

Elevidys

delandistrogene
moxeparvovec-rokl

suspension for intravenous infusion

BILLING & CODING GUIDE

IMPORTANT SAFETY INFORMATION

BOXED WARNING: Acute Serious Liver Injury and Acute Liver Failure

Acute serious liver injury, including life-threatening and fatal acute liver failure, has occurred. Patients with preexisting liver impairment may be at higher risk.

Prior to infusion, assess liver function by clinical examination and laboratory testing. Administer systemic corticosteroids before and after ELEVIDYS infusion. Continue to monitor liver function weekly for the first 3 months after infusion and continue until results are unremarkable.

Instruct patients to maintain proximity to an appropriate healthcare facility, as determined by the healthcare provider, for at least 2 months following ELEVIDYS infusion.

Obtain prompt consultation with a specialist (e.g., gastroenterologist or hepatologist) if acute serious liver injury or impending acute liver failure is suspected.

INDICATION

ELEVIDYS is indicated for the treatment of ambulatory patients 4 years of age and older with Duchenne muscular dystrophy (DMD) who have a confirmed mutation in the *DMD* gene.

Limitations of Use

ELEVIDYS is not recommended in patients with:

- Preexisting liver impairment (defined as gamma-glutamyl transferase [GGT] > 2 x upper limit of normal or total bilirubin > the upper limit of normal not due to Gilbert's syndrome) or active hepatic viral infection due to the high risk of acute serious liver injury and acute liver failure.
- Recent vaccination (within 4 weeks of treatment) due to immunogenicity and potential safety concerns.
- Active or recent (within 4 weeks) infections due to safety concerns.

Please see additional [Important Safety Information](#) on pages 2-3, full [Prescribing Information](#) for ELEVIDYS, including [Boxed Warning](#) and [Medication Guide](#).

Drug information¹

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATION

ELEVIDYS is contraindicated in patients with any deletion in exon 8 and/or exon 9, including a deletion of any portion or the entirety of these exons, in the *DMD* gene.

WARNINGS AND PRECAUTIONS

Acute Serious Liver Injury and Acute Liver Failure

See *Boxed Warning*.

- Acute serious liver injury marked by elevations of liver enzymes (e.g., GGT, ALT) and total bilirubin and acute liver failure has occurred with ELEVIDYS. Onset of the liver injury typically begins within 8 weeks of ELEVIDYS administration. In non-ambulatory patients treated with ELEVIDYS, acute liver failure with fatal outcome has occurred in the clinical and post-marketing settings.
- Life-threatening mesenteric vein thrombosis, complicated by bowel ischemia and necrosis, and portal hypertension have been reported following acute liver injury associated with ELEVIDYS in a non-ambulatory patient.
- Patients with preexisting liver impairment, chronic hepatic condition, or acute liver disease (e.g., acute hepatic viral infection) may be at higher risk of acute serious liver injury or acute liver failure. Postpone ELEVIDYS administration in patients with acute liver disease until resolved or controlled.
- Systemic corticosteroid treatment is recommended for patients before and after ELEVIDYS infusion. Adjust corticosteroid regimen when indicated.

Serious Infections

- Increased susceptibility to serious infections may occur due to concomitant administration of corticosteroid regimen and additional immunosuppressants, and ELEVIDYS. Serious respiratory infections, including with fatal outcomes, have occurred in patients taking immunosuppressant corticosteroids required for ELEVIDYS administration.
- Monitor patients for signs and symptoms of infection before and after ELEVIDYS administration and treat appropriately.
- Administer immunizations according to best clinical practices and immunization guidelines prior to initiation of the corticosteroid regimen required before ELEVIDYS infusion.
- Avoid administration of ELEVIDYS to patients with active infections.

