SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Elevidys (delandistrogene moxeparvovec-rokl) **(J1413) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Height: _____ **Date:** _____

- ❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dose: The recommended dose of Elevidys is 1.33×10^{14} vector genomes per kilogram (vg/kg) of body weight (or 10 mL/kg body weight). For the number of vials required, refer to table below. Calculate the dose 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 ELEVIDYS vials needed = ELEVIDYS dose (in mL) divided by 10 (round to the nearest number of vials).

- 1 Elevidys kit = 1 billable unit

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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
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

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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

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Authorization: One treatment per lifetime or until 6 years of age, whichever is first

- ❑ Member is between 4 and 5 years of age
- ❑ Member is **NOT** on concomitant therapy with DMD-directed antisense oligonucleotides and will stop therapy prior to Elevidys administration (e.g., golodirsen, casimersen, viltolarsen, eteplirsen)
- ❑ Member has a **NOT** received a DMD-directed antisense oligonucleotide within the past 30 days
- ❑ Member does **NOT** have an active infection, including clinically important localized infections
- ❑ Member has been on a stable dose of a corticosteroid, unless contraindicated or intolerance, prior to start of therapy and will be used concomitantly with a corticosteroid regimen pre- and post- infusion **(refer to the package insert for recommended corticosteroid dosing during therapy; verified by chart notes and/or pharmacy paid claims)**
- ❑ Member's troponin-I levels will be monitored at baseline and subsequently as clinically indicated
- ❑ Provider will submit member's baseline liver function assessed 30 days prior to request and following therapy for at least 3 months and as indicated **(submit documentation; Provider please note: Requested medication will not be approved if GGT is < 3 times upper limit of normal and Total bilirubin is < 3 times the upper limit of normal)**
- ❑ Member has a confirmed mutation of the DMD gene between exons 18-58 **(submit genetic testing)**
- ❑ Member is ambulatory (able to independently ambulate 10 meters **OR** no requirement for permanent use of a wheelchair) **(submit documentation)**
- ❑ Member is receiving physical and/or occupational therapy
- ❑ Member must have a baseline anti-AAVrh74 total binding antibody titer of < 1:400 as measured by ELISA **(submit analysis)**
- ❑ Member does **NOT** have any deletion in exon 8 and/or exon 9 in the DMD gene
- ❑ Member has **NOT** had gene therapy, cell-based therapy, or clustered regularly interspaced short palindromic repeats (CRISPR/Cas9)

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

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For urgent reviews: Practitioner should call Optima Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Optima's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

***Approved by Pharmacy and Therapeutics Committee:** ~~9/21/2023;~~ **9/26/2024**
REVISED/UPDATED/REFORMATTED: ~~9/11/2023;10/17/2023;~~ **10/15/2024**