Xenpozyme®
(olipudase alfa-rpcp)
For Injection, 20 mg

XENPOZYME® (olipudase alfa-rpcp)
BILLING & CODING GUIDE FOR REIMBURSEMENT

Using This Billing & Coding Guide

This guide is provided for informational purposes only and does not constitute legal or reimbursement advice. Use of this guide does not guarantee that the payer will provide coverage for XENPOZYME® (olipudase alfa-rpcp) and it is not intended to substitute for the physician's independent diagnosis or treatment of each patient.

TThe information contained herein is gathered from various resources and is subject to change. Providers are solely responsible for the accuracy of all coding and claims submitted for reimbursement to any third-party payer.

The codes listed herein may not apply to all patients or to all health plans. Conversely, additional codes not listed in this guide may apply to some patients. In addition, be aware that codes may change over time.

Sanofi is committed to working with providers, as well as public and private payers, to help ensure access to XENPOZYME as indicated. If you still have questions after reviewing this guide, please contact CareConnectPSS® Services at 1-800-745-4447, Option 3. Our CareConnectPSS Case Managers have expertise in reimbursement, insurance, case management, and the healthcare delivery system, and can provide information to physicians and their patients about the reimbursement process.

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INDICATION

XENPOZYME® (olipudase alfa-rpcp) is indicated for treatment of non–central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.

IMPORTANT SAFETY INFORMATION

WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

Patients treated with XENPOZYME have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Appropriate medical monitoring and support measures, including cardiopulmonary resuscitation equipment, should be readily available during XENPOZYME administration. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue XENPOZYME immediately, and initiate appropriate medical treatment. In patients with severe hypersensitivity reactions, a desensitization procedure to XENPOZYME may be considered.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions Including Anaphylaxis

See Boxed WARNING. Prior to XENPOZYME administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids.

- If a *severe* hypersensitivity reaction occurs, discontinue XENPOZYME immediately and initiate appropriate medical treatment. Consider the risks and benefits of re-administering XENPOZYME following severe hypersensitivity reactions.
- If a *mild or moderate* hypersensitivity reaction occurs, consider temporarily holding the infusion, slowing the infusion rate, and/or reducing the XENPOZYME dose.

Infusion-Associated Reactions

Antihistamines, antipyretics, and/or corticosteroids may be given prior to XENPOZYME administration to reduce the risk of infusion-associated reactions (IARs). However, IARs may still occur in patients after receiving pretreatment.

- If *severe* IARs occur, discontinue XENPOZYME immediately and initiate appropriate medical treatment. Consider the risks and benefits of re-administering XENPOZYME following severe IARs.
- If a *mild or moderate* IAR occurs, the infusion rate may be slowed or temporarily withheld, and/or the XENPOZYME dosage may be reduced.

Acute phase reactions (APRs), acute inflammatory responses accompanied by elevations in inflammatory serum protein concentrations, have been observed. Most APRs occurred at 48 hours post infusion during the dose escalation period. APRs were managed similar to other IARs.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Elevated Transaminase Levels

XENPOZYME may be associated with elevated transaminases (ALT, AST, or both) within 24 to 48 hours after infusion. Levels generally returned to levels observed prior to the XENPOZYME infusion. To manage the risk of elevated transaminase levels, assess ALT and AST:

- within one month prior to initiation of XENPOZYME,
- within 72 hours prior to any infusion during dose escalation, which includes the first 3 mg/kg dose, or prior to the next scheduled XENPOZYME infusion upon resuming treatment following a missed dose.

Upon reaching the recommended maintenance dose, transaminase testing is recommended to be continued as part of routine clinical management of ASMD.

Risk of Fetal Malformations During Dosage Initiation or Escalation in Pregnancy

XENPOZYME dosage initiation or escalation, at any time during pregnancy, is not recommended as it may lead to elevated sphingomyelin metabolite levels that may increase the risk of fetal malformations. The decision to continue or discontinue XENPOZYME maintenance dosing in pregnancy should consider the female's need for XENPOZYME, the potential drug-related risks to the fetus, and the potential adverse outcomes from untreated maternal ASMD disease.

