| Division: Pharmacy Policy | Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria |
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| Original Development Date:<br>Original Effective Date:<br>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 $1.5 \times 10^{11}$ 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.