

# SENTARA HEALTH PLANS

## MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST\*

**Directions:** The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed.**

**For Medicare Members:** Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>. Additional indications may be covered at the discretion of the health plan.

**Drug Requested:** Luxturna™ (voretigen neparvovec-rzy) Subretinal Injection (**Medical**) (J-3398)

**Luxturna™ should ONLY be administered in a surgical suite under controlled aseptic conditions by a surgeon experienced in performing intraocular surgery.**

**MEMBER & PRESCRIBER INFORMATION:** Authorization may be delayed if incomplete.

Member Name: \_\_\_\_\_

Member Sentara #: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

Prescriber Name: \_\_\_\_\_

Prescriber Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Office Contact Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

DEA OR NPI #: \_\_\_\_\_

**DRUG INFORMATION:** Authorization may be delayed if incomplete.

Drug Form/Strength: \_\_\_\_\_

Dosing Schedule: \_\_\_\_\_ Length of Therapy: \_\_\_\_\_

Diagnosis: \_\_\_\_\_ ICD Code, if applicable: \_\_\_\_\_

Weight: \_\_\_\_\_ Date: \_\_\_\_\_

- Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

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**CLINICAL CRITERIA:** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

**INITIAL AUTHORIZATION: ONE DOSE PER EYE/PER LIFETIME. RENEWAL IS NOT AUTHORIZED**

- Has member received Luxturna™ in the past?  Yes  No
- Yes, in the same eye (Provide details and progress notes with date and time stamp.)
- Yes, but in the other eye only (Provide details and progress notes with date and time stamp.)
- No
- Unknown

**MEDICAL INFORMATION. Supportive documentation must be provided for all answers below or request may be delayed or denied.**

1. Does member have vision loss due to inherited retinal dystrophy?  Yes  No

**AND**

2. Did member undergo genetic testing?

- Yes – include a copy of the test results  No – denial of drug

If YES:

- a) Did genetic testing confirm biallelic mutation of the RPE65 gene (two confirmed pathogenic or likely pathogenic loss of function variants)?  Yes  No

**AND**

- b) Indicate which of the following genetic test was performed to confirm biallelic pathogenic and/or likely pathogenic RPE65:

- Single-gene test  None listed

Provide the date of the test: \_\_\_\_\_

3. Are the RPE65 gene mutations classifications based on the ACMG standards and guidelines for the interpretation of sequence variants (2015)?  Yes  No

Which eye is being treated?  Left Eye  Right Eye  Both Eyes

If both eyes, does prescriber agree that the initial eye's injection and the second eye's injection will be administered at **least six days apart?**  Yes  No

4. Does member have sufficiently viable retinal cells as determined by optical coherence tomography (OCT) and/or ophthalmoscopy?  Yes  No (denial of drug)

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If **YES**, does the optical coherence tomography (OCT) and/or ophthalmoscopy show any of the following? (**Check and provide documentation of at least one of the below.**)

- Area of retina within the posterior pole of greater than 100  $\mu\text{m}$  thickness per OCT

**OR**

- At least 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole

**AND**

- Visual field within 20 degrees in any meridian as measured by III4e isopter **OR** equivalent in both eyes

**OR**

- Visual acuity worse than 20/60 in **both** eyes

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

***\*\*Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.\*\****

***\*Previous therapies will be verified through pharmacy paid claims or submitted chart notes.\****