POLICY AND PROCEDURE

POLICY NAME: Voretigene neparvovec-rzyl (Luxturna®) Criteria	**POLICY ID:** TX.PHAR.49
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	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of voretigene naparvovec-rzyl (Luxturna).

PURPOSE:
HHSC will account for the ingredient cost of Luxturna coverage in managed care using a non-risk based payment process. Therefore, the drug should follow state guidance for medical necessity review criteria for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Superior 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. In addition, the procedure code J3398 (used for Luxturna®) will be limited to once per eye per lifetime, by any provider.

Description/Mechanism of Action:
Luxturna (voretigene neparvovec-rzyl) 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.
Luxturna was published on the July 2018 Healthcare Common Procedure Coding System to National Drug Code Crosswalk, with an effective date of Jul. 1, 2018.

Formulations:
Luxturna (voretigene neparvovec-rzyl): suspension for subretinal injection supplied as 0.5mL voretigene neparvovec and 2 (each) diluents, free of preservatives.

FDA Approved Indications:
Luxturna (voretigene neparvovec-rzyl) is indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.

SCOPE:
Superior HealthPlan Pharmacy Department, Medical Directors

DEFINITIONS: N/A

POLICY:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of voretigene naparvovec-rzyl (Luxturna).

PROCEDURE:

I. Initial Approval Criteria

A. Biallelic RPE65 mutation-associated retinal dystrophy

1. All prior authorization approvals or denials will be determined by a Superior HealthPlan Medical Director.
2. Medical necessity determinations will be supported by PDAC UM recommendation. The SHP pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the SHP Medical Director but will not make the ultimate determination on any case.
3. Client age is no less than 1 year of age and no greater than 65 years of age.
4. Diagnosis of 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 must confirm biallelic mutations of the RPE65 gene.
6. Treatment plan must 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 voretigene neparvovec-rzyl to each eye and followed by a tapering dose.
7. Client has viable retinal cells in each eye as determined by the treating physician, assessed in the previous 6 months. If viable retinal calls are not present then the authorization is not approvable. Verification of viable retinal cells must be documented and evident by one of the following:
    a. An area of retina within the posterior pole of greater than 100 µm thickness shown on optimal coherence tomography (OCT).
    b. Greater than or equal to 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole.
    c. Remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent.
8. Prescribed and administered by a retinal surgeon at an ocular gene therapy treatment center with experience performing intraocular surgery.
9. Member has not previously received RPE65 gene therapy in intended eye(s).
10. Injection of the second eye must be administered at least 6 days after the first eye.
11. For each eye indicated for treatment, have not had intraocular surgery within 6 months.
12. Benefit not to exceed more than 1 injection per eye per lifetime. Authorization is valid for a period of 6 months from approval.

II. Continued Therapy

A. Biallelic RPE65 mutation-associated retinal dystrophy

1. Luxturna is not a benefit for patients who have previously received RPE65 gene therapy in intended eye. Benefit not to exceed more than 1 injection per eye per lifetime.

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

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: 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

POLICY AND PROCEDURE APPROVAL

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