Voretigene neparvovec (Luxturna)

Goal(s):
Restrict use of voretigene neparvovec to patients with retinal dystrophy associated with biallelic RPE65 mutations

Length of Authorization:
Up to 6 months

Requires PA:
Voretigene neparvovec (applies to both physician administered and pharmacy claims)

Covered Alternatives:
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request from a provider at a center of excellence who is trained for and following administration and treatment protocols for voretigene neparvovec?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Is the patient greater than 1 year of age?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Has the patient been previously enrolled in clinical trials of gene therapy for retinal dystrophy RPE65 mutations or been previously been treated with gene therapy for retinal dystrophy in the eye(s) receiving treatment?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #5
5. Does the patient have other pre-existing eye conditions or complicating systemic diseases that would eventually lead to irreversible vision loss and prevent the patient from receiving full benefit from treatment (eg. severe diabetic retinopathy)?	**Yes**: Pass to RPh. Deny; medical appropriateness	**No:** Go to #6
6. Does the patient have retinal dystrophy with confirmed biallelic RPE65 mutations?	**Yes:** Go to #7 Document genetic testing	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
7. Does the patient have a visual acuity of at least 20/800 OR have remaining light perception in the eye(s) receiving treatment?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Does the patient have visual acuity of less than 20/60 OR a visual field of less than 20 degrees?	**Yes:** Go to #9 Document baseline visual function	**No:** Pass to RPh. Deny; medical appropriateness
9. Does the provider document presence of neural retina and a retinal thickness >100 microns within the posterior pole as assessed by optical coherence tomography with AND have sufficient viable retinal cells as assessed by the treating physician?	**Yes:** Approve up to 2 doses for up to 6 months. Document retinal thickness and physician attestation	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 3/18 (SS)
Implementation: 4/16/18