Policy Title:	Luxturna (voretigene neparvovec-rzyl)		
		Department:	PHA
Effective Date:	02/13/2019		
Review Date:	10/23/2019		
Revision Date:	10/23/2019		

Purpose: To support safe, effective and appropriate use of Luxturna (voretigene neparvovec-rzyl) in retinal dystrophy, in patients with viable retinal cells and confirmed biallelic RPE65 mutation.

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Luxturna (voretigene neparvovec-rzyl) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage (voretigene neparvovec-rzyl) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria Coverage:

- Confirmation of the patient's age; AND
- Diagnosis of confirmed biallelic RPE65 mutation-associated retinal dystrophy and genetic testing documentation of biallelic mutations of the RPE65 gene; AND
- Member has viable retinal cells as determined by optical coherence tomography (OCT) confirming an area of retina within the posterior pole of greater than 100 um thickness;
- Patient has not had intraocular surgery within six months; AND
- Patient must have an adequate washout period from retinoid therapies prior to receipt of Luxturna (voretigene); AND
- Prescribed and administered by ophthalmologist or retinal surgeon with experience providing sub-retinal injections; AND
- Patient has not previously received RPE65 gene therapy in intended eye; AND
- The patient has not exceeded the program limit of 1 injection per eye per lifetime

Note: Due to the area of expertise needed for this procedure, the only local hospital able to perform the sub retinal administration of Luxturna is Massachusetts Eye and Ear in Boston, Ma.

Renewal coverage:

- Coverage cannot be renewed.

Coverage durations:

- Initial coverage criteria = 150 units per eye for one dose
  Note: One treatment course consists of 1 injection per eye per lifetime

** Neighborhood considers repeat administration of Luxturna in the same eye experimental and investigational because the effectiveness of this approach has not been established. Neighborhood does not provide coverage for drugs when used for investigational purposes.

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
67036	Vitrectomy, mechanical, pars plana approach
67299	Unlisted procedure, posterior segment
J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes

References:

1. Luxturna prescribing information. Philadelphia, PA: Spark Therapeutics; 2018 January.