Verify pregnancy status in females of reproductive potential prior to initiating XENPOZYME treatment. Advise females of reproductive potential to use effective contraception during XENPOZYME treatment and for 14 days after the last dose if XENPOZYME is discontinued.

ADVERSE REACTIONS

- Most frequently reported adverse drug reactions in adults (incidence ≥10%) were headache, cough, diarrhea, hypotension, and ocular hyperemia.
- Most frequently reported adverse drug reactions in pediatric patients (incidence ≥20%) were pyrexia, cough, diarrhea, rhinitis, abdominal pain, vomiting, headache, urticaria, nausea, rash, arthralgia, pruritus, fatigue, and pharyngitis.

Coding Summary

Diagnosis

Codes used to formalize diagnosis come from the *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM), which was originally developed by the World Health Organization.[1] There are several ICD-10-CM diagnosis codes for acid sphingomyelinase deficiency (ASMD), which is historically known as Niemann-Pick disease types A, A/B, and B.[2] Depending on the diagnosis by the treating physicians, any of the codes in the bottom row can be used in conjunction with the administration of XENPOZYME.

ICD-10-CM Code[2]	
E-00-E89	Endocrine, nutritional, and metabolic diseases
▶ E75	Disorders of sphingolipid metabolism and other lipid storage disorders
▶ E75.24	Niemann-Pick disease, acid sphingomyelinase deficiency (ASMD)
▶ E75.240	Niemann-Pick disease type A
▶ E75.241	Niemann-Pick disease type B
▶ E75.244	Niemann-Pick disease type A/B
▶ E75.248	Other Niemann-Pick disease
▶ E75.249	Niemann-Pick disease, unspecified (NOS)

National Drug Code (NDC)

NDC codes are unique 3-segment numbers that serve as a universal product identifier for human drugs in the US.[3] XENPOZYME has two NDC codes, one for each vial size (see table below). On its packaging, XENPOZYME displays a 10-digit NDC code. Note that when an NDC is used for medical claims adjudication, use of an 11-digit NDC code may be required.[4] Payer requirements for NDC use and format may vary. Please contact each payer for specific coding policies.

	XENPOZYME 20 mg	XENPOZYME 4 mg
10-digit NDC	58468-0050-1	58468-0051-1
11-digit NDC	58468-0050-01	58468-0051-01

Place of Service Codes

Because XENPOZYME can be administered in various settings (eg, infusion center, physician office, or patient's home if recommended by the treating physician), it is important to populate a claim with the appropriate 2-digit Place of Service (POS) code.[5] Always verify the preferred POS codes for your patient's health plan before submitting a claim.

IMPORTANT SAFETY INFORMATION

WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

Patients treated with XENPOZYME have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Appropriate medical monitoring and support measures, including cardiopulmonary resuscitation equipment, should be readily available during XENPOZYME administration. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue XENPOZYME immediately, and initiate appropriate medical treatment. In patients with severe hypersensitivity reactions, a desensitization procedure to XENPOZYME may be considered.

Please see Important Safety Information on pages 3-4 and full Prescribing Information, including Boxed WARNING.

Coding Summary (cont'd)

CPT® Code

Current Procedural Terminology (CPT) codes are used to describe procedures performed on a patient and/or how a drug or supply being billed was administered.[6] The CPT codes most commonly associated with the administration of IV-infused biologic therapies like XENPOZYME are listed below. Confirm preferred coding policy with payer prior to administration whenever possible.

Infusion codes[7]	
96365	Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Each additional hour (list separately in addition to code for primary procedure); report 96366 for infusion intervals of greater than 30 minutes beyond 1-hour increments*

*Per CMS guidelines, if the incremental amount of infusion time is 30 minutes or less, the time is not to be billed separately. Note that some payers may require reporting the actual number of minutes on the claim.

