POLICY AND PROCEDURE

POLICY NAME: Elevidys (delandistrogene moxeparvovec-rokl)	**POLICY ID:** TX.PHAR.120
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:	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
The purpose of this Clinical Policy is to provide a guide to medical necessity reviews for Elevidys (delandistrogene moxeparvovec-rokl).

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

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 policy and prior authorization requirements.

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.

Note: Elevidys (J1413) requests are limited to one approval per lifetime, by any provider.

SCOPE:
This policy applies to Centene Pharmacy Services, Pharmacy Department, Medical Directors, Claims.

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 Elevidys (delandistrogene moxeparvovec-rokl).

Description:
Elevidys (delandistrogene moxeparvovec-rokl) 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 Indication(s):

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):

1. The client is between 4 and 5 years of age.
2. The client has a confirmed mutation in the DMD gene between exons 18-58 (diagnosis code: 71.01).
3. The client does not have any deletion in exon 8 or exon 9 in the DMD gene.
4. Documentation that the client is ambulatory and not wheelchair-bound (able to walk with or without assistance).
5. The client is not on concomitant DMD antisense oligonucleotide therapy (e.g., golodirsen, casimersen, viltolarsen, eteplirsen, etc.).
6. Documentation of client's baseline testing for the presence of anti-AAVrh74 total binding antibody titers of less than 1:400.
7. 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.
8. 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.*
9. 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.*
10. 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:

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document	N/A	01/01/2024

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.