Louisiana Medicaid
Delandistrogene Moxeparvovec-rokl (Elevidys™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for delandistrogene moxeparvovec-rokl (Elevidys™).

Additional Point-of-Sale edits may apply.

This indication is approved under accelerated approval based on expression of Elevidys™ microdystrophin in skeletal muscle observed in patients treated with Elevidys™. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Approval Criteria

- The recipient is 4 or 5 years of age on date of the request; **AND**
- The recipient has a diagnosis of Duchenne muscular dystrophy (DMD) confirmed by genetic testing; **AND**
- The recipient had baseline laboratory tests demonstrating rAAVrh74 antibody titers < 1:400 as determined by ELISA binding immunoassay; **AND**
- This medication is prescribed by a neurologist; **AND**
- The following are true and **stated on the request:**
    - Elevidys™ is not prescribed concurrently with exon skipping therapies; **AND**
    - The recipient has been receiving oral corticosteroid therapy for DMD; **AND**
    - The recipient will continue to receive oral corticosteroid therapy, unless contraindicated or clinically significant adverse effects are experienced; **AND**
    - The recipient **has never received a dose** of Elevidys; **AND**
    - The recipient does **NOT** have any deletion in exon 8 and/or exon 9 in the DMD gene; **AND**
    - The recipient has ambulatory function; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - If the recipient has a deletion in the DMD gene in exon 1 to 17 and/or exons 59 to 71, the recipient will be monitored for severe immune-mediated myositis reaction; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any contraindications, minimum age requirements, recommended dosing, prior treatment requirements and required storage and handling procedures; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of approval: 6 months – allow 1 dose per lifetime

References

ClinicalTrials.gov. A Gene Transfer Therapy Study to Evaluate the Safety and Efficacy of Delandistrogene Moxeparvovec (SRP-9001) in Participants With Duchenne Muscular Dystrophy (DMD) (EMBARK). https://classic.clinicaltrials.gov/ct2/show/NCT05096221

Elevidys (delandistrogene moxeparvovec-rokl) [package insert]. Cambridge, MA: Sarepta Therapeutics, Inc; June 2023. https://www.elevidys.com/PI

Revision / Date	Implementation Date
Policy created / July 2023	January 2024