

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

Effective Date: 02/13/2019

Review date: 10/23/2019, 10/5/2020

Revision date: 10/23/2019, 10/5/2020

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. 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:

Retinal Dystrophy †

- Patient must be at least 4 years old; **AND**
- 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 had intraocular surgery within six months; **AND**
 - Patient must have an adequate washout period, defined as a minimum of 3 months, from retinoid therapies prior to receipt of voretigene
 - Patient has not previously received RPE65 gene therapy in intended eye; **AND**
 - The patient has not exceeded the program limit of 1 injection per eye per lifetime
- † FDA Approved Indication(s); ‡ Compendium Recommended Indication(s)

IV. 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.

V. Dosage/Administration

Indication	Dose
Biallelic RPE65 mutation-associated retinal dystrophy	<p>For subretinal injection only.</p> <p><u>Preparing for Administration:</u></p> <ul style="list-style-type: none"> • 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. <p><u>Luxturna Injection:</u></p> <ul style="list-style-type: none"> • Under direct visualization, administer Luxturna into the affected eye [1.5×10^{11} vector genomes (vg) in a total volume of 0.3 mL]

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| | <ul style="list-style-type: none"> • 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 |
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- Store Luxturna and Diluent frozen at $\leq -65^{\circ}\text{C}$. 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.

VI. 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

VII. References

1. Luxturna [package insert]. Philadelphia, PA; Spark Therapeutics, Inc., December 2017. Accessed December 2019.
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: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

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

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