

# SENTARA COMMUNITY PLAN (MEDICAID)

## 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 1-844-305-2331. 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.

**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 Name/Form/Strength: \_\_\_\_\_

Dosing Schedule: \_\_\_\_\_ Length of Therapy: \_\_\_\_\_

Diagnosis: \_\_\_\_\_ ICD Code, if applicable: \_\_\_\_\_

Weight (if applicable): \_\_\_\_\_ Date weight obtained: \_\_\_\_\_

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  $1.33 \times 10^{14}$  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 ( $1.33 \times 10^{14}$  vg/kg) divided by the amount of vector genome copies per mL of the ELEVIDYS suspension ( $1.33 \times 10^{13}$  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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**PA Elevidys (Medical) (Medicaid)**

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<b>Patient Weight (kg)</b>	<b>Total Vials per Kit</b>	<b>Total Dose Volume per Kit (mL)</b>	<b>NDC Number</b>
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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**PA Elevidys (Medical) (Medicaid)**

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<b>Patient Weight (kg)</b>	<b>Total Vials per Kit</b>	<b>Total Dose Volume per Kit (mL)</b>	<b>NDC Number</b>
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 to be administered within 180 days of approval**

- Member is ambulatory
- Member is at least 4 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 does **NOT** have an active infection, including clinically important localized infections
- Elevidys will be used concomitantly with a corticosteroid regimen pre- and post- infusion (refer to the package insert for recommended corticosteroid dosing during therapy)
- Member's troponin-I levels will be monitored at baseline and subsequently as clinically indicated
- Member will have baseline liver function assessed prior to and following therapy for at least 3 months and as indicated
- 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

**Medication being provided by: Please check applicable box below.**

- Location/site of drug administration:** \_\_\_\_\_
- NPI or DEA # of administering location:** \_\_\_\_\_

**OR**

- Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Plans 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.\***