Medical Policy

BlueCross BlueShield Kansas
An Independent licensee of the
Blue Cross Blue Shield Association

Title: Elevidys (Intravenous)

Professional / Institutional
Original Effective Date: November 13, 2023
Latest Review Date: January 8, 2026
Current Effective Date: January 8, 2026

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

Indication	Dose
Duchenne Muscular Dystrophy	• For patients weighing less than 70 kg, the recommended dose is 1.33×10^{14} vector genomes per kilogram (vg/kg) of body weight (or 10 mL/kg body weight) • For patients weighing 70 kg or greater, the recommended dose is 9.31×10^{15} vector genomes (equal to 700mL/70 vials) as a total fixed dose* Calculate the dose for patients weighing less than 70 kg as follows: Elevidys dose (in mL) = patient body weight (in kilogram) x 10 *The multiplication factor 10 represents the per kilogram dose (1.33×10^{14} vg/kg) divided by the amount of vector genome copies per mL of the Elevidys suspension (1.33×10^{13} vg/mL).* Number of vials needed = Elevidys dose (in mL) divided by 10 (round to the nearest number of vials).
– *Immune responses to the AAVrh74 vector can occur after administration of Elevidys. To reduce the risk associated with an immune response, corticosteroids should be administered starting 1 day prior to Elevidys infusion. Initiate a corticosteroid regimen following the appropriate schedule. This regimen is recommended for a minimum of 60 days after the infusion unless earlier tapering is clinically indicated. See the PI for the recommended corticosteroid regimen dose modification for patients with liver function abnormalities following Elevidys infusion. If acute serious liver injury is suspected, a consultation with a specialist is recommended.* – *For patients previously taking corticosteroids at baseline, taper off the additional peri-Elevidys corticosteroids (back to baseline corticosteroid dose) over 2 weeks, or longer as needed. For patients not previously taking corticosteroids at baseline, taper the added peri-Elevidys corticosteroids off (back to no corticosteroids) over 4 weeks, or longer, as needed, and the corticosteroids should not be stopped abruptly.*	
• Elevidys is shipped frozen at ≤ -60 °C. Elevidys can be refrigerated but must be used within 14 days of receipt. DO NOT RE-FREEZE. • Elevidys is an adeno-associated virus vector-based gene therapy. Follow precautions for viral vector shedding for one month after the infusion. • For single-dose intravenous infusion only.	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Policy

Elevidys® (delandistrogene moxeparvovec-rokl) suspension is considered **experimental/investigational** for all indications including treatment of Duchenne's muscular dystrophy.

Note: There is insufficient clinical evidence for demonstrated efficacy.

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CLINICAL RATIONALE

See package insert for FDA preshttps://dailymed.nlm.nih.gov/dailymed/index.cfm

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

HCPCS code:

- J1413 – Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose; 1 billable unit = 1 therapeutic dose

NDC(s):

Elevidys kit sizes:

Patient Weight (kg)	Total Vials (and mL) per Kit	NDC	Patient Weight (kg)	Total Vials (and mL) per Kit	NDC
10.0 – 10.4	10 (100)	60923-0501-10	40.5 – 41.4	41 (410)	60923-0532-41
10.5 – 11.4	11 (110)	60923-0502-11	41.5 – 42.4	42 (420)	60923-0533-42
11.5 – 12.4	12 (120)	60923-0503-12	42.5 – 43.4	43 (430)	60923-0534-43
12.5 – 13.4	13 (130)	60923-0504-13	43.5 – 44.4	44 (440)	60923-0535-44
13.5 – 14.4	14 (140)	60923-0505-14	44.5 – 45.4	45 (450)	60923-0536-45
14.5 – 15.4	15 (150)	60923-0506-15	45.5 – 46.4	46 (460)	60923-0537-46
15.5 – 16.4	16 (160)	60923-0507-16	46.5 – 47.4	47 (470)	60923-0538-47
16.5 – 17.4	17 (170)	60923-0508-17	47.5 – 48.4	48 (480)	60923-0539-48
17.5 – 18.4	18 (180)	60923-0509-18	48.5 – 49.4	49 (490)	60923-0540-49
18.5 – 19.4	19 (190)	60923-0510-19	49.5 – 50.4	50 (500)	60923-0541-50
19.5 – 20.4	20 (200)	60923-0511-20	50.5 – 51.4	51 (510)	60923-0542-51
20.5 – 21.4	21 (210)	60923-0512-21	51.5 – 52.4	52 (520)	60923-0543-52
21.5 – 22.4	22 (220)	60923-0513-22	52.5 – 53.4	53 (530)	60923-0544-53
22.5 – 23.4	23 (230)	60923-0514-23	53.5 – 54.4	54 (540)	60923-0545-54
23.5 – 24.4	24 (240)	60923-0515-24	54.5 – 55.4	55 (550)	60923-0546-55
24.5 – 25.4	25 (250)	60923-0516-25	55.5 – 56.4	56 (560)	60923-0547-56
25.5 – 26.4	26 (260)	60923-0517-26	56.5 – 57.4	57 (570)	60923-0548-57