CPT® is a registered trademark of the American Medical Association.

HCPCS Procedure Code

The Healthcare Common Procedure Coding System (HCPCS) is a standardized system to facilitate submission of healthcare claims by medical providers.[8] As part of that system, XENPOZYME has been issued a permanent J code as of April 1, 2023,[9] which is listed below. This permanent J code replaces any previously used temporary codes. Claims filed with temporary J or C codes after April 1 will no longer be valid. Note: The fact that a permanent J code exists does not imply coverage, only that the product may be reimbursed if covered. Each payer makes determinations on coverage and payment outside this coding process.

Permanent J Code[9]		
Code #	**Short Description**	**Long Description**
J0218	Inj olip alfa-rpcp 1 mg	Injection, olipudase alfa-rpcp, 1 mg

JW modifier: Medicare and some commercial payers require providers and suppliers to report the JW modifier on Part B drug claims for discarded drugs and biologicals.[10] Refer to each payer's policy for coding and documentation requirements.

CMS, Centers for Medicare & Medicaid Services; IV, intravenous.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions Including Anaphylaxis

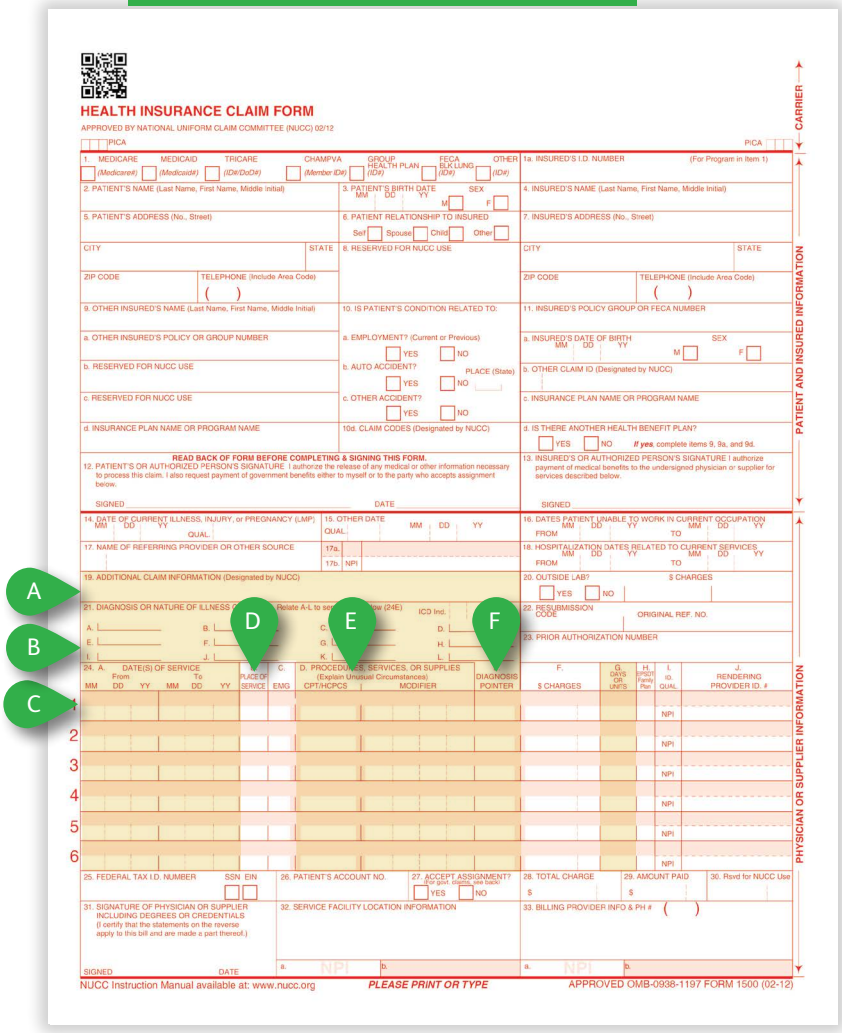
See Boxed WARNING. Prior to XENPOZYME administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids.