Myocarditis

- Acute, serious, life-threatening myocarditis and troponin-I elevations have been observed within 24 hours to more than 1 year following ELEVIDYS infusion.
- If a patient experiences myocarditis, those with pre-existing left ventricle ejection fraction (LVEF) impairment may be at higher risk of adverse outcomes.
- Monitor troponin-I before ELEVIDYS infusion and weekly for the first month following infusion and continue monitoring if clinically indicated, until results return to near baseline levels or stabilize.
- More frequent monitoring may be warranted in the presence of cardiac symptoms, such as chest pain or shortness of breath.
- Advise patients to contact a physician immediately if they experience cardiac symptoms.

Infusion-related Reactions

- Infusion-related reactions, including hypersensitivity reactions and anaphylaxis, have occurred during or up to several hours following ELEVIDYS administration. Closely monitor patients during and for at least 3 hours after the end of infusion. If symptoms of infusion-related reactions occur, slow or stop the infusion and give appropriate treatment. Once symptoms resolve, the infusion may be restarted at a lower rate.
- ELEVIDYS should be administered in a setting where treatment for infusion-related reactions is immediately available.
- Discontinue infusion for anaphylaxis.

Drug information¹ (continued)

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Immune-mediated Myositis

- Immune-mediated myositis, including serious and life-threatening events, has occurred approximately 1 month following ELEVIDYS infusion. Signs and symptoms include severe muscle weakness, including dysphagia, dyspnea, dysphonia, and hypophonia.
- Severe to life-threatening immune-mediated myositis has been reported in patients with deletions including portions of exons 1-17 and/or exons 59-71 of the *DMD* gene.
- Regardless of genetic mutation, advise patients to contact a physician immediately if they experience any unexplained increased muscle pain, tenderness, or weakness, including dysphagia, dyspnea, dysphonia, or hypophonia, as these may be symptoms of myositis. Consider additional immunomodulatory treatment based on patient's clinical presentation and medical history if these symptoms occur.

Preexisting Immunity against AAVrh74

- In AAV-vector based gene therapies, preexisting anti-AAV antibodies may impede transgene expression at desired therapeutic levels. Following treatment with ELEVIDYS, all patients developed anti-AAVrh74 antibodies.
- Perform baseline testing for the presence of anti-AAVrh74 total binding antibodies prior to ELEVIDYS administration.
- ELEVIDYS administration is not recommended in patients with elevated anti-AAVrh74 total binding antibody titers $\geq 1:400$.

ADVERSE REACTIONS

- The most common adverse reactions (incidence $\geq 5\%$) reported in clinical studies were vomiting, nausea, liver injury, pyrexia, thrombocytopenia, and troponin-I increased.

Report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Sarepta Therapeutics at 1-888-SAREPTA (1-888-727-3782).

Please see the full [Prescribing Information](#) for ELEVIDYS, including [Boxed Warning](#) and [Medication Guide](#).

Overview

This guide has been developed to provide you with billing and coding information that may be useful as you seek to obtain insurance reimbursement for ELEVIDYS (delandistrogene moxeparvovec-rokl).

This information is provided for your education only. Sarepta does not guarantee coverage or reimbursement by using any particular codes. Individual insurers have the necessary flexibility to classify specific products in accordance with their own policies. Please confirm the appropriate code with the specific insurer (Medicare, Medicaid, or commercial) in whose jurisdiction a claim would be filed.

ELEVIDYS distribution

ELEVIDYS is available through Cardinal Health 3PL Services

You can order ELEVIDYS at [Sarepta.pharmarxorder.com](https://www.sarepta-pharmarxorder.com) or by calling **1-833-508-4422**.

You can also place an order via the **Sarepta Gene Therapy Buy & Bill Order Form** by requesting the form from your Sarepta Director Market Access and Reimbursement (DMAR). The form can be filled out electronically and emailed to GMB-SPS-Sarepta@cordlogistics.com or printed and filled out manually and faxed to **1-614-652-8224**.

Cardinal Health customer service representatives are available Monday through Friday 7 AM–6 PM CT

Note that the site of care must establish a purchasing account with Cardinal Health 3PL **prior to ordering Sarepta gene therapy products**.

