

PHARMACY POLICY STATEMENT

BILLING CODE	J3490, J3590; NDC: 58468-0050-1
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

If all the above requirements are met , the medication will be approved for 6 months.

For _____:

1. Chart notes must show improvement from baseline in at least one of the following: improved lung function (increased % predicted DLco), reduction of splenomegaly, reduction of hepatomegaly, increased platelet count, or improvement in children experiencing growth delay; AND
2. Chart notes must show that ALT and AST are continuing to be monitored.

If all the above requirements are met , the medication will be approved for an additional 1 year .

New policy for Xenpozyme created.

References:

1. Xenpozyme. Package Insert. Sanofi; 2022. Accessed October 21, 2022.
2. Xenpozyme. Prescribing information. Sanofi; 2022. Accessed October 21, 2022. <https://products.sanofi.us/xenpozyme/xenpozyme.pdf>
3. Xenpozyme: olipudase alfa-rpcp. Accessed October 21, 2022. <https://www.xenpozyme.com/>
4. Keam SJ. Olipudase Alfa: First Approval. *Drugs*. 2022 Jun;82(8):941-947. doi: 10.1007/s40265-022-01727-x. PMID: 35639287.
5. Xenpozyme (olipudase alfa-rpcp) approved by FDA as first disease-specific treatment for ASMD (non-CNS manifestations). Sanofi. Accessed October 21, 2022. <https://www.news.sanofi.us/2022-08-31-XenpozymeTM-olipudase-alfa-rpcp-approved-by-FDA-as-first-disease-specific-treatment-for-ASMD-non-CNS-manifestations?>
6. Diagnosing ASMD. ASMD. Updated March 2022. Accessed October 21, 2022. <https://www.asmdfacts.com/hcp/diagnosing-asmd>
7. Xenpozyme. Lexi-Drugs. Lexicomp Online. Wolters Kluwer Health, Inc. October 3, 2022. Accessed October 21, 2022. <http://online.lexi.com>
8. 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. *Genetics in Medicine*. 2021; 23 (8): 1543-1550. doi:10.1038/s41436-021-01156-3
9. 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. *Genetics in Medicine*. 2022; 24 (7): 1425-1436. doi:10.1016/j.gim.2022.03.021
10. McGovern M, Dionisi-Vici C, Giugliani R, et al. Consensus recommendation for a diagnostic guideline for acid sphingomyelinase deficiency. *Genetics in Medicine*. 2017; 19: 967–974. doi:10.1038/gim.2017.7

Effective date: 04/01/2023

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