- If a *severe* hypersensitivity reaction occurs, discontinue XENPOZYME immediately and initiate appropriate medical treatment. Consider the risks and benefits of re-administering XENPOZYME following severe hypersensitivity reactions.

Sample Reimbursement Forms

The sample claim forms shown below are intended for use only as a reference. Reimbursement codes are subject to continual change. Please confirm the accuracy of the codes you use to bill for the prescribed medications with each payer.

Annnotated claim form CMS-1500[11]



Physician Office

A **Field 19:** Provide any required detailed information such as drug name, total dosage and strength, method of administration, 11-digit NDC, and basis of measurement (attach separately if needed)

B **Field 21**: Enter the appropriate ICD-10-CM diagnosis codes

C **Field 24A:** Enter the date of service for each procedure. Include NDC information, if required, in the shaded areas above each date

D **Field 24B:** Enter appropriate Place of Service code (office, infusion center, etc)

E **Field 24D:** Include payer-required details such as HCPCS (J code), CPT codes, and modifiers. When reporting a "not otherwise classified" (NOC) code, include a detailed description in Field 19

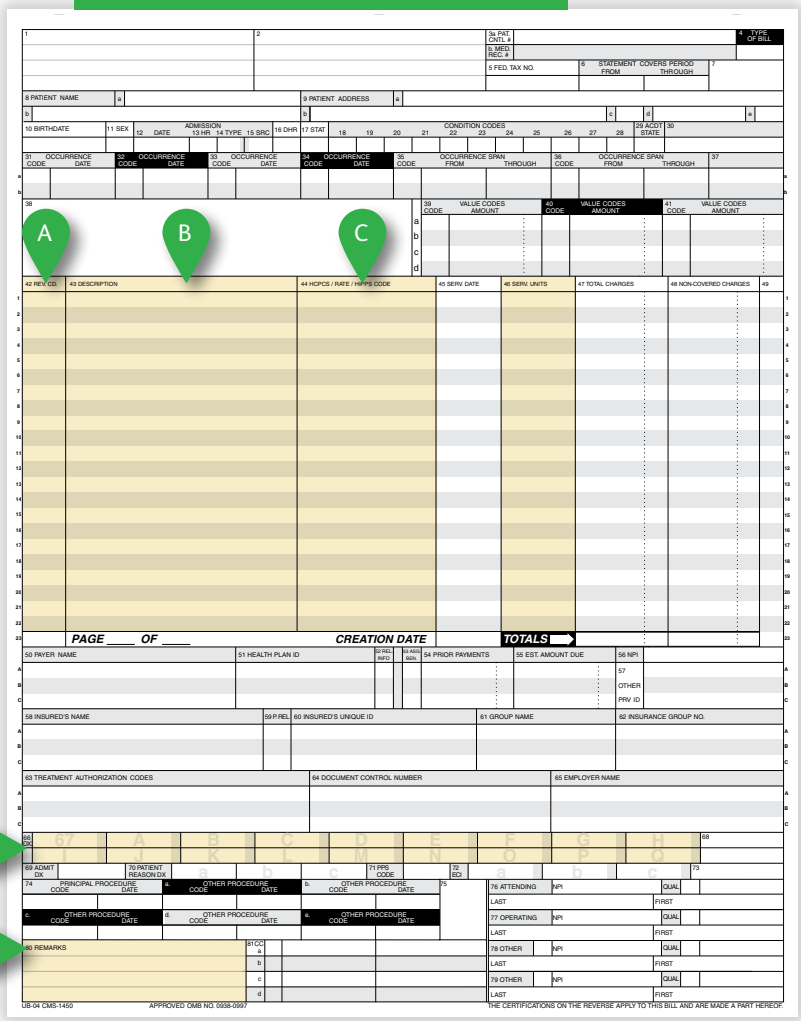
F **Field 24E:** Enter the diagnosis code reference letter or number from Field 21 that relates to the date of service and the services or procedures performed that are entered on that same line under 24D

This sample form is for informational purposes only.

