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.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

~~*The indication for non-ambulatory patients is approved under accelerated approval based on expression of Elevidys® 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).*~~

Approval Criteria

- The recipient is 4 years of age or older on the 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.

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

ClinicalTrials.gov. A Gene Transfer Therapy Study to Evaluate the Safety of and Expression From Delandistrogene Moxeparvovec (SRP-9001) in Participants With Duchenne Muscular Dystrophy (DMD) (ENDEAVOR). https://classic.clinicaltrials.gov/ct2/show/NCT04626674

Elevidys (delandistrogene moxeparvovec-rokl) [package insert]. Cambridge, MA: Sarepta Therapeutics, Inc; June 2024. https://www.elevidyshcp.com/pi

Revision / Date	Implementation Date
Policy created / July 2023	January 2024
Formatting changes, updated references / March 2024	July 2024
Expanded age to 4 years and older, removed ambulatory requirement, updated references / June 2024	January 2025
Reinstated ambulatory requirement / June 2025	July 2025