Sarepta has partnered with select specialty pharmacies to support ELEVIDYS

Please contact your Sarepta DMAR if you have questions.

If you are unsure of who your Sarepta DMAR is, ask a SareptAssist Case Manager to facilitate an introduction.

This guide provides codes for:



Product ordering



Infusion for ELEVIDYS



Lab testing and diagnosis



You can always reach out to your DMAR or to SareptAssist, a personalized patient support program for your patient's treatment journey, with any questions you have about this guide. Contact SareptAssist by calling 1-888-727-3782 Monday through Friday, 8:30 AM–6:30 PM ET.

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Please see [Important Safety Information](#) on pages 1-3, full [Prescribing Information](#) for ELEVIDYS, including [Boxed Warning](#) and [Medication Guide](#).

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Coverage

The benefits investigation starts with an enrollment form

The **Sarepta Gene Therapy Enrollment Form** is required to verify eligibility for ELEVIDYS and initiate the process to receive therapy. Once the form is submitted, a SareptAssist Case Manager will conduct a **benefits investigation** to determine the type of insurance your patient has and the expected coverage it provides for gene therapy, including **prior authorization policies** and **out-of-pocket expenses**.

Prior authorization overview

Prior authorization guidelines should be followed and obtained prior to providing service. If you choose to white bag, the specialty pharmacy may provide necessary information when submitting for prior authorization.

Documentation payers may require for prior authorization include:

- ✓ Screening tests, including antibody assay (as specified in the product label)
- ✓ Letter of medical necessity
- ✓ Patient's medical history, including chart notes
- ✓ Patient's current weight
- ✓ Genetic test results confirming eligibility
- ✓ Copy of the patient's insurance card(s)
- ✓ ELEVIDYS Food and Drug Administration approval letter
- ✓ ELEVIDYS Prescribing Information
- ✓ Relevant articles published in medical or scientific journals
- ✓ Letters from other members of the patient's care team
- ✓ Signed copy of physician's order

Coverage (continued)

Prior authorization considerations

If your office or facility receives a request for prior authorization for treatment with ELEVIDYS, here are some tips that may be helpful:

- 1 Contact** the payer directly to inquire about prior authorization requirements such as the mode of submission (eg, phone, fax, online, letter)
- 2 Determine** if the insurer has a specific prior authorization form; it may be on the payer website
- 3 Draft** a patient-specific letter of medical necessity that describes the clinical rationale for treatment with ELEVIDYS
- 4 Follow up** after you submit a prior authorization to confirm the insurer received the information
- 5 Ask** the insurer how long it will take for them to review the prior authorization request and make a decision
- 6 Ask** the insurer how you will be informed if the prior authorization is approved or denied
- 7 Follow up** to check on the prior authorization request status at regular intervals
- 8 Document** the prior authorization approval number and duration; if possible, obtain written confirmation
- 9 Include** the prior authorization reference number on the claim form



Execute **single case agreements (SCAs)** as necessary to ensure that gene therapy administration is covered and reimbursable when administered at the chosen site of care. Criteria that typically must be met for SCAs include:

- Specialty care for the patient's needs
- Proximity to the patient's location
- Reducing out-of-pocket costs to the patient
- Patient cannot find the same level of care elsewhere

Coding

The following pages contain appropriate codes and additional information necessary for receiving reimbursement for ELEVIDYS*:

HCPCS code²

Code	Description	Site of service	Payers
J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose	Hospital outpatient	Medicaid and commercial

Revenue codes³

Code	Description	Appropriate use
0260	IV therapy, general	Commercial payers or Medicaid plans
0636	Drugs requiring detailed coding	Required by Medicare OPPS and any payer not yet aligned to 0892
0892 ¹	Special Processed Drugs—FDA Approved Gene Therapy	Drug line vs administration line (not payer-only)

These may be appropriate when billing ELEVIDYS and its administration in the hospital outpatient setting.