Sample Reimbursement Forms (cont'd)

The sample claim form shown below is an example of the form used for claims submitted by hospitals, nursing facilities, and other inpatient institutions. Although fields are organized differently than in the CMS-1500, the information captured is essentially the same.

Annotated claim form CMS-1450[12]



Outpatient Hospital

- **A** — **Field 42:** Enter the 4-digit revenue code that best describes the service provided, in accordance with the hospital billing policy
- **B** — **Field 43:** Enter the corresponding description of service (eg, IV therapy)
- **C** — **Field 44:** Include payer-required details such as relevant HCPCS and CPT codes
- **D** — **Field 66:** Enter appropriate ICD-10-CM diagnosis codes
- **E** — **Field 80:** Provide any required detailed information such as drug name, total dosage and strength, method of administration, and 11-digit NDC (attach separately if needed)

This sample form is for informational purposes only.

Dosing Information

Dosing Protocols[13]

XENPOZYME is administered by intravenous infusion every 2 weeks. Dosage is based on body weight and the respective dose-escalation regimen, with infusion times ranging from approximately 20 minutes up to 4 hours, depending on patient characteristics.

- Therapy with XENPOZYME should be directed in consultation with physicians knowledgeable in the management of ASMD
- In order to avoid dosing errors including overdosage, follow all instructions for dosage and administration in Section 2 of the full Prescribing Information

XENPOZYME requires 2 dosing phases[13,*]:

- A dose-escalation phase lasting a minimum of 14 weeks for adults and a minimum of 16 weeks for pediatric patients;
- An ongoing maintenance phase, for which the target maintenance dose is 3 mg/kg every 2 weeks

In order to monitor for potential life-threatening hypersensitivity and infusion-related reactions, XENPOZYME should be administered in a clinic or hospital setting during the dose-escalation phase as well as during any re-escalation after missed doses (see Section 2.4 of the Prescribing Information for more details)[13]

- Home infusion by a healthcare provider may be an option during the maintenance phase, if recommended by the treating physician and if dosing remains constant

*The rapid metabolism of accumulated sphingomyelin by XENPOZYME generates pro-inflammatory breakdown products, which may induce infusion-associated reactions and/or transient liver enzyme elevations. A dose-escalation regimen may reduce the frequency and/or severity of these adverse events.[14]

Please refer to Sections 2.2 to 2.7 of the full Prescribing Information for complete details regarding dose escalation, as well as additional details regarding preparation and administration.

How supplied[13]

XENPOZYME is supplied as a sterile white to off-white lyophilized powder for reconstitution in a single-dose vial. XENPOZYME does not contain any preservatives. After reconstitution, the resultant solution concentration is 4 mg/mL.

Storage[13]

Store refrigerated at 2°C to 8°C (36°F to 46°F). Do not freeze. Reconstituted vials can be stored for up to 24 hours at refrigerated temperature, or at controlled temperature at 20°C to 25°C (68°F to 77°F) for up to 6 hours.

HCP, healthcare provider.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity Reactions Including Anaphylaxis (cont'd)

- If a *mild or moderate* hypersensitivity reaction occurs, consider temporarily holding the infusion, slowing the infusion rate, and/or reducing the XENPOZYME dose.

Please see Important Safety Information on pages 3-4 and full Prescribing Information, including Boxed WARNING.

Additional Billing & Coding Considerations

Reimbursement Considerations

XENPOZYME is designed to be prepared and administered by a healthcare provider. The drug costs are expected to be covered under the Medicare Part B benefit.[15] Please refer to the individual patient's plan to determine any applicable coverage requirements. The specifics of coverage may vary by payer.

