

Elevidys (delandistrogene moxeparvovec-rokl) Prior Authorization Form

Member Name: _____ **Date of Birth:** _____ **Member ID#:** _____

Drug Information

Physician billing (HCPCS code: _____) Pharmacy billing (NDC: _____)

Dose: _____ **Regimen:** _____ **Start Date (or date of next dose):** _____

Billing Provider Information

Provider NPI: _____ **Provider Name:** _____

Provider Phone: _____ **Provider Fax:** _____

Prescriber Information

Prescriber NPI: _____ **Prescriber Name:** _____

Prescriber Phone: _____ **Prescriber Fax:** _____ **Specialty:** _____

Criteria

For Authorization: (approvals will be for 1 dose per lifetime)

1. Please indicate the diagnosis and information:
 - Duchenne muscular dystrophy (DMD)
 - Other _____
2. Does the member have a confirmed mutation in the DMD gene? Yes ___ No ___
 - a. If yes, please submit results of genetic test.
3. Is the member ambulatory? Yes ___ No ___
 - a. Please submit the results of 1 of the following tests (select one):
 - ___ North Star Ambulatory Assessment (NSAA)
 - ___ 6-minute walk test (6MWT)
 - ___ 10-meter walk test (10mWT)
 - ___ Ascend 4 Steps
 - ___ Time to Rise (TTR)
 - ___ 100-meter timed test
4. Is Elevidys being prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD)? Yes ___ No ___
5. Are the member's baseline anti-AAVrh74 total binding antibody titers <1:400? Yes ___ No ___
6. Does the member have any deletion in exon 8 and/or exon 9 in the DMD gene? Yes ___ No ___
7. Does the member have a deletion in the DMD gene in exon 1-17 and/or exons 59-71? Yes ___ No ___
 - a. If yes, will prescriber monitor the member for severe immune-mediated myositis reaction? Yes ___ No ___
8. Does the member have preexisting liver impairment [defined as gamma-glutamyl transferase (GGT) >2x upper limit of normal or total bilirubin > the upper limit of normal not due to Gilbert's syndrome], or active hepatic viral infection? Yes ___ No ___

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<p>PLEASE PROVIDE THE INFORMATION REQUESTED AND RETURN TO:</p> <p>University of Oklahoma College of Pharmacy Pharmacy Management Consultants Product Based Prior Authorization Unit</p> <p>Fax: 1-800-224-4014 Phone: 1-800-522-0114 Option 4</p>	<p><u>CONFIDENTIALITY NOTICE</u></p> <p><i>This document, including any attachments, contains information which is confidential or privileged. If you are not the intended recipient, be aware that any disclosure, copying, distribution, or use of the contents of this information is prohibited. If you have received this document in error, please notify the sender immediately by telephone to arrange for the return of the transmitted documents or to verify their destruction.</i></p>
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Member Name: _____ **Date of Birth:** _____ **Member ID#:** _____

Criteria

For Authorization (continued):

- 9. Will the member receive any vaccinations within 4 weeks of Elevidys infusion? Yes ___ No ___
- 10. Does the member have any active or recent infections (within 4 weeks of Elevidys infusion)? Yes ___ No ___
 - a. If yes, will the Elevidys infusion be postponed? Yes ___ No ___
- 11. Has the member been instructed to maintain proximity to an appropriate health care facility, as determined by the health care provider, for at least 2 months following the Elevidys infusion? Yes ___ No ___
- 12. Will the member initiate a corticosteroid regimen one day prior to the infusion of Elevidys and continue for a minimum of 60 days to reduce the risk of an immune response as specified in the package labeling? Yes ___ No ___
- 13. Will liver function tests (LFTs) (e.g., GGT and total bilirubin) be performed prior to Elevidys administration? Yes ___ No ___
- 14. Will LFTs be monitored weekly for the first 3 months following Elevidys infusion then as clinically indicated? Yes ___ No ___
- 15. Will the oral corticosteroid regimen be modified according to the package labeling for members with liver function abnormalities following Elevidys infusion and prompt consultation with a specialist (i.e., gastroenterologist or hepatologist) will occur if acute serious liver injury or impending acute liver failure is suspected? Yes ___ No ___
- 16. Will troponin-I be monitored before Elevidys infusion and weekly for the first month following infusion then as clinically indicated? Yes ___ No ___
- 17. Will platelet counts be monitored before Elevidys infusion and weekly for the first 2 weeks then as clinically indicated? Yes ___ No ___
- 18. Will the member and/or caregiver be given a copy of the Elevidys medication guide and will it be reviewed with the member and/or caregiver including when to contact their health care provider? Yes ___ No ___
- 19. Is the member currently receiving exon therapy (e.g. Amondys 45, Exondys 51, Viltepso[®], and Vyondys 53)? Yes ___ No ___
 - a. If yes, will exon therapy be discontinued before the Elevidys infusion? Yes ___ No ___
- 20. Member's weight: _____: Date taken: _____
- 21. Anticipated date of Elevidys infusion: _____

Please note: Member will not be approved for concomitant treatment with exon skipping therapy (e.g. Amondys 45, Exondys 51, Viltepso[®], and Vyondys 53) following Elevidys infusion (current authorizations for exon skipping therapy will be discontinued upon Elevidys approval).

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Prescriber Signature: _____ **Date:** _____

I certify that the indicated treatment is medically necessary and all information is true and correct to the best of my knowledge. Failure to complete all pages will result in processing delays.

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