blue california
Promise Health Plan

delandistrogene moxeparvovec-rokl (Elevidys)

Medical Benefit Drug Policy

Place of Service
Outpatient Facility Administration
Hospital Administration

Drug Details

USP Category: Genetic or Enzyme or Protein Disorder
Mechanism of Action: Gene transfer therapy
HCPCS:

- **Through 12/31/2023**: C9399, J3490, J3590
- **Effective 1/1/2024 and after**: J1413 per therapeutic dose

How supplied
NDCs:

60923-501-10: 10 vials (100mL total dose volume)	60923-532-41: 41 vials (410mL total dose volume)
60923-502-11: 11 vials (110mL total dose volume)	60923-533-42: 42 vials (420mL total dose volume)
60923-503-12: 12 vials (120mL total dose volume)	60923-534-43: 43 vials (430mL total dose volume)
60923-504-13: 13 vials (130mL total dose volume)	60923-535-44: 44 vials (440mL total dose volume)
60923-505-14: 14 vials (140mL total dose volume)	60923-536-45: 45 vials (450mL total dose volume)
60923-506-15: 15 vials (150mL total dose volume)	60923-537-46: 46 vials (460mL total dose volume)
60923-507-16: 16 vials (160mL total dose volume)	60923-538-47: 47 vials (470mL total dose volume)
60923-508-17: 17 vials (170mL total dose volume)	60923-539-48: 48 vials (480mL total dose volume)
60923-509-18: 18 vials (180mL total dose volume)	60923-540-49: 49 vials (490mL total dose volume)
60923-510-1: 19 vials (190mL total dose volume)	60923-541-50: 50 vials (500mL total dose volume)
60923-511-20: 20 vials (200mL total dose volume)	60923-542-51: 51 vials (510mL total dose volume)
60923-512-21: 21 vials (210mL total dose volume)	60923-543-52: 52 vials (520mL total dose volume)
60923-513-22: 22 vials (220mL total dose volume)	60923-544-53: 53 vials (530mL total dose volume)
60923-514-23: 23 vials (230mL total dose volume)	60923-545-54: 54 vials (540mL total dose volume)
60923-515-24: v vials (240mL total dose volume)	60923-546-55: 55 vials (550mL total dose volume)
60923-516-25: 25 vials (250mL total dose volume)	60923-547-56: 56 vials (560mL total dose volume)
60923-517-26: 26 vials (260mL total dose volume)	60923-548-57: 57 vials (570mL total dose volume)
60923-518-27: 27 vials (270mL total dose volume)	60923-549-58: 58 vials (580mL total dose volume)
60923-519-28: 28 vials (280mL total dose volume)	60923-550-59: 59 vials (590mL total dose volume)
60923-520-29: 29 vials (290mL total dose volume)	60923-551-60: 60 vials (600mL total dose volume)
60923-521-30: 30 vials (300mL total dose volume)	60923-552-61: 61 vials (610mL total dose volume)
60923-522-31: 31 vials (310mL total dose volume)	60923-553-62: 62 vials (620mL total dose volume)
60923-523-32: 32 vials (320mL total dose volume)	60923-554-63: 63 vials (630mL total dose volume)
60923-524-33: 33 vials (330mL total dose volume)	60923-555-64: 64 vials (640mL total dose volume)
60923-525-34: 34 vials (340mL total dose volume)	60923-556-65: 65 vials (650mL total dose volume)
60923-526-35: 35 vials (350mL total dose volume)	60923-557-66: 66 vials (660mL total dose volume)
60923-527-36: 36 vials (360mL total dose volume)	60923-558-67: 67 vials (670mL total dose volume)
60923-528-37: 37 vials (370mL total dose volume)	60923-559-68: 68 vials (680mL total dose volume)
60923-529-38: 38 vials (380mL total dose volume)	60923-560-69: 69 vials (690mL total dose volume)
60923-530-39: 39 vials (390mL total dose volume)	60923-561-70: 70 vials (700mL total dose volume)
60923-531-40: 40 vials (400mL total dose volume)	

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Condition(s) listed in policy *(see coverage criteria for details)*

- Duchenne Muscular Dystrophy

Special Instructions and pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure member has met all medical necessity requirements.

Covered under the Medical Benefit, please submit clinical information for prior authorization review

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice:

Duchenne Muscular Dystrophy

1. Being prescribed by a DMD specialist (e.g. pediatric neurologist), AND
2. Patient has anti-AAVrh74 total binding antibody titers <1:400, AND
3. Patient does not have an active infection, AND
4. Patient has not previously received gene therapy, AND
5. DMD diagnosis with a confirmed mutation in the dystrophin gene, AND
6. Patient does not have any deletion in exon 8 and/or exon 9 in the DMD gene, AND
7. Age is between 4 and 5 years of age, AND
8. Patient is ambulatory, AND
9. Not being used in combination with exon-skipping therapies for DMD

Covered Doses
1.33×10^{14} vector genomes per kilogram (vg/kg) of body weight (or 10 mL/kg body weight) given as an IV infusion

Coverage Period
One-time treatment per lifetime

Additional Information:

References

1. AHFS®. Available by subscription at http://www.lexi.com
2. DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Elevidys (delandistrogene moxeparvovec-rokl). [Prescribing information]. Cambridge, MA: Sarepta Therapeutics, Inc.; June 2023.

Policy Update

Date of Last Annual Review: 8/30/2023

Date of last revision: 1/3/2024
Changes from previous policy version:

- Added HCPCS J1413 per therapeutic dose, effective 1/1/2024 and after

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee