



Vyondys 53

Prior Authorization Request

Your patient's benefit plan requires prior authorization for certain medications. In order to make appropriate medical necessity determinations, your patient's diagnosis and other clinical information is required. **Please complete the information requested on the form below and fax this form along with supporting clinical documentation to Priority Partners, toll-free at 1-866-212-4756 to initiate the review process.** If you have questions regarding the prior authorization please contact Priority Partners at 888-819-1043 Option 4.

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

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*

Please indicate the place of service for the requested drug:

- Ambulatory Surgical (POS Code 24) Home (POS Code 12)
- Off Campus Outpatient Hospital (POS Code 19) On Campus Outpatient Hospital (POS Code 22)
- Office (POS Code 11)

Drug Information:

Strength/Measure _____ *Units* ml Gm mg ea Un
Directions(sig) _____ *Route of administration* _____
Dosing frequency _____

Criteria Questions:

What is the ICD-10 code? _____

1. What is the diagnosis?

- Duchenne muscular dystrophy (DMD), *Continue to 2*
- Other, please specify. _____, *Continue to 2*

2. Is the requested drug 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*

Send completed form to: Priority Partners Fax: 1-866-212-4756

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Vyondys 53 SGM 3463-A – 09/2023.

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3. Will the requested medication be used concomitantly with viltolarsen (Viltepso)?
 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 drug?
 Yes, *Continue to 6*
 No, *Continue to 8*
6. Was the patient previously established on treatment and is re-starting therapy with the requested drug after administration of gene replacement therapy?
 Yes, *Continue to 8*
 No, *Continue to 7*
7. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program?
 Yes, *Continue to 8*
 No, *Continue to 17*
 Unknown, *Continue to 8*
8. Was genetic testing conducted to confirm the diagnosis of Duchenne muscular dystrophy (DMD)?
 Yes, *Continue to 9*
 No, *Continue to 9*
9. 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. **ACTION REQUIRED:** Submit supporting documentation
 Yes, *Continue to 10*
 No, *Continue to 12*
10. Please indicate the DMD gene mutation:
 Please specify DMD gene mutation. _____, *Continue to 11*
 Unknown, *Continue to 12*
11. Is the DMD gene mutation amenable to exon 53 skipping?
 Yes, *Continue to 12*
 No, *Continue to 12*
12. Is the patient able to achieve an average distance of at least 250 meters while walking independently over 6 minutes?
 Yes, *Continue to 13*
 No, *Continue to 13*
13. Will treatment with the requested drug be initiated prior to age 16?
 Yes, *Continue to 14*
 No, *Continue to 14*

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14. Has the patient previously received gene replacement therapy for DMD (e.g., Elevidys)?

Yes, *Continue to 15*

No, *Continue to 16*

15. 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, please attach medical records confirming a worsening in clinical status since receiving gene therapy. **ACTION REQUIRED:** Submit supporting documentation

Yes, *Continue to 16*

No, *Continue to 16*

16. What is the patient's weight in kilograms (kg)?

_____kg, *No Further Questions*

17. 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. **ACTION REQUIRED:** Submit supporting documentation

Yes, *Continue to 18*

No, *Continue to 18*

18. What is the patient's weight in kilograms (kg)?

_____kg, *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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