| Voretigene neparvovec-rzyl (Luxturna®) | Place of Service<br>Hospital Administration<br>Outpatient Facility Administration<br><br>HCPCS: J3398 per 1 billion vector genomes |
|---|---|

Condition listed in policy *(see criteria for details)*

- RPE65 mutation-associated retinal dystrophy

**AHFS therapeutic class:** Gene therapy

**Mechanism of action**: Adeno-associated virus vector-based gene therapy

## (1) Special Instructions and Pertinent Information

**Covered under the Medical Benefit,** please submit clinical information for prior authorization review via fax.

## (2) Prior Authorization/Medical Review is required for the following condition(s)

**All requests for voretigene neparvovec-rzyl (Luxturna®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

RPE65 mutation-associated retinal dystrophy

1. Prescribed by an ophthalmologist, **AND**
2. Patient is 12 months of age or older, **AND**
3. Patient has genetic laboratory documentation of two pathogenic or likely pathogenic variants in the RPE65 gene or one pathogenic or likely pathogenic variant on both alleles in the RPE65 gene, **AND**
4. Patient has documentation for sufficient viable retinal cells, **AND**
5. Patient has not received prior gene therapy for treatment of vision loss, **AND**
6. Being administered subretinally to each eye on separate days, at least 6 days apart

**Covered Dose**

$1.5 \times 10^{11}$ vector genomes (0.3 mL) in each eye

**Coverage Period**

Once per eye per lifetime

**ICD-10:**

H35.50, H35.52, H35.54

## (3) The following condition(s) DO NOT require Prior Authorization/Preservice

**All requests for voretigene neparvovec-rzyl (Luxturna®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

## (4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

## (5) Additional Information

- How Supplied:
  Each carton contains one single-dose vial of Luxturna [5 x $10^{12}$ vector genomes (vg) per mL] and two vials of Diluent

- Luxturna is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.
- Patients must have viable retinal cells to respond to the missing protein and restore visual function.

## (6) References


- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Luxturna® (voretigene neparvovec-rzyl) [Prescribing Information]. Philadelphia, PA: Spark Therapeutics, Inc.; 2018.
- Mahajan VB, Bennett J, Maguire A et al. RPE65 Mutation Subtype Effect on Baseline Visual Function and Treatment Response in Phase 3 Voretigene Neparvovec Trial. Abstract P0220. Presented at the American Academy of Ophthalmology Annual Meeting, October 27–30, 2018, McCormick Place, Chicago, IL.


## (7) Policy Update

Date of last review: 3Q2023
Date of next review: 3Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity*
*Reviewed by P&T Committee*