

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 1.33×10^{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 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.****