When Filing a Claim

It is recommended that XENPOZYME coverage be confirmed with all payers prior to patient administration, as patient benefits vary among payers and by plans.

Some payers also have policies that may affect coverage for XENPOZYME. These include:

- **Setting of care:** Some payers may have coverage rules that restrict where patients can receive certain types of medical care, such as infusions
- **Network providers:** Some payers have exclusive contracts with in-network or participating providers to administer infusion therapies. These may include contracts for coverage in physician offices and outpatient settings or with specialty pharmacies that provide drugs and biologics to the provider
- **Prior authorization:** Plans may require providers to obtain prior authorization (e.g., through documentation of medical necessity) to begin treatment. Check with the payer to determine the process, requirements, and method for requesting authorization

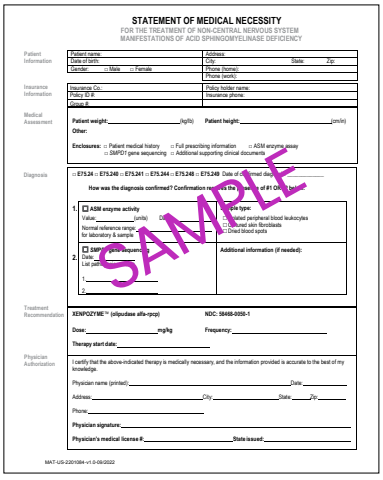
Documenting Medical Necessity

As a medication used to treat an extremely rare disease, XENPOZYME may be unfamiliar to some insurers, who might require additional information in order to process either a prior authorization or a claim upon receipt. Examples of documentation that may be required:

- Statement of medical necessity from the treating physician
- XENPOZYME Prescribing Information
- Details on the patient's case history, previous therapy, and clinical course

Example of a Statement of Medical Necessity

Note that some payers have their own specific form for medical necessity, which should be used in those cases. Check with the patient's insurer for details that will be needed in the statement of medical necessity and how the insurer prefers to receive this information.



STATEMENT OF MEDICAL NECESSITY

FOR THE TREATMENT OF NON-CENTRAL NERVOUS SYSTEM MANIFESTATIONS OF ACID SPHINGOMYELINASE DEFICIENCY

Patient Information

Patient name: | Address:
Date of birth: | City: State: Zip:
Gender: ☐ Male ☐ Female | Phone (home):
Phone (work):

Insurance Information

Insurance Co.: | Policy holder name:
Policy ID #: | Insurance phone:
Group #

Medical Assessment

Patient weight: (kg/lb) Patient height: (cm/in)
Other:

Enclosures: ☐ Patient medical history ☐ Full prescribing information ☐ ASM enzyme assay ☐ SMPD1 gene sequencing ☐ Additional supporting clinical documents

Diagnosis

☐ E75.24 ☐ E75.240 ☐ E75.241 ☐ E75.244 ☐ E75.248 ☐ E75.249 Date of confirmed diagnosis:

How was the diagnosis confirmed? Confirmation via the ☐ of #1 OR ☐

1. ☐ ASM enzyme activity
Value: (units) Date:
Normal reference range for laboratory & sample type:
☐ Cultured peripheral blood leukocytes
☐ Cultured skin fibroblasts
☐ Dried blood spots

2. ☐ SMPD1 gene sequencing
Date:
List pathogenic variants:
1.
2.
Additional information (if needed):

SAMPLE

Treatment Recommendation

XENPOZYME™ (olipudase alfa-rpcp) NDC: 38468-9000-1
Dose: mg/kg Frequency:
Therapy start date:

Physician Authorization

I certify that the above-indicated therapy is medically necessary, and the information provided is accurate to the best of my knowledge.
Physician name (printed): Date:
Address: City: State: Zip:
Phone:
Physician signature:
Physician's medical license #: State issued:

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infusion-Associated Reactions

Antihistamines, antipyretics, and/or corticosteroids may be given prior to XENPOZYME administration to reduce the risk of infusion-associated reactions (IARs). However, IARs may still occur in patients after receiving pretreatment.