CPT codes⁴

Code	Description	Site of service
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial up to 1 hour	Hospital outpatient
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug), each additional hour (list separately in addition to primary procedure code, 96365)	Hospital outpatient

Additional codes may be required for postinfusion observation care and discharge services.

Drug administration services are typically reported with CPT codes in outpatient sites of care. These CPT codes may be appropriate for reporting an infusion of ELEVIDYS.

Diagnosis code⁵

Code	Description
G71.01	Duchenne or Becker muscular dystrophy

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) Codes.

See a sample coding scenario on the following page



CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System.

*Please note that these codes do not include office visits for diagnosis and prescribing of medication. Appropriate codes can vary by setting of care, patient, and payer. It is the provider's responsibility to determine the appropriate health care setting and to submit true and correct claims for actual products and services rendered. Please check with the payer to verify codes and special billing requirements.

¹Value Code 87 (Gene therapy Invoice Cost) may be required by some payers/payment methodologies when billing under 0892.

National Drug Codes^{1*}

Many payers (including Medicaid) will require healthcare professionals to report the NDC in an 11-digit format in addition to the HCPCS code when billing for a drug. The table below lists the 10-digit NDCs assigned to ELEVIDYS; the 11-digit format is required for claims submission. Add a "0" before the second set of numbers, after the first dash, to make this an 11-digit code. See the sample form on page 9 for an example.

Patient weight (kg)	Total vials per kit	Total dose volume per kit (mL)	NDC number
10.0 - 10.4	10	100	60923-501-10
10.5 - 11.4	11	110	60923-502-11
11.5 - 12.4	12	120	60923-503-12
12.5 - 13.4	13	130	60923-504-13
13.5 - 14.4	14	140	60923-505-14
14.5 - 15.4	15	150	60923-506-15
15.5 - 16.4	16	160	60923-507-16
16.5 - 17.4	17	170	60923-508-17
17.5 - 18.4	18	180	60923-509-18
18.5 - 19.4	19	190	60923-510-19
19.5 - 20.4	20	200	60923-511-20
20.5 - 21.4	21	210	60923-512-21
21.5 - 22.4	22	220	60923-513-22
22.5 - 23.4	23	230	60923-514-23
23.5 - 24.4	24	240	60923-515-24
24.5 - 25.4	25	250	60923-516-25
25.5 - 26.4	26	260	60923-517-26
26.5 - 27.4	27	270	60923-518-27
27.5 - 28.4	28	280	60923-519-28
28.5 - 29.4	29	290	60923-520-29
29.5 - 30.4	30	300	60923-521-30
30.5 - 31.4	31	310	60923-522-31
31.5 - 32.4	32	320	60923-523-32
32.5 - 33.4	33	330	60923-524-33
33.5 - 34.4	34	340	60923-525-34
34.5 - 35.4	35	350	60923-526-35
35.5 - 36.4	36	360	60923-527-36
36.5 - 37.4	37	370	60923-528-37
37.5 - 38.4	38	380	60923-529-38
38.5 - 39.4	39	390	60923-530-39
39.5 - 40.4	40	400	60923-531-40

