TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Delandistrogene moxeparvovec-rokl (Elevidys®)	**CRITERIA ID:** TX.CC.PHAR.32
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 01/01/2024	**PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 4/3/2024	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for delandistrogene moxeparvovec-rokl (Elevidys®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

Additionally, this medication is a Precision Drug. Centene's Precision Drug Action Committee (PDAC) creates a standardized approach for Centene to manage Precision Drugs and the associated costs for their administration, prior to members presenting with a request for one of these agents. All Precision Drug requests or potential requests must be reported to the PDAC for tracking, regardless of whether agents are carved out, passed through, etc. All Precision Drug medical necessity determinations will be supported by PDAC UM recommendation, utilizing specialist input as directed and allowed by turnaround times.

The procedure code J1413 (used for Elevidys) will be limited to one approval per lifetime, by any provider. If the code is updated in the future, it will still be limited to once per lifetime.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
DMD = Duchenne muscular dystrophy

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of delandistrogene moxeparvovec-rokl (Elevidys®); procedure code J1413.

Description/Mechanism of Action:
Delandistrogene moxeparvovec-rokl (Elevidys ®) is an adeno-associated virus vector-based gene therapy indicated for the treatment of ambulatory pediatric clients ages 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene.

FDA Approved Indications:
Delandistrogene moxeparvovec-rokl (Elevidys®) is indicated for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Duchenne muscular dystrophy (DMD) (must meet all):

Note: Pharmacy clinician will make one outreach attempt to the servicing provider (SP) to determine which NDC will be utilized for drug administration. (**Please Note** Sometimes not all NRB drug NDC's are covered on the VDP CAD Formulary). If the requested NDC is not covered, clinician should steer servicing provider to an NDC covered on VDP's CAD formulary based on client's weight. Call note details should be documented under applicable PA.

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. Medical necessity determinations will be supported by PDAC UM recommendation. The pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the Medical Director but will not make the ultimate determination on any case.
3. The client is between 4 and 5 years of age.
4. The client has a confirmed mutation in the DMD gene (diagnosis code: G71.01).
   Note: Prescribers should monitor clients with a mutation in exons 1-17 and/or 59-71 of the DMD gene, for immune-mediated myositis.
5. The client does not have any deletion in exon 8 or exon 9 in the DMD gene.
6. Documentation that the client is ambulatory and not wheelchair-bound (able to walk with or without assistance).
7. The client is not on concomitant DMD antisense oligonucleotide therapy (e.g., golodirsen, casimersen, viltolarsen, eteplirsen, etc.).
8. Documentation of client's baseline testing for the presence of anti-AAVrh74 total binding antibody titers of less than 1:400.
9. The client has no current infection. If there are signs of infection prior to infusion, treatment with Elevidys should be postponed until the infection clears.
10. Prescriber attestation that the client's baseline liver function will be documented and monitored prior and post Elevidys therapy, due to the possibility of acute serious liver injury.
    Note: Liver function should be monitored upon initiation of therapy and continued on a weekly schedule for the first 3 months after infusion.
11. Prescriber attestation that the client's platelet count and troponin-I level will be documented before infusion.
    Note*:* Troponin–I level should be monitored weekly for the first month after infusion.
12. The client does not have a history of previously receiving treatment with Elevidys infusion.

Approval duration: Only 1 dose per lifetime will be provided on this drug regardless of Provider.

REFERENCES:
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS:

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED

New Policy Document	N/A	01/01/2024
Ad hoc review	Updated diagnosis code to G71.01; added NRB and PDAC requirement statement Updated to TX.CC.PHAR format template Added Centene copyright statement and criteria requirement PDAC review must be completed prior to final determination and final determination must be made by a medical director Changed criteria step from: “The client has a confirmed mutation in the DMD gene between exons 18-58 (diagnosis code: G71.01)” to “The client has a confirmed mutation in the DMD gene (diagnosis code: G71.01). **Note:** Prescribers should monitor clients with a mutation in exons 1-17 and/or 59-71 of the DMD gene, for immune-mediated myositis.” Based on TMHP CAD Manual update effective 4/1/24.	4/3/2024

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