COMMON GROUND
HEALTHCARE COOPERATIVE

PHARMACY POLICY STATEMENT
Common Ground Healthcare Cooperative (CGHC)

DRUG NAME	**Elevidys (delandistrogene moxeparvovec-rokl)**
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Elevidys is an adeno-associated virus vector-based gene therapy indicated for the treatment of ambulatory and non-ambulatory pediatric patients at least 4 years of age with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene. It is the first recombinant gene therapy product marketed for DMD. The DMD indication in non-ambulatory patients is approved under accelerated approval based on expression of ELEVIDYS microdystrophin. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
DMD is a rare and lethal X-linked recessive neuromuscular disorder caused by mutations in the dystrophin gene that result in absent or insufficient functional dystrophin, a cytoskeletal protein that enables the strength, stability, and functionality of myofibres. Progressive muscular damage and degeneration occurs in people with DMD, resulting in muscular weakness, associated motor delays, loss of ambulation, respiratory impairment, and cardiomyopathy.

Elevidys (delandistrogene moxeparvovec-rokl) will be considered for coverage when the following criteria are met:

Duchenne muscular dystrophy (DMD)

For **initial** authorization:

1. Member is a male; AND
2. Member is at least 4 years of age; AND
3. Medication is being prescribed by or in consultation with a DMD specialist (i.e., neurologist); AND
4. Member has a diagnosis of DMD with a confirmed mutation between exons 18 to 58 in the DMD gene (genetic testing results required); AND
5. Member has an anti-AAVrh74 total binding antibody level <1:400 confirmed by ELISA; AND
6. Member meets **BOTH** of the following:
   a) Has been stable on a corticosteroid for at least 12 weeks prior to starting therapy with Elevidys;
   b) Will continue corticosteroid use for at least 60 days after therapy with Elevidys; AND
7. Documentation of baseline liver function, platelet count and troponin-I is included in chart notes; AND
8. Provider attests medication is **NOT** being used with exon skipping therapy (ex. Exondys 51, Vyondys 53, Amondys 45); AND
9. Member does not have **ANY** of the following:
   a) Deletion in the exon 8 and/or exon 9 of the DMD gene;
   b) Prior use of gene therapy; AND

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10. Member's weight is provided for dose calculation.
11. **Dosage allowed/Quantity limit:**
    a) 10 to 69 kg: 1.33 $\times 10^{14}$ vector genomes (vg)/kg given intravenously;
    b) 70 kg or greater: 9.31 $\times 10^{15}$ vg given intravenously.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Elevidys is a one-time single infusion and will not be reauthorized.

CareSource considers Elevidys (delandistrogene moxeparvovec-rokl) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/18/2023	New policy for Elevidys created.
07/03/2024	Modified age limit from 4-5 to at least 4 years of age; removed ambulatory requirement; updated dosing; added provider attestation to absence of use with exon skipping therapy.

References:

1. Elevidys [package insert]. Cambridge, MA; Sarepta Therapeutics, Inc. 2024.
2. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management [published correction appears in *Lancet Neuro*l. 2018 Apr 4;:]. Lancet Neurol. 2018;17(3):251-267. doi:10.1016/S1474-4422(18)30024-3
3. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 2: respiratory, cardiac, bone health, and orthopaedic management. *Lancet Neurol.* 2018;17(4):347-361. doi:10.1016/S1474-4422(18)30025-5.
4. A Randomized, Double-blind, Placebo-controlled Study of SRP-9001 (Delandistrogene Moxeparvovec) for Duchenne Muscular Dystrophy (DMD). ClinicalTrials.gov identifier: NCT03769116. Updated July 1, 2022. Accessed July 19, 2023. https://classic.clinicaltrials.gov/ct2/show/study/NCT03769116.
5. A Gene Transfer Therapy Study to Evaluate the Safety and Efficacy of Delandistrogene Moxeparvovec (SRP-9001) in Participants With Duchenne Muscular Dystrophy (DMD) (EMBARK). ClinicalTrials.gov identifier: NCT05096221. Updated July 10, 2023. Accessed July 26, 2023. https://classic.clinicaltrials.gov/ct2/show/NCT05096221.
6. A Gene Transfer Therapy Study to Evaluate the Safety of and Expression From Delandistrogene Moxeparvovec (SRP-9001) in Participants With Duchenne Muscular Dystrophy (DMD) (ENDEAVOR). ClinicalTrials.gov identifier: NCT04626674. Updated July 5, 2023. Accessed July 26, 2023. https://classic.clinicaltrials.gov/ct2/show/NCT04626674

Effective date: 01/01/2025
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