Patient weight (kg)	Total vials per kit	Total dose volume per kit (mL)	NDC number
40.5 - 41.4	41	410	60923-532-41
41.5 - 42.4	42	420	60923-533-42
42.5 - 43.4	43	430	60923-534-43
43.5 - 44.4	44	440	60923-535-44
44.5 - 45.4	45	450	60923-536-45
45.5 - 46.4	46	460	60923-537-46
46.5 - 47.4	47	470	60923-538-47
47.5 - 48.4	48	480	60923-539-48
48.5 - 49.4	49	490	60923-540-49
49.5 - 50.4	50	500	60923-541-50
50.5 - 51.4	51	510	60923-542-51
51.5 - 52.4	52	520	60923-543-52
52.5 - 53.4	53	530	60923-544-53
53.5 - 54.4	54	540	60923-545-54
54.5 - 55.4	55	550	60923-546-55
55.5 - 56.4	56	560	60923-547-56
56.5 - 57.4	57	570	60923-548-57
57.5 - 58.4	58	580	60923-549-58
58.5 - 59.4	59	590	60923-550-59
59.5 - 60.4	60	600	60923-551-60
60.5 - 61.4	61	610	60923-552-61
61.5 - 62.4	62	620	60923-553-62
62.5 - 63.4	63	630	60923-554-63
63.5 - 64.4	64	640	60923-555-64
64.5 - 65.4	65	650	60923-556-65
65.5 - 66.4	66	660	60923-557-66
66.5 - 67.4	67	670	60923-558-67
67.5 - 68.4	68	680	60923-559-68
68.5 - 69.4	69	690	60923-560-69
69.5 and above	70	700	60923-561-70

NDC=National Drug Code.

*A 10-mL single-dose vial carton for ELEVIDYS (NDC 60923-562-01) is not sold individually.

Frequently asked questions



Ordering ELEVIDYS

How do I order ELEVIDYS (delandistrogene moxeparvovec-rokl)?

ELEVIDYS is available through Cardinal Health. You can order ELEVIDYS by visiting Sarepta.pharmarxorder.com or by calling 1-833-508-4422. Cardinal Health customer service representatives are available to help with questions about ordering Monday through Friday, 7 AM–6 PM CT.



Insurance coverage

What other federal or state insurance programs may my patient be qualified for?

Programs that your patient may qualify for include SSDI, Children's Health Insurance Program (CHIP), Social Security Administration Compassionate Allowances (CAL), or Medicaid waiver (also known as a "Katie Beckett").⁷⁻¹⁰ Program qualification varies by state and your patient's individual circumstances. SareptAssist Case Managers can help determine which programs may be able to help your patient and how to enroll.



Infusion

Where can ELEVIDYS be infused?

ELEVIDYS will be infused in the hospital outpatient setting. Sarepta partners with hospitals prior to treatment to ensure they are prepared for gene therapy and have the necessary steps in place to facilitate infusion.

ELEVIDYS should be administered in a setting where treatment for infusion-related reactions is immediately available.¹

How long is ELEVIDYS infusion?

Infusion may last approximately 1 to 2 hours, or longer at the care team's discretion, with the dose amount based on the patient's weight. ELEVIDYS is infused at a rate of less than 10 mL/kg/hour. Patients need to be closely monitored during and for at least 3 hours after the end of infusion for signs and symptoms of infusion-related reactions.¹

What medications should patients be on prior to infusion?

To reduce the risk associated with an immune response to the ELEVIDYS vector, administration of corticosteroids is recommended starting 1 week to 1 day prior to ELEVIDYS infusion depending on baseline corticosteroid status.¹ (See full [Prescribing Information](#).)



Postinfusion

How long should patients continue a corticosteroid regimen following ELEVIDYS infusion?

Patients should continue on corticosteroids for at least 60 days after infusion unless earlier tapering is clinically indicated. Dosing modifications to this regimen may be required for patients with liver function abnormalities following ELEVIDYS infusion.¹ (See full [Prescribing Information](#).)

How long should patients be monitored postinfusion?

Assess liver function (clinical exam, AST, ALT, GGT, albumin, aPTT, INR, and total bilirubin) weekly for the first 3 months. Obtain platelet counts weekly for the first 2 weeks. Measure troponin-I weekly for the first month. For all these assessments, continue monitoring if clinically indicated.¹ (See full [Prescribing Information](#).)

ALT=alanine aminotransferase; aPTT=activated partial thromboplastin time; AST=aspartate aminotransferase; GGT=gamma-glutamyl transpeptidase; INR=international normalized ratio.

Frequently asked questions (continued)



Shipping and storage

How is ELEVIDYS shipped to the site of care?

