Corporate Medical Policy: Delandistrogene moxeparvovec-rokl (Elevidys®) **"Notification"** **POLICY EFFECTIVE APRIL 1, 2026**

Restricted Product(s):

- delandistrogene moxeparvovec-rokl (Elevidys®) intravenous infusion for administration by a healthcare professional

FDA Approved Use:

- 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] > 2 x 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

*Use of delandistrogene moxeparvovec-rokl (Elevidys®) is considered investigational for this indication due to insufficient clinical evidence to establish safety, efficacy, and improved health outcomes

Criteria for Medical Necessity:

Not applicable

The use of delandistrogene moxeparvovec-rokl (Elevidys®) is considered investigational for all indications including treatment of Duchenne muscular dystrophy (DMD). BCBSNC does not provide coverage for investigational services or procedures.

- The use of delandistrogene moxeparvovec-rokl is considered investigational for all indications including treatment of Duchenne muscular dystrophy (DMD)

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units**
delandistrogene moxeparvovec-rokl (Elevidys®) intravenous (IV) infusion	Duchenne muscular dystrophy (DMD)	10 to 70 kg: 1.33 x 10^{14} vector genomes (vg) per kg of body weight (or 10 mL/kg body weight) via IV infusion ≥ 70 kg: 9.31 x 10^{15} vector genomes (vg) per kg of body weight via IV infusion	J1413	**N/A**

Other revenue codes that may be applicable to this policy: 0891, 0892

References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q4 annually.

April 2026: Coding change: Added the following applicable revenue codes associated with policy HCPCS code(s): 0891 (Special Processed Drugs – FDA Approved Cell Therapy) and 0892 (Special Processed Drugs – FDA Approved Gene Therapy). **Policy notification given 2/1/2026 for effective date 4/1/2026**.
December 2025: Criteria change: For FDA approved use section, removed accelerated approval indication for non-ambulatory patients with DMD. Updated wording for ambulatory patients with DMD and added limitations of use statements according to updated FDA labeling. Removed non-ambulatory safety data statement from FDA label reference table to reflect updated FDA labeling.
November 2024: Criteria change: Adjusted FDA approved use section to reflect traditional FDA approval for ambulatory DMD patients for clarity with no change to policy intent, and added clarification for this indication that use is considered investigational due to insufficient clinical evidence to establish safety, efficacy, and improved health outcomes. Adjusted FDA approved use section to add accelerated approval for non-ambulatory DMD patients with clarification that continued FDA approval of this indication is contingent upon verification and description of clinical benefit in a confirmatory trial(s). Changed FDA labeled age within FDA approved use section to at least 4 years for clarity according to updated label. Use of delandistrogene moxeparvovec-rokl is considered investigational for all indications including treatment of Duchenne muscular dystrophy (DMD).

January 2024: Coding change: Added HCPCS code J1413 to dosing reference table effective 1/1/2024; deleted C9399, J3490, and J3590 termed 12/31/2023.
July 2023: Original medical policy criteria issued: Use of delandistrogene moxeparvovec-rokl (Elevidys) is considered investigational for all indications including treatment of Duchenne muscular dystrophy (DMD).