Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

Elevidys® (delandistrogene moxeparvovec-rokl) PA Criteria

Evrysdi is indicated for the treatment of ambulatory pediatric patients aged 4 years of age and older with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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

☐ Yes ☐ No Patient is 4 years of age or older;

AND

☐ Yes ☐ No Patient has been diagnosed with Duchenne Muscular Dystrophy (DMD)

AND

☐ Yes ☐ No Patient has a confirmed mutation of the DMD gene between exons 18 to exon 58;

☐ Yes ☐ No The mutation of the DMD gene is **NOT** a deletion in exon 8 or exon 9;

AND

☐ Yes ☐ No Patient must have a baseline anti-AArh74 total binding antibody titer of < 1:400 as measured by ELISA;

AND

☐ Yes ☐ No Patient is ambulatory, and provider will attest.

AND

☐ Yes ☐ No Patient is receiving physical and/or occupational therapy;

AND

☐ Yes ☐ No Patient is **NOT** on concomitant therapy with DMD-directed antisense oligonucleotides (e.g. golodirsen, casimersen, viltolarsen, eteplirsen, etc.);

AND

☐ Yes ☐ No Patient has **NOT** received a DMD-directed antisense oligonucleotides within the past 30 days;

AND

☐ Yes ☐ No Patient does **NOT** have an active infection, including clinically important localized infections;

AND

☐ Yes ☐ No 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

☐ Yes ☐ No Patient's troponin-1 levels will be monitored at baseline, weekly for the first month, and subsequently as clinically indicated;

AND

☐ Yes ☐ No Patient's platelet counts will be monitored at baseline, weekly for the first two weeks, and subsequently as clinically indicated;

AND

☐ Yes ☐ No 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 is 1.33×10^{14} vector genomes per kilogram (vg/kg) of body weight (or 10 mL/kg body weight).

Calculate the dose as follows:
Elevidys dose (in mL) = patient body weight (in kilogram) x 10

The multiplication factor 10 represents the per kilogram dose (1.33 × 1014 vg/kg) divided by the amount of vector genome copies per mL of the Elevidys suspension (1.33 × 1013 vg/mL).

Number of vials needed = Elevidys dose (in mL) divided by 10 (round to the nearest number of vials).