Sarepta works with specialty couriers capable of handling specific temperature and timing requirements. ELEVIDYS will be shipped and delivered at $\leq -60^{\circ}\text{C}$ (-76°F)¹ in a container equipped with an active condition-monitoring system to collect temperature data that will be accessible via a live link emailed to the point of contact for shipment.

How will ELEVIDYS be stored at the site of care?

ELEVIDYS can be refrigerated for up to 14 days when stored at 2°C to 8°C (36°F to 46°F) in the upright position. Do not refreeze, shake, or place back in the refrigerator once brought to room temperature.¹



Patient support

Does Sarepta have a patient support program?

SareptAssist is a patient support program in the United States that helps patients and their families navigate the treatment journey with Sarepta products, including ELEVIDYS.

How can my patient find financial assistance options?

A SareptAssist Case Manager can help provide patients with information about options and check if they are eligible for the patient co-pay assistance program or a third-party patient assistance foundation.

What does the patient co-pay assistance program cover?

This program may help with some out-of-pocket costs for ELEVIDYS (not the cost of supplies or other treatment-related costs). It is for eligible individuals with commercial insurance only (not Medicaid or Medicare) in the United States who are prescribed treatment with a Sarepta product.

How can I connect my patient with a SareptAssist Case Manager?

Once you submit a patient enrollment form, a SareptAssist Case Manager will be assigned to help with the benefits investigation process and guide your patient through their treatment journey with ELEVIDYS. **Download the form to fill out with your patient.**



Download



Please see [Important Safety Information](#) on pages 1-3, full [Prescribing Information](#) for ELEVIDYS, including [Boxed Warning](#) and [Medication Guide](#).

References: **1.** ELEVIDYS. Prescribing information. Sarepta Therapeutics, Inc; 2025. **2.** October 2024 HCPCS Quarterly Update. Centers for Medicare & Medicaid Services. Updated September 23, 2025. Accessed November 13, 2025. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update> **3.** Revenue codes. Noridian Healthcare Solutions. Updated June 17, 2025. Accessed December 12, 2025. <https://med.noridianmedicare.com/web/jca/topics/claim-submission/revenue-codes> **4.** Injection and Infusion Services Coding. Johns Hopkins Medicine. July 1, 2019. Accessed November 13, 2025. <https://www.hopkinsmedicine.org/-/media/compliance/documents/infusion-guideline-092020.pdf> **5.** ICD-10-CM code for Duchenne or Becker muscular dystrophy G71.01. American Hospital Association. Accessed November 13, 2025. <https://www.aapc.com/codes/icd-10-codes/G71.01> **6.** National Drug Code (NDC) conversion table. Maryland Department of Health. 2023. Accessed November 13, 2025. <https://health.maryland.gov/phpa/OIDEOR/IMMUN/Shared%20Documents/Handout%20%20-%20NDC%20conversion%20to%202011%20digits.pdf> **7.** Benefits for children with Duchenne muscular dystrophy. Harold W. Conick & Associates Ltd. Accessed November 13, 2025. <https://conicklaw.com/benefits-for-children-with-duchenne-muscular-dystrophy/> **8.** State Children's Health Insurance Program (CHIP) fact sheet. Medicaid and CHIP Payment and Access Commission. February 2018. Accessed November 13, 2025. <https://www.macpac.gov/publication/state-childrens-health-insurance-program-chip-fact-sheet/> **9.** Compassionate allowances. Social Security Administration. Accessed November 13, 2025. <https://www.ssa.gov/compassionateallowances/> **10.** Musumeci M, O'Malley Watts M, Ammula M, Burns A. Medicaid financial eligibility in pathways based on old age or disability in 2022: findings from a 50-state survey. KFF. July 11, 2022. Accessed November 13, 2025. <https://www.kff.org/report-section/medicaid-financial-eligibility-in-pathways-based-on-old-age-or-disability-in-2022-findings-from-a-50-state-survey-issue-brief/>



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