delandistrogene moxeparvovec-rokl (Elevidys)

Commercial Medical Benefit Drug Policy

Place of Service
Hospital Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Gene replacement therapy
HCPCS:
J1413:Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose
How Supplied:

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: 24 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)	
60923-518-27: 27 vials (270mL total dose volume)	
60923-519-28: 28 vials (280mL total dose volume)	
60923-520-29: 29 vials (290mL total dose volume)	
60923-521-30: 30 vials (300mL total dose volume)	
60923-522-31: 31 vials (310mL total dose volume)	
60923-523-32: 32 vials (320mL total dose volume)	
60923-524-33: 33 vials (330mL total dose volume)	
60923-525-34: 34 vials (340mL total dose volume)	
60923-526-35: 35 vials (350mL total dose	

volume) 60923-527-36: 36 vials (360mL total dose volume) 60923-528-37: 37 vials (370mL total dose volume) 60923-529-38: 38 vials (380mL total dose volume) 60923-530-39: 39 vials (390mL total dose volume) 60923-531-40: 40 vials (400mL total dose volume)	60923-548-57: 57 vials (570mL total dose volume) 60923-549-58: 58 vials (580mL total dose volume) 60923-550-59: 59 vials (590mL total dose volume) 60923-551-60: 60 vials (600mL total dose volume) 60923-552-61: 61 vials (610mL total dose volume) 60923-553-62: 62 vials (620mL total dose volume) 60923-554-63: 63 vials (630mL total dose volume) 60923-555-64: 64 vials (640mL total dose volume) 60923-556-65: 65 vials (650mL total dose volume) 60923-557-66: 66 vials (660mL total dose volume) 60923-558-67: 67 vials (670mL total dose volume) 60923-559-68: 68 vials (680mL total dose volume) 60923-560-69: 69 vials (690mL total dose volume) 60923-561-70: 70 vials (700mL total dose volume)

The following does not meet the safety and efficacy criteria established by Blue Shield of California's Pharmacy & Therapeutics committee and is not covered:

Elevidys for the treatment of DMD (Duchenne muscular dystrophy). Elevidys is considered not medically necessary due to insufficient evidence of clinical benefit for DMD while showing evidence of significant safety risk.

Special Instructions and Pertinent Information

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

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

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]. Sarepta Therapeutics, Inc., Cambridge, MA. June 2024.

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- Removed coverage for DMD. *(Rationale: The FDA continues to investigate reported deaths associated with Elevidys use in DMD patients. Elevidys will be considered investigational due to insufficient evidence of clinical benefit for Duchenne muscular dystrophy (DMD) while showing evidence of significant safety risk.)*

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