Medical Coverage Policy | Luxturna™ (voretigene neparvovec-rzyl)

EFFECTIVE DATE: 04|01|2018
POLICY LAST UPDATED: 04|03|2018

OVERVIEW

Luxturna™ (voretigene neparvovec-rzyl) is used in the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physician(s)

MEDICAL CRITERIA

Luxturna is medically necessary when ALL of the following are met:

1. The prescriber has provided documentation confirming the diagnosis of biallelic RPE65 mutation associated retinal dystrophy
   AND
2. The prescriber has indicated the patient has viable retinal cells as determined by retinal thickness on spectral domain optical coherence tomography (>100 microns within the posterior pole), fundus photography, and clinical examination
   AND
3. The patient is 12 months of age or greater at the time of therapy initiation with the requested agent
   AND
4. The patient will be on a concomitant systemic oral corticosteroid as part of therapy with the requested agent
   AND
5. The patient does not have any FDA labeled contraindications to the requested agent
   AND
6. The requested dose is within FDA labeling
   AND
7. The patient has not exceeded the program limit of 1 injection per eye per lifetime

Approval: 1 treatment course of 1 injection per eye per lifetime

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial Products

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products
Luxturna™ (voretigene neparvovec-rzyl) is medically necessary when the medical criteria are met.

Note: Blue Cross and Blue Shield of Rhode Island reserves the right to request information from the provider regarding the members response to the therapy.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable not medically necessary benefits/coverage.

BACKGROUND

Voretigene was studied in a randomized, controlled, open-label, phase 3 study. The study included 31 individuals aged 3 years or older with a confirmed genetic diagnosis of biallelic RPE65 gene mutations with

visual acuity of 20/60 or worse, or visual field less than 20 degrees in any meridian, or both in both eyes. Individuals had to have sufficient viable retinal cells as determined by retinal thickness on spectral domain optical coherence tomography (>100 microns within the posterior pole), fundus photography, and clinical examination; and they were able to perform a standardized multi-luminance mobility test (MLMT) within the luminance range evaluated, but unable to pass the MLMT at 1 lux, the lowest luminance level tested. Individuals were excluded if they had participated in previous gene therapy or invitational drug study, used high-dose (7500 retinol equivalent units [or >3300 IU] per day of vitamin A) retinoid compounds in the past 18 months, had known hypersensitivity to medications planned for use in the peri-operative period, or had ocular or systemic conditions that would interfere with study interpretation. Voretigene was injected in the first eye and then injected on day 6-18 in the second eye. Individuals in the control group were eligible to receive voretigene after 1 year after baseline evaluations.[2]

For the primary endpoint of MLMT change scores at year 1 compared to baseline, voretigene had an average of 1.9 to 2.1 improvement in MLMT scores while placebo had an average of 0.1 to 0.2 score improvement depending on the eye. Differences between voretigene and controls scores were statistically significant. Improvements in MLMT scores for voretigene was stable throughout year 1.[2]

For the secondary endpoint of full-field light sensitivity threshold (FST) testing average over both eyes, voretigene had a greater than 2 log unit improvement by day 30 in light sensitivity that remained stable over 1 year. The control group had no meaningful change in this measure over 1 year. The difference between voretigene and control of -2.11 (95% CI -3.19 to -1.04) was statistically significant (p=0.0004).[2]

For another secondary endpoint of best corrected visual acuity (BCVA) averaged over both eyes, voretigene had a mean improvement of 8·1 letters on the eye chart while control had a mean gain of 1·6 letters which was not statistically significant.[2]

The study also examined visual field testing. While the Goldmann visual field III4e testing and the Humphrey visual field - macular threshold testing showed statistically significant improvements in visual field for voretigene vs. control, the Humphrey visual field - foveal sensitivity testing did not.[2]

Safety
Voretigene neparvovec-rzyl carries no black box warnings or contraindications.[1]

In clinical trial, voretigene exhibited no product related serious adverse events and no deleterious immune responses. The most common ocular adverse events were transient mild ocular inflammation, transient elevated intraocular pressure, and intraoperative retinal tears.[2]

Use in infants under 12 months of age is not recommended because of potential dilution or loss of voretigene neparvovec-rzyl after administration due to the active retinal cells proliferation occurring in this age group

CODING

BlueCHiP for Medicare and Commercial
There is no specific HCPCS code for this drug. Claims must be filed with an unlisted code such as J3490 and the NDC number

RELATED POLICIES

None

PUBLISHED

Provider Update, June 2018

REFERENCES

1. Luxturna prescribing information. Spark Therapeutics, Inc. December 2017.

2. Russel, S, Bennett, J, Wellman JA, et al. Efficacy and safety of voretigene neparvovec (AAV2-hRPE65v2) in patients with RPE65-mediated inherited retinal dystrophy: a randomized, controlled, open-label, phase 3 trial. The Lancet. 2017;390: 849-860.