STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Services
Prior Authorization Criteria

LUXTURNA® (voretigene neparvovec-rzyl)
Billed under: J3398

LUXTURNA is a prescription gene therapy product used for the treatment of patients with inherited retinal disease due to mutations in both copies of the RPE65 gene, which can only be confirmed through genetic testing. You must also have enough remaining cells in your retina (the thin layer of tissue in the back of your eyes) as determined by your healthcare professional.
LUXTURNA is FDA approved for 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). Other applications are considered investigational and are NOT a covered benefit.

Initial authorization requires review by the Medical Director and may be approved when all of the following criteria is met:

1. Must be prescribed and administered by an Ophthalmic surgeon at a certified treatment center; **AND**

2. Member is ≥ 12 months and < 65 years of age; **AND**

3. The following documentation must be submitted with the request:
   a. Genetic testing confirming a genetic diagnosis of biallelic RPE65 gene mutation; **AND**
   b. Presence of viable retinal cells as determined by treating physicians as assessed by optical coherence tomography imaging and/or ophthalmoscopy:
      i. An area of retina within the posterior pole of > 100 µm thickness shown on optical coherence tomography, **OR**
      ii. ≥ 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole, **OR**
      iii. Remaining visual field within 30° of fixation as measured by III4e isopter or equivalent; **AND**

Updated: 5/3/24 KNB

4. The member does not have any of the following:
   a. Pregnancy in females
   b. Breastfeeding
   c. Use of high dose (> 7500 retinol equivalent units [or > 3300 IU] per day of vitamin A) retinoid compounds in the past 18 months
   d. Intraocular surgery within 6 months
   e. Prior RPE65 gene therapy in the intended eye
   f. Preexisting eye conditions or complicating systemic diseases that would interfere with this gene therapy including but not limited to:
      i. Malignancies whose treatment could affect central nervous system function (e.g., radiotherapy of the orbit; leukemia with central nervous system/optic nerve involvement)
      ii. Retinopathy associated with diabetic macular edema or sickle cell disease
      iii. Immunodeficiency (acquired or congenital) making the member susceptible to opportunistic infection.

Lifetime Limits Apply: 1 injection per eye
Approval is for 6 months (1 treatment course of 1 injection per eye per lifetime)

Dosing and Administration:

1. The recommended dose of Luxturna for each eye is 1.5×10^{11} vector genomes (vg), administered by subretinal injection in a total volume of 0.3 mL
2. Subretinal administration of Luxturna to each eye must be performed on separate days within a close interval, but no fewer than 6 days apart
3. Systemic oral corticosteroids equivalent to prednisone at 1 mg/kg/day (maximum, 40 mg/day) recommended for a total of 7 days (starting 3 days before administration of Luxturna to each eye) and followed by a tapering dose during the next 10 days.

References:

Government Agency, Medical Society, and Other Authoritative Publications:

1. LUXTURNA [package insert]. Philadelphia, PA: Spark Therapeutics, Inc; 2022. https://sparktx.com/LUXTURNA_US_Prescribing_Information.pdf (Accessed 5/19/2023)
2. http://www.aetna.com/cpb/medical/data/900_999/0927.html (Accessed 5/27/2022)
3. https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm589507.htm (Accessed 5/19/2023)
4. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/luxturna-voretigene-neparvovec-rzyl.pdf? (Accessed 5/19/2023)
5. https://www.bluecrossnc.com/content/dam/bcbsnc/pdf/providers/formulary/commercial/voretigene_neparvovec_criteria.pdf (Accessed 5/19/2023)

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member according to BMS coverage and policy guidelines.