



## Clinical Policy: Elevidys – Pharmacy Prior Approval Criteria

Reference Number: WNC.CP.303

Last Review Date: 06/2025

Coding Implications

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

**Note:** When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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### Description<sup>1</sup>

This policy discusses medical necessity criteria for Elevidys (delandistrogene moxeparvovec-rokl) Pharmacy Prior Approval Criteria.

**Therapeutic Class Code: Z16**

**Therapeutic Class Description:** Gene Therapy Agents - Protein Deficiency

### Policy/Criteria<sup>1</sup>

- I. WellCare of North Carolina<sup>®</sup> shall cover Elevidys when **ALL** the following requirements are met:
  - A. Member has a Diagnosis of Duchenne muscular dystrophy (DMD); **AND**
  - B. Member is aged  $\geq 4$  years and  $< 8$ -years old; **AND**
  - C. Medication is prescribed by or in consultation with a Pediatric Neuromuscular Specialist; **AND**
  - D. Member has a confirmed mutation of the DMD gene; **AND**
  - E. Member does not have any deletion in exon 8 and/or exon 9 in the DMD gene; **AND**
  - F. Member must have a baseline anti-AAVrh74 total binding antibody titer of  $< 1:400$  as measured by ELISA; **AND**
  - G. Chart documentation indicates the member is ambulatory; **AND**
  - H. Member is not on concomitant therapy with DMD-directed antisense

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oligonucleotides (e.g., golodirsen, casimersen, viltolarsen, eteplirsen); **AND**

- I.** Member has not received a DMD-directed antisense oligonucleotide within the past 30 days; **AND**
  - J.** Member does not have an active infection, including clinically important localized infections; **AND**
  - K.** Member has been on a stable dose of a corticosteroid, unless contraindicated or intolerance, prior to start of therapy and will be used concomitantly with a corticosteroid regimen pre- and post-infusion (refer to the package insert for recommended corticosteroid dosing during therapy); **AND**
  - L.** Member's troponin-I levels will be monitored at baseline and subsequently as clinically indicated; **AND**
  - M.** Member will have liver function and platelet count assessed prior to and following therapy for at least 3 months and as indicated; (to include at a minimum GGT and total bilirubin); **AND**
  - N.** Member must meet FDA-approved label for use (e.g., **use outside of studied population will be considered investigational**).
  - O.** While there are ongoing trials, North Carolina Medicaid are not aware of a resulted trial for ages above 8 so even though the FDA approval is not age based, since it hasn't been studied in older ages, North Carolina Medicaid consider usage in older ages to be investigational.
  - P.** Use should be avoided where the benefits of therapy versus risk are less well known. The indication for non-ambulatory patients is approved by the FDA under accelerated approval based on expression of microdystrophin in skeletal muscle. Continued approval by the FDA for this indication may be contingent upon verification of a clinical benefit in confirmatory trials. Use in non-ambulatory members is considered to be investigational until confirmatory trials are published.
  - Q.** The ENVISION trial NCT05881408 will confirm clinical benefit for non-ambulatory patients and is expected to be completed January 2027.
  - R.** The provider attests that they are reasonably certain Elevidys can be administered before the Member turns 8 years old.
- II.** WellCare of North Carolina's® Duration of Approval is **ONE TREATMENT**.

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**Coding Implications**

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2025, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS®* Codes	Description
J1413	Elevidys (delandistrogene moxeparvovec-rokl)

Reviews, Revisions, and Approval	Reviewed Date	Approval Date
Original Approval Date	06/25	06/25

**References**

1. State of North Carolina Medicaid Outpatient Pharmacy Prior Approval Criteria - Casgevy. [Program Specific Clinical Coverage Policies | NC Medicaid \(ncdhhs.gov\)](https://www.ncdhhs.gov/Program-Specific-Clinical-Coverage-Policies-NC-Medicaid). Published June 20, 2025. Accessed June 23, 2025.

**North Carolina Guidance**

*Eligibility Requirements*

1. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
2. Provider(s) shall verify each Medicaid beneficiary’s eligibility each time a service is rendered.
3. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

*EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age*

- 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]  
Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a

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condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure:

- I. that is unsafe, ineffective, or experimental or investigational.
- II. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

**EPSDT and Prior Approval Requirements**

- If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
- **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:  
*NCTracks Provider Claims and Billing Assistance Guide:*  
<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>  
*EPSDT provider page:* <https://medicaid.ncdhhs.gov/>

*Provider(s) Eligible to Bill for the Procedure, Product, or Service*

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

- i. meet Medicaid qualifications for participation;
- ii. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and

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- iii. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

*Compliance*

Provider(s) shall comply with the following in effect at the time the service is rendered:

- A. All applicable agreements, federal, state, and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- B. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

*Claims-Related Information*

Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

- Claim Type - as applicable to the service provided:
  - Professional (CMS-1500/837P transaction)
  - Institutional (UB-04/837I transaction)Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
- International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
- Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

*Unlisted Procedure or Service*

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service

- Modifiers - Providers shall follow applicable modifier guidelines.

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- Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
- Co-payments -  
For Medicaid refer to Medicaid State Plan:  
<https://medicaid.ncdhhs.gov/meetingsnotices/medicaid-state-plan-public-notices>
- Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>.

### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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