Pharmacy Drug Policy & Procedure

Policy Name:	Luxturna (voretigene neparvovec)	Policy #:	2650P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Luxturna. (voretigene neparvovec)

Statement of the Policy

Health Alliance Medical Plans will approve the use of Luxturna (voretigene neparvovec) under the specialty medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

1.1 Documented vision loss due to biallelic (double gene mutation) RPE65 variant associated retinal dystrophy confirmed by genetic testing;
- Single RPE65 pathogenic variant found in the homozygous state
- Two RPE65 pathogenic variants found in the trans configuration (compound heterozygous state) by segregation analysis

1.2 Presence of viable retinal cells as determined by treating physician as assessed by retina scan pictures (optical coherence tomography imaging) and/or fundus scope (ophthalmoscopy)
- An area of retina within the posterior pole of > 100µm thickness shown on optical coherence tomography, OR
- 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole, OR
- Remaining visual field within 30° of fixation as measured by III4e isopter or equivalent

1.3 Age 12 months or older

2. Exclusion Criteria

2.1 Pregnancy

2.2 Breastfeeding

2.3 Use of retinoid compounds or precursors that could potentially interact with the biochemical activity of the RPE65 enzyme within the previous 18 months

2.4 Prior intraocular surgery within 6 months

2.5 Preexisting eye conditions or complicating systemic diseases that would preclude the planned surgery or interfere with the interpretation of treatment. Complicating systemic diseases would include those in which the disease itself, or the treatment for the disease, can alter ocular function. Examples are malignancies whose treatment could affect central nervous system function (e.g., radiotherapy of the orbit, leukemia with central nervous system/optic nerve involvement). Subjects with diabetes or sickle cell disease would be excluded if they had any manifestation of advanced retinopathy (e.g., macular edema, proliferative changes). Also excluded would be subjects with immunodeficiency (acquired or congenital) becausethey could be susceptible to opportunistic infection (e.g., cytomegalovirus retinitis).

3. Approval Period

3.1 2 total injections per lifetime (one in each eye) approved over a period of 6 months

CPT Codes

HCPCS Codes	
J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes

References

1. Luxturna (voretigene neparvovec-rzyl) [prescribing information]. Philadelphia, PA: Spark Therapeutics Inc; May 2022.
2. Farmer C, Bullement A, Packman D, et al. Voretigene Neparvovec for Treating Inherited Retinal Dystrophies Caused by RPE65 Gene Mutations: An Evidence Review Group Perspective of a NICE Highly Specialised Technology Appraisal. Pharmacoeconomics, 2020 Dec;38(12):1309-1318.
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; 390:849.

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