Patient Support Services

careconnect™
PERSONALIZED SUPPORT SERVICES

CareConnectPSS®

Personalized support services, designed to support each patient's unique journey. Support includes:

- Dedicated CareConnectPSS Case Managers and Patient Education Liaisons
- Disease-specific content and resources, including information about how rare diseases may run in families
- Information regarding genetic testing options and diagnostics
- Care coordination for treatment
- Help with handling insurance issues

CareConnectPSS Co-Pay Program

Helps eligible patients in the United States who are prescribed XENPOZYME pay for eligible out-of-pocket drug costs and specified infusion-related charges, including co-pays, coinsurance, and deductibles, up to the program maximum.*

CareConnectPSS Patient Assistance Program

Provides XENPOZYME at no cost to eligible patients who do not have health insurance or cannot access XENPOZYME under the terms of their insurance plan(s), until insurance coverage for XENPOZYME is secured.†

To find out more, contact a Case Manager at

1-800-745-4447 (Option 3)

or visit www.CareConnectPSS.com

*Patients must be eligible under applicable state law(s). Patients whose medication or infusion-related costs are covered by a state or federal health care program, including but not limited to Medicare, Medicare Part D, Medigap, Medicaid, Veterans Affairs (VA), Department of Defense (DoD), or TRICARE, are not eligible. Patient must live in the US or a US territory. Other terms and conditions of the Program apply.

Co-Pay Program does not cover or provide support for MD office visits/evaluations, nursing services/observation periods, blood work, x-rays or other testing, pre-medications/other medications, transportation or other related services associated with treatment. In accordance with state law, infusion-related costs are not covered for commercially insured patients residing in MA or RI. Sanofi reserves the right to modify or discontinue the program at any time without notice. Savings may vary depending on patients' out-of-pocket costs. All program details provided upon registration.

†Patient Assistance Program eligibility criteria include the following:
- Patient must not have insurance coverage or not have access to XENPOZYME under the terms of the patient's insurance plan(s)
- Patient must live in the US or a US territory
- Patient must have a valid prescription from a health care provider licensed in the US or a US territory
- Other terms and conditions of the Program apply

TRICARE is a registered trademark of the Department of Defense, Defense Health Agency.

Ordering Information for XENPOZYME

To order XENPOZYME, contact one of the authorized distributors listed below.

Specialty Distributor	Phone	Web
Cardinal Health	800-926-3161	cardinalhealth.com
Cardinal Health Specialty Pharmaceutical Distribution	855-855-0708	cardinalhealth.com
McKesson Specialty Health	800-482-6700	mscs.mckesson.com
McKesson Pharmaceutical Distribution	855-625-4677	mckesson.com
McKesson Plasma and Biologics (MPB)	877-625-2566	connect.mckesson.com Email: mpborders@mckesson.com
Morris & Dickson Specialty Distribution	800-388-3833	mdspecialtydist.com

XENPOZYME can be ordered directly from the manufacturer by contacting Sanofi.

Direct Order Contact	Phone	Email
Rare Disease Product Services	800-745-4447, Option 1	CO@Sanofi.com

XENPOZYME is also available through most specialty pharmacies.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infusion-Associated Reactions (cont'd)

- If *severe* IARs occur, discontinue XENPOZYME immediately and initiate appropriate medical treatment. Consider the risks and benefits of re-administering XENPOZYME following severe IARs.
- If a *mild or moderate* IAR occurs, the infusion rate may be slowed or temporarily withheld, and/or the XENPOZYME dosage may be reduced.

References

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15. Medicare. Prescription drug (outpatient). Accessed October 21, 2024. https://www.medicare.gov/coverage/prescription-drugs-outpatient

Please see Important Safety Information on pages 3-4 and full Prescribing Information, including Boxed WARNING.

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