Neighborhood Health Plan OF RHODE ISLAND™
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Luxturna® (voretigene neparvovec-rzyl)
(Subretinal Injection)

Effective Date: 02/13/2019
Review date: 10/23/2019, 10/5/2020, 1/11/2021, 1/20/2022, 2/01/2023, 12/07/2023, 01/04/2024

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

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. Summary of Evidence

Luxturna is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Clinical trials evaluating the efficacy and safety of Luxturna have demonstrated that patients experienced significant improvements in functional vision as measured by standardized visual function tests, including the multi-luminance mobility test (MLMT) and the full-field light sensitivity threshold (FST) test. These improvements were sustained over a long-term follow-up period, with patients maintaining their visual gains for up to several years after treatment.

IV. Initial Approval Criteria

- 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.

Coverage is provided in the following conditions:

- Patient must be at least 4 years old; **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**

Retinal Dystrophy †

- 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; **AND**
- Patient has not previously received sub-retinal administration of a gene therapy vector, or Luxturna in intended eye; AND
- The patient has not exceeded the program limit of 1 injection per eye per lifetime
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.
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† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s)

V. Renewal Criteria

Coverage cannot be renewed.

** Neighborhood considers repeat administration of Luxturna in the same eye experimental and investigational because the effectiveness of this approach has not been established. Neighborhood does not provide coverage for drugs when used for investigational purposes.

VI. Dosage/Administration

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 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.
- Due to the area of expertise needed for this procedure, the only local hospital able to perform the sub retinal administration of Luxturna is Massachusetts Eye and Ear in Boston, Ma.

VII. Billing Code/Availability Information

HCPCS:

- 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

VIII. References

1. Luxturna [package insert]. Philadelphia, PA; Spark Therapeutics, Inc., May 2022. Accessed November 2023.
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.

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) 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%2C	

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
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

Policy Rationale:

Luxturna was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Luxturna

according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.