



Xenpozyme

CareFirst Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518**. For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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Patient's Name: _____ **Date:** _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ☐ Same as Requesting Provider

Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ☐ Same as Referring Provider ☐ Same as Requesting Provider

Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____ *kg*

Patient Height: _____ *cm*

What is the ICD-10 code? _____

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

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Site of Service Questions:

- A. Where will this drug be administered?
- ☐ Ambulatory surgical, *skip to Clinical Criteria Questions*
 - ☐ Home infusion, *skip to Clinical Criteria Questions*
 - ☐ Off-campus Outpatient Hospital, *Continue to B*
 - ☐ On-campus Outpatient Hospital, *Continue to B*
 - ☐ Physician office, *skip to Clinical Criteria Questions*
 - ☐ Pharmacy, *skip to Clinical Criteria Questions*
- B. Is the patient less than 14 years of age?
- ☐ Yes, *skip to Clinical Criteria Questions*
 - ☐ No, *Continue to C*
- C. Is this request to continue previously established treatment with the requested medication? **ACTION REQUIRED:** *If No, please attach supporting clinical documentation.*
- ☐ Yes - This is a continuation of an existing treatment., *Continue to D*
 - ☐ No - This is a new therapy request (patient has not received requested medication in the last 6 months), *skip to Clinical Criteria Questions*
- D. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of the infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? **ACTION REQUIRED: If Yes, please attach supporting clinical documentation.**
- ☐ Yes, *skip to Clinical Criteria Questions*
 - ☐ No, *Continue to E*
- E. Does the patient have laboratory confirmed anti-olipudase alfa-rpcp IgE antibodies? **ACTION REQUIRED: If Yes, please attach supporting clinical documentation.**
- ☐ Yes, *skip to Clinical Criteria Questions*
 - ☐ No, *Continue to F*
- F. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment? **ACTION REQUIRED: If Yes, please attach supporting clinical documentation.**
- ☐ Yes, *skip to Clinical Criteria Questions*
 - ☐ No, *Continue to G*
- G. Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting? **ACTION REQUIRED: If Yes, please attach supporting clinical documentation.**
- ☐ Yes, *skip to Clinical Criteria Questions*
 - ☐ No, *Continue to H*
- H. Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver? **ACTION REQUIRED: If Yes, please attach supporting clinical documentation.**
- ☐ Yes, *skip to Clinical Criteria Questions*
 - ☐ No, *Continue to I*
- I. Are **all** alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) **greater than** 30 miles from the patient's home? **ACTION REQUIRED: If Yes, please attach supporting documentation.**
- ☐ Yes, *continue to Clinical Criteria Questions*
 - ☐ No, *continue to Clinical Criteria Questions*

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Criteria Questions:

1. What is the diagnosis?

☐ Acid sphingomyelinase deficiency (ASMD), *Continue to 2*

☐ Other, please specify. _____, *Continue to 2*

2. Will the requested drug be prescribed by or in consultation with a physician knowledgeable in the management of acid sphingomyelinase deficiency (ASMD)?

☐ Yes, *Continue to 3*

☐ No, *Continue to 3*

3. Is the patient currently receiving treatment with the requested drug?

☐ Yes, *Continue to 4*

☐ No, *Continue to 5*

4. Has the patient demonstrated a response to therapy (e.g., improvement in lung function, reduction in spleen volume, reduction in liver volume, improvement in platelet count, improvement in linear growth progression)?

ACTION REQUIRED: If Yes, attach documentation (e.g., chart notes, lab results) of a response to therapy (e.g., improvement in lung function, reduction in spleen volume, reduction in liver volume, improvement in platelet count, improvement in linear growth progression).

☐ Yes, *No Further Questions*

☐ No, *No Further Questions*

5. Will the requested drug be used for the treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD)?

☐ Yes, *Continue to 6*

☐ No, *Continue to 6*

6. Was the diagnosis confirmed by a documented deficiency of acid sphingomyelinase as measured in peripheral leukocytes, cultured fibroblasts, or lymphocytes? **ACTION REQUIRED:** If Yes, attach acid sphingomyelinase enzyme assay results supporting the diagnosis.

☐ Yes, *No Further Questions*

☐ No, *Continue to 7*

7. Was the diagnosis confirmed by genetic testing documenting pathogenic variant(s) in the sphingomyelin phosphodiesterase-1 (SMPD1) gene? **ACTION REQUIRED:** If Yes, attach genetic testing results supporting the diagnosis.

☐ Yes, *No Further Questions*

☐ No, *No Further Questions*

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X _____

Prescriber or Authorized Signature

Date (mm/dd/yy)

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