

delandistrogene moxeparvovec-rokl (Elevidys)**Medical Benefit Drug Policy**Place of Service

Hospital Administration

Outpatient Facility Infusion Administration

The following does not meet the safety and efficacy criteria established by Blue Shield of California's Pharmacy & Therapeutics committee and is not covered:

Elevidys for the treatment of DMD (Duchenne muscular dystrophy). Elevidys is considered not medically necessary due to insufficient evidence of clinical benefit for DMD while showing evidence of significant safety risk.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Elevidys (delandistrogene moxeparvovec-rokl). [Prescribing information]. Sarepta Therapeutics, Inc., Cambridge, MA. June 2024.

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- Removed coverage for DMD. *(Rationale: The FDA continues to investigate reported deaths associated with Elevidys use in DMD patients. Elevidys will be considered investigational due to insufficient evidence of clinical benefit for Duchenne muscular dystrophy (DMD) while showing evidence of significant safety risk.)*

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*