| Field Name | Field Description |
|---|---|
| Prior Authorization Group Description | Enzyme Replacement Therapy for Acid Sphingomyelinase Deficiency (ASMD) |
| Drugs | Xenpozyme (olipudase alfa-rpcp) |
| Covered Uses | Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines. |
| Exclusion Criteria | N/A |
| Required Medical Information | See "Other Criteria" |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by, or in consultation with, a specialist experienced in the treatment of ASMD |
| Coverage Duration | If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. |
| Other Criteria<br><br>Date: 2/2024 | **Initial Authorization:**<br>• Medication is prescribed at an FDA approved dose<br>• Member has a diagnosis of ASMD confirmed by one of the following:<br>  o Deficiency in acid sphingomyelinase (ASM) enzyme activity (as measured by peripheral blood leukocytes, cultured skin fibroblasts, or dried blood spots)<br>  o Sphingomyelin phosphodiesterase-1 (SMPD1) gene mutation<br>• Member has a clinical presentation consistent with ASMD type B or type A/B<br>• Documentation of members height and weight<br>• Documentation of baseline ALT and AST within 1 month prior to initiation of treatment<br><br>**Re-Authorization:**<br>• Documentation or provider attestation of positive clinical response (i.e. improvement in splenomegaly, hepatomegaly, pulmonary function, etc.)<br>• Medication is prescribed at an FDA approved dose<br><br>**If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.** |