



Luxturna™ (Voretigene neparvovec)

Last Review Date: July 26th, 2018

Number: MG.MM.PH.43av2

Medical Guideline Disclaimer

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Definition

Luxturna (voretigene neparvovec) is an adeno-associated virus vectoe-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.

Luxturna (voretigene neparvovec) is designed to deliver a normal copy of the gene encoding the human retinal pigment epithelial 65 kDa protein (RPE65) to cells of the retina in persons with reduced or absent levels of biologically active RPE65. The RPE65 is produced in the retinal pigment epithelial (RPE) cells and converts all- trans-retinol to 11-cis-retinal, which subsequently forms chromophore, 11-cis-retinal, during the visual (retinoid) cycle. The visual cycle is critical in phototransduction, which refers to the biological conversion of a photon of light into an electrical signal in the retina. Mutations in the RPE65 gene lead to reduced or absent levels of RPE65 isomerohydrolase activity, blocking the visual cycle and resulting in impairment of vision. Luxturna (voretigene neparvovec) is intended to negate the effects of mutations in the RPE65 gene.

Guideline

Provider must submit documentation (which may include office notes and lab results) supporting that the patient has met all approval criteria.

Luxturna (voretigene neparvovec) may be considered medically necessary when all the below criteria are met:

- The patient has a confirmed diagnosis of a biallelic RPE 65 mutation-associated retinal dystrophy; **AND**
- The patient must have documented genetic testing to confirm mutation in both copies of the PRE65 gene; **AND**
- The member must have sufficient viable retinal cells as determined by treating physician through optical coherence tomography (OCT) imaging and/or ophthalmoscopy indicating:
 - An area of retinal thickness >100 microns within the posterior pole; **OR**

- ≥ 3 disc areas of the retina without atrophy or pigmentary degeneration within the posterior pole; **OR**
- Any remaining visual field within 30° of fixation as measured by III4e isopter or equivalent; **AND**
- The patient is between 12 months and 65 years of age; **AND**
- The patient has not had intraocular surgery within the past six months; **AND**
- The patient has not used prescription retinoid compounds or precursors within the past 3 months; **AND**
- Luxturna (voretigene neparvovec) therapy must be prescribed and administered by an ophthalmologist or retinal surgeon at an Ocular Gene Therapy Treatment Center authorized by Spark Therapeutics; **AND**
- Patient has not previously received subretinal administration of a gene therapy vector, or Luxturna (voretigene neparvovec) into the intended eye; **AND**
- The patient will avoid air travel, scuba diving, and/or travel to high elevations until the dissipation of the air bubble formed following administration of Luxturna (voretigene neparvovec) has been verified through ophthalmic examination

Limitations/Exclusions

- Approval will be granted for 3 months or as determined through review
- Coverage cannot be renewed; a maximum of 1 injection per eye per lifetime will apply.
- Use in infants under 12 months of age is not recommended because of potential dilution or loss of Luxturna (voretigene neparvovec) after administration due to the active cells proliferation occurring in this age group.
- The recommended dose of Luxturna (voretigene neparvovec) for each eye is 1.5×10^{11} vector genomes administered by sub-retinal injection in a total volume of 0.3ml
- If both eyes are to be treated, Luxturna (voretigene neparvovec) must be administered to each eye on separate days at least 6 days apart.

Revision History

7/26/2018 – Added coverage to all lines of business

12/3/2018 – Added J3398 and removed J3490, J3590, C9399 from Applicable Procedure Codes.

Applicable Procedure Codes

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| J3398 | Injection, voretigene neparvovec-rzyl, 1 billion vector genomes |
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Applicable ICD-10 Codes

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| H35.50 | Unspecified hereditary retinal dystrophy |
| H35.52 | Pigmentary retinal dystrophy |
| H35.54 | Dystrophies primarily involving the retinal pigment epithelium |

References

1. Luxturna [package insert]. Philadelphia, PA; Spark Therapeutics, Inc. December 2017.
2. FDA Advisory Committee Briefing Document: Spark Therapeutics, INC, Luxturna (voretigene neparvovec).2017;
<https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/CellularTissueandGeneTherapiesAdvisoryCommittee/UCM579300.pdf> Accessed April 10, 2018.

3. 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.