Delandistrogene moxeparvovec-rokl (Elevidys®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Elevidys is indicated for the treatment of patients 4 years of age and older with Duchenne muscular dystrophy (DMD) who are ambulatory and have a confirmed mutation in the DMD gene.

Limitations of Use:
Elevidys is not recommended in patients with:

- Preexisting liver impairment (defined as gamma-glutamyl transferase [GGT] > 2x upper limit of normal or total bilirubin > the upper limit of normal not due to Gilbert's syndrome) or active hepatic viral infection due to the high risk of acute serious liver injury and acute liver failure.
- Recent vaccination (within 4 weeks of treatment) due to immunogenicity and potential safety concerns.
- Active or recent (within 4 weeks) infections due to safety concerns.

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- Genetic test results confirming the DMD diagnosis.
- Medical records (e.g., chart notes and/or laboratory reports) documenting ambulation status.

EXCLUSIONS

Coverage will not be provided for members with any deletion in exon 8 and/or exon 9, including a deletion of any portion or the entirety of these exons, in the DMD gene.

COVERAGE CRITERIA

Duchenne Muscular Dystrophy

Authorization of 3 months for one dose total may be granted for treatment of Duchenne muscular dystrophy when all of the following criteria are met:

- Member has a diagnosis of DMD with a confirmed mutation in the DMD gene
- Member is ambulatory.
- Member is 4 through 5 years of age (at least 4 years 0 days and less than 6 years old)
- Member has anti-recombinant adeno-associated virus serotype rh74 (anti-AAVrh74) total binding antibody titers of < 1:400.
- Member does not currently have an active infection.
- Member does not have significant liver dysfunction or disease, defined as at least one of the following:
  - Preexisting liver impairment; or
  - Chronic hepatic condition; or
  - Acute liver disease (e.g., acute hepatic viral infection)

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Elevidys [package insert]. Cambridge, MA: Sarepta Therapeutics, Inc.; November 2025.
2. ClinicalTrials.gov. NCT03769116. A randomized, double-blind placebo-controlled study of delandistrogene moxeparvovec (SRP-9001) for Duchenne Muscular Dystrophy. Accessed May 9, 2025.
3. Zaidman CM, Proud CM, McDonald CM, et al. Delandistrogene Moxeparvovec Gene Therapy in Ambulatory Patients (Aged ≥4 to <8 Years) with Duchenne Muscular Dystrophy: 1-Year Interim Results from Study SRP-9001-103 (ENDEAVOR). Ann Neurol. 2023 Nov;94(5):955-968

EFFECTIVE DATE 1/30/2027

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