



Prior Authorization Criteria

MISSISSIPPI DIVISION OF
MEDICAID

ELEVIDYS® (delandistrogene moxeparvovec-rokl) PA Criteria

ELEVIDYS® is indicated for the treatment of patients 4 years of age and older with Duchenne muscular dystrophy (DMD) who are ambulatory and have a confirmed mutation in the DMD gene.

Prior authorization is required for ELEVIDYS®. Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation (such as office chart notes, lab results, or other clinical information).

Limitation: One single dose per lifetime. One kit based on patient weight.

1. Patient is 4 years of age or older;
AND
2. Patient has been diagnosed with Duchenne muscular dystrophy (DMD);
AND
3. Patient is ambulatory (i.e., able to walk without assistive devices and not wheelchair dependent);
AND
4. Patient has a confirmed mutation of the DMD gene between exon 18 to exon 58;
AND
5. The mutation of the DMD gene is **NOT** a deletion in exon 8 and/or exon 9;
AND
6. Patient must have a baseline anti-AAVrh74 total binding antibody titer of < 1:400 as measured by enzyme-linked immunosorbent assay (ELISA);
AND
7. Patient is receiving physical and/or occupational therapy;
AND
8. Patient is **NOT** on concomitant therapy with DMD-directed antisense oligonucleotides (e.g., golodirsen, casimersen, viltolarsen, eteplirsen, etc.);
AND

9. Patient does **NOT** have a preexisting liver impairment [defined as gamma-glutamyl transferase (GGT) more than 2x the upper limit of normal or total bilirubin more than the upper limit of normal not due to Gilbert's syndrome] or active hepatic viral infection;

AND

10. Patient has **NOT** received a DMD-directed antisense oligonucleotide within the past 30 days;

AND

11. Patient does **NOT** have a recent vaccination (within 4 weeks of treatment);

AND

12. Patient does **NOT** have an active or recent (within 4 weeks) infection, including clinically important localized infections;

AND

13. Patient has been on a stable dose of a corticosteroid, unless contraindicated or intolerance, prior to the 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

14. Patient's troponin-1 levels will be monitored at baseline, weekly for the first month, and subsequently as clinically indicated;

AND

15. Patient's platelet counts will be monitored at baseline, weekly for the first two weeks, and subsequently as clinically indicated;

AND

16. Patient will have laboratory liver assessments performed prior to and following therapy weekly for the first 3 months, and as indicated;

AND

17. Prescriber attests that patient will maintain proximity to an appropriate healthcare facility for at least 2 months following ELEVIDYS® infusion.

See Package Insert for specific details on Contraindications/Warnings/Precautions

Dosing

The recommended dose of ELEVIDYS® is 1.33×10^{14} vector genomes per kilogram (vg/kg) of body weight (or 10 mL/kg body weight) for patients weighing less than 70 kg or 9.31×10^{15} vg total fixed dose for patients weighing 70 kg or greater.

Please see the Package Insert for further information regarding how to calculate the dosing, the number of vials required for treatment, and how ELEVIDYS® is supplied.