Pharmacy Drug Policy & Procedure

Policy Name:	Elevidys (delandistrogene moxeparvovec)	Policy#:	2778P

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	
HCPCS Codes	
J1413	Injection, delandistrogene moxeparvovec-rokl

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.micro-dystrophin 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 ≥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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