



# Pharmacy Drug Policy & Procedure

<b>Policy Name:</b>	<b>Elevidys (delandistrogene moxeparvovec)</b>	<b>Policy#:</b>	<b>2778P</b>
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## Purpose of the Policy

The purpose of this policy is to define coverage criteria for Elevidys (delandistrogene moxeparvovec)

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Elevidys (delandistrogene moxeparvovec) under the specialty medical benefit if the following criteria are met.

## Criteria

### 1. Coverage Criteria

- 1.1 Diagnosis of Duchenne muscular dystrophy as confirmed by genetic testing documenting a mutation in the dystrophin (DMD) gene
- 1.2 Documentation of muscle biopsy documenting lack of muscle dystrophin
- 1.3 Prescribed by or in consultation with a doctor who specializes in the treatment of Duchenne Muscular Dystrophy (DMD)
- 1.4 Documentation supports patient is currently able to walk independently and not wheelchair dependent
- 1.5 Patient is age 4-7 years
- 1.6 Documentation of a baseline motor milestone score from North Star Ambulatory Assessment (NSAA)
- 1.7 Patient will receive a corticosteroid regimen prior to and following receipt of Elevidys
- 1.8 Review of clinical information confirming that patient has met all of the above requirements for treatment completed by both a pharmacist and medical director

### 2. Exclusion Criteria

- 2.1 Patient is non-ambulatory (unable to walk independently)
  - Use in these patients is still pending further clinical benefit confirmation
- 2.2 Patient has previously received treatment with an exon-skipping DMD therapy or Elevidys
- 2.3 Member has a deletion in exon 8 and/or exon 9 in the DMD gene

### 3. Approval Period

- 3.1 One-time approval over 6 months
- 3.2 Limit one infusion per lifetime

## CPT Codes

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## HCPCS Codes

J1413	Injection, delandistrogene moxeparvovec-rokl
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## References

1. Elevidys (delandistrogene moxeparvovec) [prescribing information]. Cambridge, MA: Sarepta Therapeutics Inc; June 2024.
2. Mendell JR, Sahenk Z, Lehman K, et al. Assessment of Systemic Delivery of rAAVrh74.MHCK7.microdystrophin in Children With Duchenne Muscular Dystrophy: A Nonrandomized Controlled Trial. *JAMA Neurol.* 2020 Sep 1;77(9):1122-1131.
3. Mendell JR, Shieh PB, McDonald CM, et al. Expression of SRP-9001 dystrophin and stabilization of motor function up to 2 years post-treatment with delandistrogene moxeparvovec gene therapy in individuals with Duchenne muscular dystrophy. *Front Cell Dev Biol.* 2023;11:1167762.
4. A Phase 3 Multinational, Randomized, Double-Blind, Placebo-Controlled Systemic Gene Delivery Study to Evaluate the Safety and Efficacy of SRP-9001 in Subjects With Duchenne Muscular Dystrophy (EMBARK).
5. Zaidman CM, Proud CM, McDonald CM, et al. Delandistrogene moxeparvovec gene therapy in ambulatory patients (aged  $\geq 4$  to  $< 8$  years) with duchenne muscular dystrophy: 1-year interim results from study SRP-9001-103 (ENDEAVOR). *Ann Neurol.* 2023;94(5):955-968.

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