

## Elevidys (delandistrogene moxeparvovec)

**Policy Number: 072**

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization Required	X	X	X
No Prior Authorization			

Elevidys (delandistrogene moxeparvovec) is a gene therapy based on an adeno-associated virus that delivers a transgene encoding a micro-dystrophin protein designed to replace the function of the mutated *DMD* gene in patients with Duchenne muscular dystrophy (DMD).

### FDA-approved indication

For the treatment of ambulatory pediatric patients aged 4-5 years with DMD and a confirmed mutation in the *DMD* gene.

### Coverage guidelines

Mass General Brigham Health Plan covers Elevidys when all of the following have been met:

1. Member is 4 or 5 years old
2. Diagnosis of DMD with a disease-causing mutation in the *DMD* gene
3. Anti-AAVrh74 total binding antibody titer <1:400
4. On a stable corticosteroid dose
5. Baseline measurements are recorded, within the past 3 months, for
  - a. North Star Ambulatory Assessment, including scores and times on individual items
  - b. Six-minute walk test (6MWT)
6. 6MWT  $\geq$  200 meters
7. Appropriate dosing
8. Prescriber is a specialist in neuromuscular disease

### Exclusions

1. Deletion in exon 8 or exon 9 of the *DMD* gene
2. Current active infection
3. Prior treatment with delandistrogene moxeparvovec
4. Current treatment with antisense oligonucleotides

### MassHealth variation

Mass General Brigham Health Plan uses the [MassHealth Drug List](#) for coverage determinations for members of the MGB ACO. Criteria for Elevidys are found in [Table 76 - Neuromuscular Agents – Duchenne Muscular Dystrophy and Spinal Muscular Atrophy](#).

### Medicare variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations

(NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, Medicare had no NCD or LCD for Elevidys (delandistrogene moxeparvovec).**

## Codes

The following codes are included for informational purposes only; inclusion of a code does not constitute or imply coverage.

The list of codes applies to commercial and MassHealth plans only.

Authorized CPT/HCPCS Codes	Code Description
J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose

## Effective

April 2024: Effective date

## References

Delandistrogene moxeparvovec [package insert]. Cambridge, MA: Sarepta Therapeutics, 2023.

Klimchak AC, Sedita LE, Rodino-Klapac LR. Assessing the value of delandistrogene moxeparvovec (SRP-9001) gene therapy in patients with Duchenne muscular dystrophy in the United States. *J Market Access & Health Policy* 2023;11:2216518.

Mendell JR, Sahenk Z, Lehman K. Assessment of systemic delivery of rAAVrh74.MHCK7.micro-dystrophin in children with Duchenne muscular dystrophy: a nonrandomized controlled trial. *JAMA Neurol.* 2020;77(8):1122-1131.

Mendell JR, Sahenk Z, Lehman KJ. Phase 1/2a trial of delandistrogene moxeparvovec in patients with DMD: 4-year update.

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 Nov; 94(5):955-968.

