Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

ELEVIDYS® (delandistrogene moxeparvovec-rokl) PA Criteria

ELEVIDYS® is indicated for the treatment of ambulatory and non-ambulatory pediatric patients aged 4 years and older with Duchenne muscular dystrophy (DMD) with 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 has a confirmed mutation of the DMD gene between exon 18 to exon 58;

   AND

4. The mutation of the DMD gene is **NOT** a deletion in exon 8 and/or exon 9;

   AND

5. Patient must have a baseline anti-AAVrh74 total binding antibody titer of < 1:400 as measured by enzyme-linked immunosorbent assay (ELISA);

   AND

6. Patient is receiving physical and/or occupational therapy;

   AND

7. Patient is **NOT** on concomitant therapy with DMD-directed antisense oligonucleotides (e.g., golodirsen, casimersen, viltolarsen, eteplirsen, etc.);

   AND

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

   AND

9. Patient does **NOT** have an active infection, including clinically important localized infections;

   AND

10. 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

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

    AND

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

    AND

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

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. There is limited safety data available in non-ambulatory patients weighing 70 kg or greater, who received the maximum dose of ELEVIDYS®, 9.31×10^{15} vg, in clinical trials.

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.