Elevidys

delandistrogene moxeparvovec-rokl

suspension for intravenous infusion

The Sarepta Gene Therapy **Enrollment Form** is required to verify eligibility for ELEVIDYS and initiate the process to receive therapy.

INDICATION

ELEVIDYS is indicated for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene. This indication is approved under accelerated approval based on expression of ELEVIDYS micro-dystrophin observed in patients treated with ELEVIDYS. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION:

ELEVIDYS is contraindicated in patients with any deletion in exon 8 and/or exon 9 in the *DMD* gene.

Distribution

- **ELEVIDYS is available through Cardinal Health**
  You can order ELEVIDYS at: **Sarepta.pharmarxorder.com** or by calling 833-508-4422
- **Cardinal Health customer service representatives are available**
  Monday through Friday
  7 AM–6 PM CST
- **Sarepta has partnered with select specialty pharmacies to support ELEVIDYS**
  Please contact your Sarepta Director of Market Access and Reimbursement (DMAR) if you have any questions

Shipping

ELEVIDYS will be shipped and delivered at ≤-60 °C (-76 °F).[1] Sarepta is working with specialty couriers capable of handling specific temperature and timing requirements. The shipping container will be 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. Please reach out to your Sarepta DMAR with any shipping-related questions.

Product receipt

- Inspect immediately for signs of damage or tampering[2]
- Confirm the correct number of vials have been received[2]
- Move ELEVIDYS from its shipment container to a freezer (–80 °C)[2]
- Remove from freezer storage ONLY when ready to use[2]
- Note that sizes for the package containing the vials range from 7.7" x 7.7" x 2.7" to 10.1" x 7.7" x 5.2", and weigh from 1.1 to 2.6 kg

ELEVIDYS product specifications[1]

How supplied	Administration	Storage

As single-dose 10-mL vials in a customized kit containing 10 to 70 vials, with each kit constituting a dosage unit based on the patient's body weight	• For single-dose intravenous infusion only
	• The duration of infusion with ELEVIDYS is 1 to 2 hours
	• ELEVIDYS administration is not recommended in patients with elevated anti-AAVrh74 total binding antibody titers (≥1:400)
	• At least one day prior to infusion, initiate a corticosteroid regimen for a minimum of 60 days after infusion. For full corticosteroid regimen instructions, see Table 1 and Table 2 in ELEVIDYS Prescribing Information
		• ELEVIDYS is shipped and delivered at ≤-60 °C (-76 °F)
		• 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**
		  • **Do not shake**
		  • **Do not place back in the refrigerator once brought to room temperature**

For complete dosing information, see full Prescribing Information, and for additional information, visit ELEVIDYSHCP.com

Contact your Sarepta DMAR for questions regarding the ordering and procurement process, patient support programs, or to report product issues.

SAREPTA THERAPEUTICS

Please see Important Safety Information throughout and the full Prescribing Information.

Billing and coding

Coverage

1. Complete Sarepta Gene Therapy **Enrollment Form** to start benefits investigation
2. Select procurement method
3. Obtain prior authorization

Documentation may include:

- Letter of medical necessity
- Patient medical history, including chart notes
- Genetic test results confirming eligibility
- Screening tests, including antibody assay (as specified in the product label)
- ELEVIDYS US 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

4. Submit claims

For assistance at any point in the process, contact SareptAssist at **1-888-SAREPTA (1-888-727-3782), Monday through Friday, 8:30 AM–6:30 PM ET.**

The following codes may be appropriate for use with ELEVIDYS:

Miscellaneous codes[3]

Code	Description	Site of service	Payers
J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose	Hospital outpatient	Medicaid and commercial payers
C9399	Unclassified drugs or biologicals	Hospital outpatient	Medicare

Revenue codes[4]

Code	Description	Appropriate use
0260	IV therapy, general	Commercial payers or Medicaid plans
0636	Drugs requiring detailed coding	Required by Medicare

Current Procedural Terminology (CPT) codes[5]

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.

Diagnosis code[6]

Code	Description
G71.01	Duchenne or Becker muscular dystrophy

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

Ensure payer contracts are updated to include ELEVIDYS and administration.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS:

Acute Serious Liver Injury:

- Acute serious liver injury has been observed with ELEVIDYS, and administration may result in elevations of liver enzymes (such as GGT, GLDH, ALT, AST) or total bilirubin, typically seen within 8 weeks. (cont'd)

Please see additional Important Safety Information throughout and the full Prescribing Information.

