Vyondys 53

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.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

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

 Vyondys 53 3463-A SGM SOC 5381-A - 11/2024.

CVS Caremark Specialty Pharmacy ● 2211 Sanders Road NBT-6 ● Northbrook, IL 60062
Phone: 1-888-877-0518 ● Fax: 1-855-330-1720 ● www.caremark.com

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. 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 F*

F. 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 G*

G. 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 H*

H. 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?

❒ Duchenne muscular dystrophy (DMD), *Continue to 2*

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

2. Will the requested medication be prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD)?

❒ Yes, *Continue to 3*
❒ No, *Continue to 3*

3. Will the requested medication be used concomitantly with viltolarsen?

❒ Yes, *Continue to 4*
❒ No, *Continue to 4*

4. Does the patient's dose exceed 30 mg/kg once weekly?

❒ Yes, *Continue to 5*
❒ No, *Continue to 5*

5. Is the patient currently receiving treatment with the requested medication?

❒ Yes, *Continue to 6*
❒ No, *Continue to 7*

6. Was the patient previously established on treatment and is re-starting therapy with the requested medication after administration of gene replacement therapy?

❒ Yes, *Continue to 7*
❒ No, *Continue to 15*

7. Was genetic testing conducted to confirm the diagnosis of Duchenne muscular dystrophy (DMD)?

❒ Yes, *Continue to 8*
❒ No, *Continue to 8*

8. Was genetic testing conducted to identify the specific type of DMD gene mutation? ***ACTION REQUIRED***: If Yes, attach laboratory confirmation of Duchenne muscular dystrophy (DMD) diagnosis with a DMD gene mutation that is amenable to exon 53 skipping (refer to examples in Appendix).

❒ Yes, *Continue to 9*
❒ No, *Continue to 11*

9. Please indicate the DMD gene mutation:

❒ Please specify DMD gene mutation. _____, *Continue to 10*

❒ Unknown, *Continue to 11*

10. Is the DMD gene mutation amenable to exon 53 skipping?

❒ Yes, *Continue to 11*
❒ No, *Continue to 11*

11. Is the patient able to achieve an average distance of at least 250 meters while walking independently over 6 minutes?

❒ Yes, *Continue to 12*
❒ No, *Continue to 12*

12. Will treatment with the requested medication be initiated prior to age 16?
❒ Yes, *Continue to 13*
❒ No, *Continue to 13*

13. Has the patient previously received gene replacement therapy for DMD (e.g., Elevidys)?
❒ Yes, *Continue to 14*
❒ No, *No Further Questions*

14. Has the patient experienced a worsening in clinical status (e.g., decline in ambulatory function) since receiving gene replacement therapy for DMD (e.g., Elevidys)? ***ACTION REQUIRED***: If Yes, attach medical records confirming a worsening in clinical status since receiving gene replacement therapy.
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

15. Has the patient demonstrated a response to therapy as evidenced by remaining ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent)? ***ACTION REQUIRED***: If Yes, attach documentation (e.g., chart notes) of response to therapy.
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

APPENDIX

Examples of DMD gene mutations (exon deletions) amenable to exon 53 skipping (not an all-inclusive list):

1. Deletion of exon 52
2. Deletion of exon 45-52
3. Deletion of exon 47-52
4. Deletion of exon 48-52
5. Deletion of exon 49-52
6. Deletion of exon 50-52

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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