

**voretigene neparvovec-rzyl (Luxturna)**

HCPCS: J3398, Injection, voretigene neparvovec-rzyl, 1 billion vector genomes (Luxturna)

|                              |                                             |
|------------------------------|---------------------------------------------|
| <b>LOB:</b>                  | MCAL                                        |
| <b>Duration of Approval:</b> | One injection per eye per lifetime          |
| <b>Quantity Limit:</b>       | Per FDA-Approved/Compendia-Supported Dosing |
| <b>MCG Available:</b>        | Yes                                         |
| <b>DHCS Drug Policy:</b>     | No                                          |

**Requires Prior Authorization (PA)**

Luxturna (voretigene neparvovec-ryl) injection

**\*\*All requests must be approved by a Medical Director\*\*****PA CRITERIA FOR APPROVAL:**

1. The member has a diagnosis for a Food and Drug Administration (FDA)-approved indication (refer to package insert under References) **OR** a compendia-supported (Drugdex or American Hospital Formulary Service [AHFS]) indication **AND**
2. The medication is prescribed by an ophthalmologist or retinal specialist **AND**
3. The member is 12 or more months of age **AND**
4. Diagnosis is confirmed by genetic test showing biallelic RPE65 mutation **AND**
5. Documentation is provided confirming the member has viable retinal cells defined as **ONE** of the following **(a–c)**:
  - a. An area of retinal thickness > 100 µm (microns) within the posterior pole as measured by optical coherence tomography (OCT)
  - b. Three or more 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 III4e isopter or equivalent**AND**
6. The member has not received a previous treatment course of Luxturna for the requested eyes **AND**
7. The member did not have intraocular surgery in the past six months

**OTHER INFORMATION:**

| <b>HCPCS</b> | <b>Description</b>                                              | <b>Brand name</b> |
|--------------|-----------------------------------------------------------------|-------------------|
| J3398        | Injection, voretigene neparvovec-rzyl, 1 billion vector genomes | Luxturna          |

**REFERENCES:**

1. Luxturna Prescribing Information. [sparktx.com/LUXTURNA\\_US\\_Prescribing\\_Information.pdf](https://sparktx.com/LUXTURNA_US_Prescribing_Information.pdf). 05/2022.
2. Spark Therapeutics, Inc. Safety and Efficacy Study in Subjects with Leber Congenital Amaurosis (Phase III). [clinicaltrials.gov/study/NCT00999609](https://clinicaltrials.gov/study/NCT00999609). NLM Identifier: NCT00999609.
3. DHCS Cell and Gene Therapy Overview. [mcweb.apps.prd.cammis.medi-cal.ca.gov/assets/821726E2-2EAB-4A86-AA42-4778E89A38FD/celgenover.pdf?access\\_token=6UyVkrRfByXTZEWIh8j8QaYyIPyP5ULO](https://mcweb.apps.prd.cammis.medi-cal.ca.gov/assets/821726E2-2EAB-4A86-AA42-4778E89A38FD/celgenover.pdf?access_token=6UyVkrRfByXTZEWIh8j8QaYyIPyP5ULO). 09/2025.