 Grant Street  
Denver, CO 80203

## Health First Colorado (Colorado's Medicaid Program) Coverage Standards for Xenpozyme (olipudase alfa-rpcp)

September 2023

Xenpozyme (olipudase alfa-rpcp) requests will be evaluated for medical necessity and reviewed on a case-by-case basis for all Health First Colorado Members based on the following coverage standards. If request is for use outside of stated coverage standards, support with peer reviewed medical literature and/or subsequent clinical rationale shall be provided and will be evaluated at the time of request.

1. Member has a documented diagnosis of acid sphingomyelinase deficiency (ASMD) with non-central nervous system (CNS) manifestations confirmed by
  - a. Biallelic pathogenic variants in SMPD1 **AND**
  - b. Residual acid sphingomyelinase enzyme activity is <10% of controls
2. Member has clinical manifestations of ASMD defined as ONE of the following
  - a. Spleen volume of  $\geq 6$  MN for members  $\geq 18$  years of age or  $\geq 5$  MN for members <18 years of age **OR**
  - b. Pulmonary function  $DL_{CO} \leq 70\%$  of predicted normal
3. Member has the following baseline labs documented:
  - a. LFTs (ALT, AST, and total bilirubin)
  - b. Pulmonary function tests
  - c. Lipid levels
  - d. Platelet counts
4. Reauthorization requests may be approved if member has shown a documented clinical benefit with at least ONE of the following
  - a. Reduced liver volume from baseline
  - b. Reduced spleen volume from baseline
  - c. Improved platelet count from baseline
  - d. Improved  $DL_{CO}$  score from baseline

### References:

1. Xenpozyme [package insert]. Genzyme Corporation, 2023.

