

Gene Therapies for Duchenne Muscular Dystrophy Prior Authorization Request Form for Elevidys[™] (delandistrogene moxeparvovec-rokl), #025

Medical Policy #022 Gene Therapies for Duchenne Muscular Dystrophy

CLINICAL DOCUMENTATION

- Clinical documentation that supports the medical necessity criteria for Elevidys[™] (delandistrogene moxeparvovecrokl) must be submitted.
- If the patient does not meet all the criteria listed below, please submit a letter of medical necessity with a request for <u>Clinical Exception (Individual Consideration)</u> explaining why an exception is justified.

Requesting Prior Authorization Using Authorization Manager

Providers will need to use <u>Authorization Manager</u> to submit initial authorization requests for services. Authorization Manager, available 24/7, is the quickest way to review authorization requirements, request authorizations, submit clinical documentation, check existing case status, and view/print the decision letter. For commercial members, the requests must meet medical policy guidelines.

To ensure the request is processed accurately and quickly:

- Enter the facility's NPI or provider ID for where services are being performed.
- Enter the appropriate surgeon's NPI or provider ID as the servicing provider, *not* the billing group.

Authorization Manager Resources

• Refer to our <u>Authorization Manager</u> page for tips, guides, and video demonstrations.

Complete Prior Authorization Request Form for Elevidys (delandistrogene moxparvovec-rokl) (025) using Authorization Manager.

For out of network providers: Requests should still be faxed to 888-973-0726.

Patient Information	
Patient Name:	Today's Date:
BCBSMA ID#:	Date of Treatment:
Date of Birth:	Place of Service: Outpatient Inpatient
	Distributor:

Physician Information	Facility Information
Name:	Name:
Address:	Address:
Phone #:	Phone #:
Fax#:	Fax#:
NPI#:	NPI#:

Please check off if the patient has the following diagnosis: Duchenne muscular dystrophy (DMD)

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1. Diagnosis of DMD by or in consultation with a pediatric neuromuscular specialist in DMD with: . a. A confirmed mutation in the DMD gene; AND . b. Mutation is not a deletion in exon 8 and/or 9; AND . 2. Elevidys is prescribed by or in consultation with a pediatric neuromuscular specialist in DMD; AND . 3. Patient is 4 - 5 years old; AND . 4. Patient is ambulatory without need of assistive devices (e.g., cane, walker, wheelchair, side-by-side assistance, etc.) as determined by medical records or physician attestation; AND . 5. Patient does not have an anti-AAVrh74 total binding antibody titer ≥ 1:400; AND . 6. Patient is on a corticosteroid regimen: a. Stable corticosteroid regimen defined as ≥ 12 weeks prior to screening for Elevidys infusion and following infusion; OR . 7. Patient has not previously received a gene therapy with Elevidys in their lifetime; AND . 8. Prescriber attestation patient will not receive any exon skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Vitepso (vittolarsen), Vyondys 53 (golodirsen)] concomitantly or following treatment with Elevidys; AND 9. Prescriber will assess liver function, platelets, and troponin-I levels prior to Elevidys infusion. .	Ple	ease check off that the patient meets <u>ALL</u> the following criteria:	
b. Mutation is not a deletion in exon 8 and/or 9; AND 2. Elevidys is prescribed by or in consultation with a pediatric neuromuscular specialist in DMD; AND 3. Patient is 4 - 5 years old; AND 4. Patient is ambulatory without need of assistive devices (e.g., cane, walker, wheelchair, side-by-side assistance, etc.) as determined by medical records or physician attestation; AND 5. Patient does not have an anti-AAVrh74 total binding antibody titer ≥ 1:400; AND 6. Patient is on a corticosteroid regimen: a. Stable corticosteroid regimen defined as ≥ 12 weeks prior to screening for Elevidys infusion and following infusion; OR b. Corticosteroid is not medically/clinically appropriate as per managing provider's recommendations; AND 7. Patient has not previously received a gene therapy with Elevidys in their lifetime; AND 8. Prescriber attestation patient will not receive any exon skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)] concomitantly or following treatment with Elevidy; AND	1.	Diagnosis of DMD by or in consultation with a pediatric neuromuscular specialist in DMD with:	
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HCPCS Codes	Code Description
J3590	Unclassified biologics
J3490	Unclassified drugs
C9399	Unclassified drugs or biologicals

Providers should enter the <u>relevant diagnosis code(s)</u> below:

Code	Description	

Providers should enter other relevant code(s) below:

Code	Description	