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

Document Number: IC-0350

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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

A. Quantity Limit (max daily dose) [NDC Unit]:

- N/A

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

- 150 billable units per eye

III. Initial Approval Criteria [1,2]

Submission of medical records 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 via direct upload through the PA web portal or by fax.

Coverage is provided in the following conditions:

- Patient is at least 4 years 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; **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); ‡ Compendium Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage cannot be renewed.

V. Dosage/Administration [1]

Indication	Dose
Biallelic RPE65 mutation-associated retinal dystrophy	**For subretinal injection only.** <u>Preparing for Administration:</u> • 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 microbicide. • Complete a vitrectomy. • Do not administer Luxturna in the immediate vicinity of the fovea. <u>Luxturna Injection:</u> • Under direct visualization, administer Luxturna into the affected eye [1.5×10^{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

<u>HCPCS code:</u>

- 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 2022.
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 03/30/2021 with effective date of 04/08/2021. Accessed December 2022.

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)

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 Determination (NCD), Local Coverage Article (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD):

Jurisdiction(s): J, M	**NCD/LCD/LCA Document (s):** A56419
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56419&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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.
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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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

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- Written information in other formats (large print, audio, accessible electronic formats, other formats)

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If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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PreferredOne Insurance Company
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Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
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