Vyondys 53

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*

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

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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 Questions*
- ❑ Home infusion, *skip to Clinical Questions*
- ❑ Off-campus Outpatient Hospital
- ❑ On-campus Outpatient Hospital
- ❑ Physician office, *skip to Clinical Questions*
- ❑ Pharmacy, *skip to Clinical Questions*

B. Is this request to continue previously established treatment with the requested medication?
- ❑ Yes - This is a continuation of an existing treatment.
- ❑ No - This is a new therapy request (patient has not received requested medication in the last 6 months). *skip to Clinical Criteria Questions*

C. 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 infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? ***ACTION REQUIRED: Attach supporting clinical documentation.*** ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

D. 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: Attach supporting clinical documentation.*** ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

E. Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting? ***ACTION REQUIRED: Attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

F. 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: Attach supporting clinical documentation.*** ❑ Yes ❑ No

Clinical Criteria Questions:

1. What is the diagnosis?
   - ❑ Duchenne muscular dystrophy
   - ❑ Other _____
2. What is the ICD-10 code? _____
3. What is the patient's weight in kilograms? _____kg
4. Is the requested drug prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy? ❑ Yes ❑ No
5. Will the requested medication be used concomitantly with vitolarsen (Viltepso)? ❑ Yes ❑ No
6. Does the patient's dose exceed 30 mg/kg once weekly? ❑ Yes ❑ No
7. Is the request for continuation of therapy with the requested drug? ❑ Yes ❑ No *If No, skip to #10*
8. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to # 10* ❑ Yes ❑ No ❑ Unknown
9. 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 *No further questions*
10. Was genetic testing conducted to confirm the diagnosis of Duchenne muscular dystrophy? ❑ Yes ❑ No

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11. Was genetic testing conducted to identify the specific type of DMD gene mutation? ***ACTION REQUIRED: If Yes, attach a copy of the genetic testing results.***
    ❑ Yes - Please indicate the DMD gene mutation _____ ❑ No
12. Is the DMD gene mutation amenable to exon 53 skipping? ❑ Yes ❑ No
13. Is the patient able to achieve an average distance of at least 250 meters while walking independently over 6 minutes? ❑ Yes ❑ No
14. Will treatment with the requested drug be initiated prior to age 16? ❑ Yes ❑ No

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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