Luxturna (voretigene neparvovec-rzyl)

Date of Origin: 01/03/2018 **Last Review Date: 05/06/2019** **Effective Date: 05/06/2019**

Dates Reviewed: 01/2018, 03/2018, 07/2018, 01/2019

Developed By: Medical Criteria Committee

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

N/A

B. Max Units (per dose and over time) [Medical Benefit]:

- 150 billable units per eye

III. Initial Approval Criteria

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 [e.g. Leber Congenital Amaurosis type 2 (LCA2)]; **AND** ○ Patient must have viable retinal cells as determined by non-invasive means, such as optical coherence tomography (OCT) and/or ophthalmoscopy indicating **1 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 a III4e isopter or equivalent; **AND**

  ○ Patient has not had intraocular surgery within six months; **AND** ○ Voretigene will be administered at a Spark Path Treatment Facility

† FDA Approved Indication(s), ‡ Compendia recommended indication

IV. Renewal Criteria

Coverage cannot be renewed.

V. Dosage/Administration

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 following10 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

Jcode:

- J3398 – Injection, voretigene neparvovec-rzyl, 1 billion vector genomes: 1 billable unit = 1.09 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 2017.

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: arandomised, 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
H35.52	Pigmentary retinal dystrophy
H35.54	Dystrophies primarily involving the retinal pigment epithelium

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):

Jurisdiction(s): 5, 8	NCD/LCD Document (s): L35053
https://www.cms.gov/medicare-coverage-database/search/lcd-datesearch.aspx?DocID=L35053&bc=gAAAAAAAAAAAAA==	

NCD/LCD Document (s): A52701
https://www.cms.gov/medicare-coverage-database/search/article-datesearch.aspx?DocID=A52701&bc=gAAAAAAAAAAAAA==

Jurisdiction(s): 6,K	NCD/LCD Document (s): A52450
https://www.cms.gov/medicare-coverage-database/search/article-datesearch.aspx?DocID=A52450&bc=gAAAAAAAAAAAAA==	

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 Corporation (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 Corporation (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, 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