Review Criteria

Review Area: **Specialty Drugs**

Date Implemented: **1/6/2019**
Last Review Date: **2/5/2019**
CPOC Approval: **00/00/0000**

Specific Item/Procedure/Service: LUXTURNA *(voretigene neparvovec-rzyl*)

Approved Criteria Set:

- ☐ InterQual
- ■ LMP
- ☐ LMP as an internal IQ edit
- ☐ BMS Criteria (based on Policy Manual
- ☐ BMS Approved Criteria

Local Medical Policy: Developed Criteria Specific

Applicable HCPCS/CPT Codes:

J3398 Injection, voretigene neparvovec-rzyl, 1 billion vector genome (Luxtuma)

Applicable ICD10 Codes: (if diagnosis specific restricted)

Background Overview with Rationale: *LUXTURNA (voretigene neparvovec-rzyl*) 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.

Criteria:

FDA-Approved Indications:

Luxturna is indicated 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.

Approval is for **6 months** (**1 treatment course of 1 injection per eye per lifetime).**

Criteria for Initial Approval:

Biallelic *RPE65* mutation-associated retinal dystrophy

1. Must be prescribed and administered by an ophthalmic surgeon at a certified treatment center.
2. Member is ≥12 months and <65 years of age.
3. Documentation of the following:

a. Genetic testing confirming a genetic diagnosis of biallelic RPE65 gene mutation
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

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 (eg, radiotherapy of the orbit; leukemia with central nervous system/optic nerve involvement)
        ii. Retinopathy associated with diabetic macular edema or sickle cell disease
        iii. Imunodeficiency (acquired or congenital) making the member susceptible to opportunistic infection

Lifetime Limits Apply:

1 injection per eye

Dosing and Administration:

• The recommended dose of voretigene neparvovec-rzyl for each eye is 1.5×10^{11} vector genomes (vg), administered by subretinal injection in a total volume of 0.3 mL

• Subretinal administration of voretigene neparvovec-rzyl to each eye must be performed on separate days within a close interval, but no fewer than 6 days apart

• Systemic oral corticosteroids equivalent to prednisone at 1 mg/kg/d (maximum, 40 mg/d) recommended for a total of 7 days (starting 3 days before administration of voretigene neparvovec-rzyl to each eye), and followed by a tapering dose during the next 10 days

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.

Resources:

https://luxturna.com/ (Accessed 12/12/18)

http://www.aetna.com/cpb/medical/data/900_999/0927.html (Accessed 12/12/18)

https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm589507.htm (Accessed 12/12/18)

https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/luxturna-voretigene-neparvovec-rzyl.pdf (Accessed 12/12/18)

https://www.bluecrossnc.com/sites/default/files/document/attachment/services/public/pdfs/medicalpolicy/voretigene_neparvovec_rzyl_luxturna.pdf (Accessed 12/12/18)

https://www.wellmark.com/Provider/MedicalDentalPharm/Pharmacy/docs/Luxturna.pdf (Accessed 12/31/18)

Review Date	Approving Authority/Responsible Party	Date Approved:
1/6/2019	Paul T. Kuryla, MD, Medical Director	1/7/2019
2/5/2019	Brian Thompson, Pharm D (BMS)	2/5/2019