Medical Policy:

Elevidys® (delandistrogene moxeparvovec-rokl) Intravenous – MEDICAID ONLY

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.420	September 12, 2024	September 12, 2024

Definitions

Elevidys is indicated for the treatment of Duchenne muscular dystrophy (DMD) in individuals at least 4 years of age:

- For patients who are ambulatory and have a confirmed mutation in the DMD gene
- For patients who are non-ambulatory and have a confirmed mutation in the DMD gene.

The DMD indication in non-ambulatory patients is approved under accelerated approval based on expression of ELEVIDYS micro-dystrophin (noted hereafter as "micro-dystrophin") in skeletal muscle. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Length of Authorization

Coverage will be provided for one dose (for Medicaid members) and may not be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time) [HCPCS Unit]:

• 1 therapeutic dose (up to 70 vials [700 mL] based on weight chart in package insert)

Guideline

1. **Duchenne Muscular Dystrophy (DMD) †**
   - A. Patient is at least 4 years of age; **AND**
   - B. Patient is not on concomitant therapy with DMD-directed antisense oligonucleotides (e.g., golodirsen, casimersen, viltolarsen, eteplirsen, etc.); **AND**
   - C. Patient has a not received a DMD-directed antisense oligonucleotide within the past 30 days; **AND**
   - D. Patient does not have an active infection, including clinically important localized infections; **AND**
   - E. Patient has been on a stable dose of a corticosteroid, unless contraindicated or intolerance, prior to start of therapy and will be used concomitantly with a corticosteroid regimen pre and post- infusion (refer to the package insert for recommended corticosteroid dosing during therapy); **AND**
   - F. Patient troponin-I levels will be monitored at baseline and subsequently as clinically indicated; **AND**
   - G. Patient will have baseline liver function assessed prior to and following therapy for at least 3 months and as indicated; **AND**
   - H. Patient has a confirmed mutation of the *DMD* gene between exons 18-58; **AND**
   - I. Patient is receiving physical and/or occupational therapy; **AND**
   - J. Patient must have a baseline anti-AAVrh74 total binding antibody titer of < 1:400 as measured by ELISA *(Note: An FDA authorized test for the detection of AAVrh74 total binding antibodies is not currently available. Currently available tests may vary in accuracy and design.)*; **AND**
   - K. Patient does NOT have any deletion in exon 8 and/or exon 9 in the DMD gene

† FDA Approved Indication(s)

Applicable Procedure Codes

Code	Description
J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose

Applicable NDCs

Code	Description
60923-0501-10	Elevidys 10.0-10.4 Kg
60923-0502-11	Elevidys 10.5-11.4 kg
60923-0503-12	Elevidys 11.5-12.4 kg
60923-0504-13	Elevidys 12.5-13.4 kg
60923-0505-14	Elevidys 13.5-14.4 kg
60923-0506-15	Elevidys 14.5-15.4 kg
60923-0507-16	Elevidys 15.5-16.4 kg
60923-0508-17	Elevidys 16.5-17.4 kg
60923-0509-18	Elevidys 17.5-18.4 kg
60923-0510-19	Elevidys 18.5-19.4 kg
60923-0511-20	Elevidys 19.5-20.4 kg
60923-0512-21	Elevidys 20.5-21.4 kg
60923-0513-22	Elevidys 21.5-22.4 kg
60923-0514-23	Elevidys 22.5-23.4 kg
60923-0515-24	Elevidys 23.5-24.4 kg
60923-0516-25	Elevidys 24.5-25.4 kg
60923-0517-26	Elevidys 25.5-26.4 kg

60923-0518-27	Elevidys 26.5-27.4 kg
60923-0519-28	Elevidys 27.5-28.4 kg
60923-0520-29	Elevidys 28.5-29.4 kg
60923-0521-30	Elevidys 29.5-30.4 kg
60923-0522-31	Elevidys 30.5-31.4 kg
60923-0523-32	Elevidys 31.5-32.4 kg
60923-0524-33	Elevidys 32.5-33.4 kg
60923-0525-34	Elevidys 33.5-34.4 kg
60923-0526-35	Elevidys 34.5-35.4 kg
60923-0527-36	Elevidys 35.5-36.4 kg
60923-0528-37	Elevidys 36.5-37.4 kg
60923-0529-38	Elevidys 37.5-38.4 kg
60923-0530-39	Elevidys 38.5-39.4 kg
60923-0531-40	Elevidys 39.5-40.4 kg
60923-0532-41	Elevidys 40.5-41.4 kg
60923-0533-42	Elevidys 41.5-42.4 kg
60923-0534-43	Elevidys 42.5-43.4 kg
60923-0535-44	Elevidys 43.5-44.4 kg
60923-0536-45	Elevidys 44.5-45.4 kg
60923-0537-46	Elevidys 45.5-46.4 kg
60923-0538-47	Elevidys 46.5-47.4 kg
60923-0539-48	Elevidys 47.5-48.4 kg
60923-0540-49	Elevidys 48.5-49.4 kg
60923-0541-50	Elevidys 49.5-50.4 kg
60923-0542-51	Elevidys 50.5-51.4 kg
60923-0543-52	Elevidys 51.5-52.4 kg
60923-0544-53	Elevidys 52.5-53.4 kg
60923-0545-54	Elevidys 53.5-54.4 kg
60923-0546-55	Elevidys 54.5-55.4 kg
60923-0547-56	Elevidys 55.5-56.4 kg
60923-0548-57	Elevidys 56.5-57.4 kg
60923-0549-58	Elevidys 57.5-58.4 kg
60923-0550-59	Elevidys 58.5-59.4 kg
60923-0551-60	Elevidys 59.5-60.4 kg
60923-0552-61	Elevidys 60.5-61.4 kg
60923-0553-62	Elevidys 61.5-62.4 kg
60923-0554-63	Elevidys 62.5-63.4 kg
60923-0555-64	Elevidys 63.5-64.4 kg
60923-0556-65	Elevidys 64.5-65.4 kg
60923-0557-66	Elevidys 65.5-66.4 kg
60923-0558-67	Elevidys 66.5-67.4 kg
60923-0559-68	Elevidys 67.5-68.4 kg
60923-0560-69	Elevidys 68.5-69.4 kg
60923-0561-70	Elevidys 69.5 kg plus

ICD-10 Diagnoses

Code	Description
G71.01	Duchenne or Becker muscular dystrophy

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	9/12/2024	New Policy

References

1. Elevidys® intravenous infusion [prescribing information]. Cambridge, MA: Sarepta Therapeutics, Inc.; June 2024.