Health Alliance™ Pharmacy Drug Policy Checklist

POLICY NAME	Luxturna (voretigene neparvovec)	POLICY #	2650P

Criteria

Coverage Criteria

- ☐ Documented vision loss due to biallelic (double gene mutation) RPE65 variant associated retinal dystrophy confirmed by genetic testing;
  - Single RPE65 pathogenic variant found in the homozygous state
  - Two RPE65 pathogenic variants found in the trans configuration (compound heterozygous state) by segregation analysis
- ☐ Presence of viable retinal cells as determined by treating physician as assessed by retina scan pictures (optical coherence tomography imaging) and/or fundus scope (ophthalmoscopy)
  - An area of retina within the posterior pole of > 100μm thickness shown on optical coherence tomography, OR

disc areas of retina without atrophy or pigmentary degeneration within the posterior pole, OR Remaining visual field within 30° of fixation as measured by III4e isopter or equivalent

- ☐ Age 12 months or older

Exclusion Criteria – Any of the following prevents coverage

- ☐ Pregnancy
- ☐ Breastfeeding
- ☐ Use of retinoid compounds or precursors that could potentially interact with the biochemical activity of the RPE65 enzyme within the previous 18 months
- ☐ Prior intraocular surgery within 6 months

- [ ] Preexisting eye conditions or complicating systemic diseases that would preclude the planned surgery or interfere with the interpretation of treatment. Complicating systemic diseases would include those in which the disease itself, or the treatment for the disease, can alter ocular function. Examples are malignancies whose treatment could affect central nervous system function (e.g., radiotherapy of the orbit, leukemia with central nervous system/optic nerve involvement). Subjects with diabetes or sickle cell disease would be excluded if they had any manifestation of advanced retinopathy (e.g., macular edema, proliferative changes). Also excluded would be subjects with immunodeficiency (acquired or congenital) becausethey could be susceptible to opportunistic infection (e.g., cytomegalovirus retinitis).