SENTARA COMMUNITY PLAN
(MEDICAID)

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 1-844-305-2331**. 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**.

Drug Requested: Luxturna® (voretigene neparvovec-rzyl) Subretinal Injection **(J3398) (Medical)**

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:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ 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.

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

Dosing Limits

A. Quantity Limit (max daily dose) [NDC 71394-0065-01 or 71394-0415-01]:
   - N/A

B. Max Units (per dose and over time) [HCPCS Unit]:
   - 150 billable units per eye
   - If both eyes are to be treated, Luxturna must be administered to each eye on separate days at least 6 days apart

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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.

Length of Authorization:

One dose per eye/per lifetime. Coverage cannot be renewed

- ❑ Member is at least 1 year of age or older
- ❑ Member must have an adequate washout period, defined as a minimum of 3 months, from retinoid therapies prior to receipt of voretigene
- ❑ Member has a confirmed diagnosis of a biallelic RPE65 mutation-associated retinal dystrophy
- ❑ Member must have viable retinal cells as determined by non-invasive means such as optical coherence tomography (OCT) and/or ophthalmoscopy indicating **ONE** or more of the following:
  - ❑ An area of retina within the posterior pole of >100 microns thickness shown on OCT
  - ❑ ≥ 3-disc areas of the retina without atrophy or pigmentary degeneration within the posterior pole
  - ❑ Remaining visual field within 30 degrees of fixation as measured by an III4e isopter or equivalent
- ❑ Member has **NOT** had intraocular surgery within the past six months
- ❑ Member has **NOT** previously received subretinal administration of a gene therapy vector, or Luxturna into the intended eye

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health'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.****

***Approved by Pharmacy and Therapeutics Committee:** ~~7/18/2019;~~ **9/26/2024**
REVISED/UPDATED/REFORMATTED: ~~10/12/2019; 10/15/2024, 4/10/2025; 4/25/2025;~~ **6/10/2026**