TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Voretigene neparvovec-rzyl (Luxturna®)	**CRITERIA ID:** TX.CC.PHAR.04
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 08/2018	**PRODUCT(S):** STAR, STAR Health, STAR Kids, STAR+PLUS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 4/23/19, 10/01/19, 01/8/20, 01/07/21, 12/10/21, 12/10/22, 12/08/2023, 02/27/2024, 2/20/2025	
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 voretigene neparvovec-rzyl (Luxturna®).

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 J3398 (used for Luxturna) will be limited to once per eye 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:
NRB = Non-risk based
PDAC = Precision Drug Action Committee
UM = Utilization Management

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of voretigene naparvovec-rzyl (Luxturna®); procedure code: J3398.

Exclusion: Luxturna is not a benefit for patients who have previously received RPE65 gene therapy and who do not have viable retinal cells in each eye as determined by the treating physician.

Description/Mechanism of Action:
Voretigene naparvovec-rzyl (Luxturna®) is an adeno-associated virus vector-based gene therapy to treat children and adult patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy that leads to vision loss and may cause complete blindness in certain patients. Luxturna is the first directly administered gene therapy approved in the United States that targets a disease caused by mutations in a specific gene. Luxturna is a clinician-administered drug. It must be prescribed and administered by a retinal surgeon at an ocular gene therapy treatment center with experience performing intraocular surgery.

FDA Approved Indication(s):
Voretigene naparvovec-rzyl (Luxturna®) is indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physician(s).

PROCEDURE:

I. Initial Approval Criteria

A. Biallelic RPE65 mutation-associated retinal dystrophy

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 CPS 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 no less than 1 year of age and no greater than 65 years of age.
4. The client has a documented diagnosis of a confirmed biallelic RPE65 mutation-associated retinal dystrophy (e.g. Leber's congenital amaurosis subtype 2, retinitis pigmentosa, early onset severe retinal dystrophy).
5. Documentation of genetic testing that confirms biallelic mutations of the RPE65 gene.
6. Documentation of a treatment plan to show that systemic corticosteroids equivalent to prednisone 1mg/kg/day will be/are administered for a total of 7 days, starting 3 days before administration of Luxturna (voretigene neparvovec-rzyl) to each eye and followed by a tapering dose.
7. The client has viable retinal cells in each eye as determined by the treating physician, assessed in the previous 6 months. Verification of viable retinal cells must be documented and evident by one of the following:
    - An area of retina within the posterior pole of greater than 100 µm thickness shown on optimal coherence tomography (OCT); OR
    - Greater than or equal to 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole; OR
    - Remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent.
8. Documentation that Luxturna will be/is prescribed and administered by a retinal surgeon at an ocular gene therapy treatment center with experience performing intraocular surgery.
9. The client has not previously received RPE65 gene therapy in intended eye(s).
10. Prescriber attestation that injection of the second eye will be administered at least 6 days after the first eye.
11. The client has not had intraocular surgery within 6 months in either eye indicated for treatment.

Approval duration: Only 1 dose, per eye, per lifetime will be provided on this drug regardless of Provider. Authorization is valid for a period of up to 6 months from approval.

<u>Exclusion</u>: Luxturna is not a benefit for patients who have previously received RPE65 gene therapy and who do not have viable retinal cells in each eye as determined by the treating physician.

REFERENCES:
Luxturna (voretigene neparvovec-rzyl) [prescribing information]. Philadelphia, PA: Spark Therapeutics Inc; May 2022.
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document	N/A	08/2018
Ad Hoc Review	Changed "Justin M.Weiss, Sr. V.P., Pharmacy Operations" to "Karen Tadlock, V.P., Pharmacy Operations" Added References	04/23/19
Ad Hoc Review	Added information and criteria step regarding Centene's Precision Drug Action Committee (PDAC) Updated information regarding new billing code J3398	10/01/19
Annual Review	Removed step 3. From initial approval criteria "Initial request must include documentation supporting medical necessity, including a prior authorization request form signed and dated by the Medicaid-enrolled prescribing provider, dated within 90 days of request. PA requests from the pharmacy will not be accepted. These must come from the Provider. It is the Provider who is responsible for providing approval information to the dispensing pharmacy. The pharmacy should not act on/facilitate prior authorization on behalf of the provider."	01/08/20
Annual Review	No changes	01/07/21
Annual Review	Updated references Minor formatting changes	12/10/21
Annual Review	Moved to new P&P Template Updated references	12/10/22
Annual Review	Included reference to Centene Pharmacy Services (CPS) throughout document Updated POLICY STATEMENT/PURPOSE sections to include regulatory requirements and reference to TMPPM Adjusted criteria point verbiage to "The client" for consistency throughout document Added DEFINITIONS, PDAC, NRB, UM Minor formatting changes in criteria steps. Removed criteria step 12 and added information as part of Approval duration to align with TMHP CAD Manual Removed Section II. Continued Therapy Added Exclusion clause	12/08/23
Ad Hoc review	Updated to TX.CC.PHAR format template Added Centene copyright statement	02/27/2024
Ad Hoc review	Annual review. No changes	2/20/2025