

Voretigene neparvovec-rzyl (Luxturna®)

Place of Service  
Hospital Administration  
Outpatient Facility Administration

HCPs: 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 x 10<sup>11</sup> 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 [ $5 \times 10^{12}$  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.; 5/2022.
- 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*