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National Drug Codes[1]*

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
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.

*An individual ELEVIDYS 10-mL single-dose vial can be provided as needed, but is not sold individually.

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.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS: (cont'd)

Acute Serious Liver Injury: (cont'd)

- Patients with preexisting liver impairment, chronic hepatic condition, or acute liver disease (eg, acute hepatic viral infection) may be at higher risk of acute serious liver injury. Postpone ELEVIDYS administration in patients with acute liver disease until resolved or controlled.

Please see additional Important Safety Information throughout and the full Prescribing Information.

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ELEVIDYS is contraindicated in patients with any deletion in exon 8 and/or exon 9 in the *DMD* gene.

WARNINGS AND PRECAUTIONS:

Acute Serious Liver Injury:

- Acute serious liver injury has been observed with ELEVIDYS, and administration may result in elevations of liver enzymes (such as GGT, GLDH, ALT, AST) or total bilirubin, typically seen within 8 weeks.
- Patients with preexisting liver impairment, chronic hepatic condition, or acute liver disease (eg, acute hepatic viral infection) may be at higher risk of acute serious liver injury. Postpone ELEVIDYS administration in patients with acute liver disease until resolved or controlled.
- Prior to ELEVIDYS administration, perform liver enzyme test and monitor liver function (clinical exam, GGT, and total bilirubin) weekly for the first 3 months following ELEVIDYS infusion. Continue monitoring if clinically indicated, until results are unremarkable (normal clinical exam, GGT, and total bilirubin levels return to near baseline levels).
- Systemic corticosteroid treatment is recommended for patients before and after ELEVIDYS infusion. Adjust corticosteroid regimen when indicated. If acute serious liver injury is suspected, consultation with a specialist is recommended.

Immune-mediated Myositis:

- In clinical trials, immune-mediated myositis has been observed approximately 1 month following ELEVIDYS infusion in patients with deletion mutations involving exon 8 and/or exon 9 in the *DMD* gene. Symptoms of severe muscle weakness, including dysphagia, dyspnea, and hypophonia, were observed.

Immune-mediated Myositis (cont'd):

- Limited data are available for ELEVIDYS treatment in patients with mutations in the *DMD* gene in exons 1 to 17 and/or exons 59 to 71. Patients with deletions in these regions may be at risk for a severe immune-mediated myositis reaction.
- Advise patients to contact a physician immediately if they experience any unexplained increased muscle pain, tenderness, or weakness, including dysphagia, dyspnea, or hypophonia, as these may be symptoms of myositis. Consider additional immunomodulatory treatment (immunosuppressants [eg, calcineurin-inhibitor] in addition to corticosteroids) based on patient's clinical presentation and medical history if these symptoms occur.

Myocarditis:

- Acute serious myocarditis and troponin-I elevations have been observed following ELEVIDYS infusion in clinical trials.
- Monitor troponin-I before ELEVIDYS infusion and weekly for the first month following infusion, and continue monitoring if clinically indicated. 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.

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 subjects developed anti-AAVrh74 antibodies.
- Perform baseline testing for 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 greater than or equal to 1:400.

Adverse Reactions:

- The most common adverse reactions (incidence ≥5%) reported in clinical studies were vomiting, nausea, liver function tests increased, pyrexia, and thrombocytopenia.
- 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.

References: 1. ELEVIDYS. Package Insert. Sarepta Therapeutics, Inc; 2023. **2.** Data on file. SRP-9001-301 EMBARK pharmacy manual, version 3.0. Sarepta Therapeutics; June 2021. **3.** Third Quarter, 2023 HCPCS Coding Cycle. Centers for Medicare and Medicaid Services. Accessed November 9, 2023. https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-3-2023-drugs-and-biologicals.pdf **4.** Revenue codes. Noridian Healthcare Solutions. Updated June 28, 2022. Accessed April 3, 2023. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **5.** Injection and infusion services coding. Johns Hopkins Medicine. July 1, 2019. Accessed April 3, 2023. https://www.hopkinsmedicine.org/compliance/forms/infusion-guideline-092020.pdf **6.** 2023 ICD-10-CM: 2023 code tables, tabular and index - updated 01/11/2023. Centers for Medicare & Medicaid Services. Accessed April 3, 2023. https://www.cms.gov/medicare/icd-10/2023-icd-10-cm

SAREPTA THERAPEUTICS