



Fax completed form to designated gene therapy fax (833) 910-1625
For Urgent requests please outreach to Cigna Gene Therapy Program at
(855) 678-0051 or email to GeneTherapyProgram@Cignahealthcare.com

Gene Therapy Elevidys®
(delandistrogene
moxeparvovec-rokl intravenous
infusion)

PHYSICIAN INFORMATION			PATIENT INFORMATION		
* Physician Name:			*Due to privacy regulations, we will not be able to respond via fax with the outcome of our review unless all asterisked (*) items under physician and patient information are completed.		
Specialty:	* DEA, NPI or TIN:				
Office Contact Person:			* Patient Name:		
Office Phone:			* Cigna ID:	* Date of Birth:	
Office Fax:			* Patient Street Address:		
Office Street Address:			City:	State:	Zip:
City:	State:	Zip:	Patient Phone:		
FACILITY BILLING INFORMATION FOR PAYMENT SUPPORT					
Billing Office Contact Name:		Billing Office Phone:		Billing Office Email:	
Billing Address:					
Billing TIN:			Billing NPI:		
CLINICAL DETAILS					
Urgency: ☐ Standard ☐ Urgent (In checking this box, I attest to the fact that applying the standard review time frame may seriously jeopardize the customer's life, health, or ability to regain maximum function)					
Medication Request Detail: ICD10: _____ HCPCS Code _____ NDC: _____ Additional Comment: _____ New Start: _____ Continuation: _____					
Where will this medication be obtained? ☐ Accredo ☐ Other (please specify): _____ ☐ Physician's office stock (billing on a medical claim form)					
Facility and/or doctor administering medication: Facility Name: _____ State: _____ Tax ID#: _____ Address (City, State, Zip Code): _____					
Where will this drug be administered? ☐ Hospital Outpatient ☐ Home ☐ Physician's Office ☐ Other (please specify): _____					
What is the indication or diagnosis? ☐ Duchenne Muscular Dystrophy ☐ other					

Clinical Information. Documentation is required for use of this gene therapy. Documentation may include, but is not limited to, chart notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information.

Check all that apply:

☐	Patient is a male* <i>In this context, the specified gender is defined as follows: males are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression.</i>
☐	Patient age is greater than or equal to 4 years 0 days and less than 8 years 0 days
☐	Patient had a genetic test confirming the diagnosis of Duchenne muscular dystrophy involving a pathogenic variant in the DMD gene [documentation required]
☐	Patient does not have any deletions in exon 8 or exon 9 in the DMD gene [documentation required]
☐	Patient has not received Elevidys in the past
☐	Patient is ambulatory [documentation required]
☐	Anti-adenovirus serotype rh74 (AAVrh74) total binding antibody titers are < 1:400 [documentation required]
☐	Patient screening is negative for ALL of the following (i, ii, and iii): ☐ i. Human immunodeficiency virus-1 and -2 [documentation required] ☐ ii. Hepatitis B virus [documentation required] ☐ iii. Hepatitis C virus [documentation required]
☐	The prescribing physician confirms that the patient has not received or will not receive any vaccinations within 4 weeks of Elevidys treatment
☐	The prescribing physician confirms that the patient does not have an active infection (e.g., bacterial, viral) or a recent infection within the past 4 weeks
☐	Patient has left ventricular ejection fraction $\geq 40\%$ [documentation required]
☐	Patient has undergone liver function testing within the past 30 days and meets ALL of the following (i, ii, iii, iv, v, and vi): ☐ i. Alanine aminotransferase levels are ≤ 2 times the upper limit of normal [documentation required]. Date obtained: ☐ ii. Aspartate aminotransferase levels are ≤ 2 times the upper limit of normal [documentation required]. Date obtained: ☐ iii. Gamma-glutamyl transferase level is ≤ 2 times the upper limit of normal [documentation required]. Date obtained: ☐ iv. Glutamate dehydrogenase level is ≤ 15 U/L [documentation required]. Date obtained: ☐ v. Total bilirubin is < than the upper limit of normal [documentation required]. Date obtained: <i>Note: A patient with Gilbert's syndrome does not have to meet this requirement.</i> ☐ vi. Coagulation parameters, such as the activated partial thromboplastin time (aPTT) and international normalized ratio (INR) are within the normal laboratory reference ranges [documentation required]. Date obtained:
☐	A complete blood cell count has been obtained within the past 30 days and the patient meets BOTH of the following (i and ii): ☐ i. White blood cell count is $< 18.5 \times 10^9/L$ [documentation required]. Date obtained: ☐ ii. Platelet count is $>150 \times 10^9/L$ [documentation required]. Date obtained:
☐	The medication is prescribed by a neurologist, neuromuscular specialist, or a physician who specializes in the management of Duchenne muscular dystrophy
☐	According to the prescribing physician, patient has started or will receive systemic corticosteroids equivalent to oral prednisone at a dose of 1 mg/kg per day or more, commencing 1 day prior to Elevidys infusion and continuing for at least 60 days
☐	Current patient body weight has been obtained within the past 30 days [documentation required]. Documented weight in kg: Date obtained:
☐	i. For a patient weighing less than 70 kg, the Elevidys dose is 1.33×10^{14} vector genomes per kg (vg/kg) based on the current patient weight in kg (or 10 mL/kg body weight) ☐ ii. For a patient weighing 70 kg or more, the Elevidys dose is 9.31×10^{15} vg total fixed dose <i>Elevidys is provided as a customized kit to meet dosing requirements for each patient based on their weight (in kilograms).</i>
☐	Concurrent Use with Anti-Sense Oligonucleotide (Exon-Skipping) Therapies. <i>Note: Examples of anti-sense oligonucleotide (exon-skipping) therapies include Exondys 51 (eteplirsen intravenous infusion), Vyondys 53 (golodirsen intravenous infusion), Viltepso (viltolarsen intravenous infusion), and Amondys 45 (casimersen intravenous infusion).</i>
☐	Prior Receipt of Gene Therapy.
☐	Prior Hematopoietic Stem Cell Transplantation

If any of the requirements listed above are not met and you feel administration of the requested gene therapy is medically necessary, please provide clinical support and rationale for the use of this gene therapy.

Additional pertinent information: (including recent history and physical, recent lab work, disease stage, prior therapy, performance status, and names/doses/admin schedule of any agents to be used concurrently)

Additional CPT and/or Administration Codes for Billing.

☐ Other

Agreement and Attestation:

Do you and your patient agree to share any required plan specific outcome measures? ☐ Yes ☐ No

I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan or insurer its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature: _____ **Date:** _____

Our standard response time for prescription drug coverage requests is 5 business days. If your request is urgent, it is important that you call us to expedite the request. View our Coverage Policies online at cigna.com.

v070126

"Cigna" is a registered service mark, and the "Tree of Life" logo is a service mark, of Cigna Intellectual Property, Inc., licensed for use by Cigna Corporation and its operating subsidiaries. All products and services are provided by or through such operating subsidiaries and not by Cigna Corporation. Such operating subsidiaries include, for example, Cigna Health and Life Insurance Company and Cigna Health Management, Inc. Address: Cigna Pharmacy Services, PO Box 42005, Phoenix AZ 85080-2005