Luxturna® (voretigene neparvovec-rzyl)
(Subretinal Injection)

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I. Length of Authorization

Coverage will be provided for one dose per eye and may not be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 150 billable units for one dose per eye

III. Initial Approval Criteria [1,2]

Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e. genetic and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax.

Coverage is provided in the following conditions:

- Patient is at least 12 months of age; **AND**
- Patient must have an adequate washout period, defined as a minimum of 3 months, from retinoid therapies prior to receipt of voretigene neparvovec-rzyl; **AND**
- Patient has not had intraocular surgery within six months; **AND**
- Patient has not previously received subretinal administration of a gene therapy vector, or Luxturna, into the intended eye; **AND**

Retinal Dystrophy † Φ [1,2]

- Patient has a definitive diagnosis confirming biallelic *RPE65* mutation-associated retinal dystrophy; **AND**
- Patient 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 µm thickness shown on OCT
  - ≥ 3-disc areas of 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

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

- Duration of authorization has not been exceeded *(refer to Section I)*.

V. Dosage/Administration [1]

Indication	Dose
Biallelic RPE65 mutation-associated retinal dystrophy	**For subretinal injection only.** Preparing for Administration: • Luxturna should be administered in the surgical suite under controlled aseptic conditions by a surgeon experienced in performing intraocular surgery. • Dilate the eye, give adequate anesthesia to the patient, and administer a topical broad spectrum microbiocide. • Complete a vitrectomy. • Do not administer Luxturna in the immediate vicinity of the fovea. Luxturna Injection: • Under direct visualization, administer Luxturna into the affected eye [1.5 x 10^{11} vector genomes (vg) in a total volume of 0.3 mL]. • Perform subretinal administration of Luxturna to each eye on separate days within a close interval, but no fewer than 6 days apart. • Recommend systemic oral corticosteroids equivalent to prednisone at 1 mg/kg/day (maximum of 40 mg/day) for a total of 7 days (starting 3 days before administration of Luxturna to the first eye) and followed by tapering the dose during the following 10 days. The same corticosteroid dosing regimen applies for the administration of Luxturna to the second eye. If the corticosteroid taper following Luxturna administration to the first eye is not complete three days prior to the planned Luxturna administration to the second eye, then the corticosteroid regimen for the second eye replaces the taper for the first eye.
• Store Luxturna and Diluent frozen at ≤ -65 °C. Thaw prior to infusion. • Luxturna is an adeno-associated virus vector-based gene therapy. Follow universal biohazard precautions for handling.	

VI. Billing Code/Availability Information

HCPCS code:

- J3398 – Injection, voretigene neparvovec-rzyl, 1 billion vector genomes; 1 billable unit = 10^9 vector genomes

NDC:

- Luxturna carton (one single-dose vial of Luxturna and two vials of diluent): 71394-0415-xx

VII. References

1. Luxturna [package insert]. Philadelphia, PA; Spark Therapeutics, Inc., May 2022. Accessed December 2024.
2. Russell S, Bennett J, Wellman JA, et al. Efficacy and safety of voretigene neparvovec (AAV2-hRPE65v2) in patients with RPE65-mediated inherited retinal dystrophy: a randomised, controlled, open-label, phase 3 trial. Lancet. 2017 Aug 26;390(10097):849-860. doi: 10.1016/S0140-6736(17)31868-8. Epub 2017 Jul 14. Erratum in: Lancet. 2017 Aug 26;390(10097):848.
3. Palmetto GBA. Local Coverage Article: Billing and Coding: Voretigene Neparvovec-rzyl (Luxturna®) (A56419). Centers for Medicare & Medicaid Services, Inc. Updated on 04/10/2023 with effective date of 04/20/2023. Accessed December 2024.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
H35.50	Unspecified hereditary retinal dystrophy

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
J, M	A56419	Palmetto GBA

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC