Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 27, 2018

LUXTURNA™ (voretigene neparvovec-rzyl)

LENGTH OF AUTHORIZATION: Date of Service

ADMINISTRATION: Outpatient

CLINICAL NOTES:

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 confirmed through genetic testing.

REVIEW CRITERIA:

- Age Recommendation – 12 months through 64 years of age
- Vision loss due to biallelic *RPE65* mutation-associated retinal dystrophy– confirmed through genetic testing
- Patient must have viable retinal cells as determined by a healthcare professional

DOSING & ADMINISTRATION:

- 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 0.3ml.
- Therapy is administered to each eye on separate days within a close interval, but no fewer than six days apart.
- Must be administered by a surgeon experienced in performing intraocular surgery under direct visualization.