Patient Weight (kg)	Total Vials (and mL) per Kit	NDC	Patient Weight (kg)	Total Vials (and mL) per Kit	NDC
26.5 – 27.4	27 (270)	60923-0518-27	57.5 – 58.4	58 (580)	60923-0549-58
27.5 – 28.4	28 (280)	60923-0519-28	58.5 – 59.4	59 (590)	60923-0550-59
28.5 – 29.4	29 (290)	60923-0520-29	59.5 – 60.4	60 (600)	60923-0551-60
29.5 – 30.4	30 (300)	60923-0521-30	60.5 – 61.4	61 (610)	60923-0552-61
30.5 – 31.4	31 (310)	60923-0522-31	61.5 – 62.4	62 (620)	60923-0553-62
31.5 – 32.4	32 (320)	60923-0523-32	62.5 – 63.4	63 (630)	60923-0554-63
32.5 – 33.4	33 (330)	60923-0524-33	63.5 – 64.4	64 (640)	60923-0555-64
33.5 – 34.4	34 (340)	60923-0525-34	64.5 – 65.4	65 (650)	60923-0556-65
34.5 – 35.4	35 (350)	60923-0526-35	65.5 – 66.4	66 (660)	60923-0557-66
35.5 – 36.4	36 (360)	60923-0527-36	66.5 – 67.4	67 (670)	60923-0558-67
36.5 – 37.4	37 (370)	60923-0528-37	67.5 – 68.4	68 (680)	60923-0559-68
37.5 – 38.4	38 (380)	60923-0529-38	68.5 – 69.4	69 (690)	60923-0560-69
38.5 – 39.4	39 (390)	60923-0530-39	≥ 69.5	70 (700)	60923-0561-70
39.5 – 40.4	40 (400)	60923-0531-40			

The total number of vials in each kit corresponds to the dosing requirement for the individual patient, based on the patient's body weight. Each kit includes a specified number of Elevidys vials (with a minimum of 10 vials for a patient with 10.0 – 10.4 kg body weight range, and a maximum of 70 vials for a patient with body weight of 69.5 kg and above).

REVISIONS	
11-13-2023	Policy added to the bcbsks.com web site maintained by Prime Therapeutics LLC
07-23-2024	Updated Coding Section ▪ Added: J1413
10-22-2024	Annual review. No changes made to the policy. Policy maintained by Prime Therapeutics LLC
Posted: 12-09-2025 Effective: 01-08-2026	Medical policy reviewed by Prime Therapeutics LLC with no updates made. Medical policy layout was updated.

REFERENCES

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3. Bushby K, Finkel R, Birnkrant DJ, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management. Lancet Neurol; 2010 Jan; 9(1):77-93.
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5. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. Lancet Neurol 2018; 17:251.
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7. Moxley RT 3rd, Ashwal S, Pandya S, et al. Practice parameter: corticosteroid treatment of Duchenne dystrophy: report of the Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. Neurology. 2005;64:13–20.
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9. Scott E, Eagle M, Mayhew A, et al. Development of a Functional Assessment Scale for Ambulatory Boys with Duchenne Muscular Dystrophy. Physiother. Res. Int. 17 (2012) 101–109.
10. Mercuri E, Coratti G, Messina S. et al. Revised North Star Ambulatory Assessment for Young Boys with Duchenne Muscular Dystrophy. PLoS ONE, 2016 Aug 5;11(8): e0160195.