

Prior Authorization Criteria  
**Luxturna (voretigene neparvovec-rzyl)**

All requests for Luxturna (voretigene neparvovec-rzyl) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of biallelic *RPE65* mutation-associated retinal dystrophy and the following criteria is met:

- Must have a diagnosis of retinal dystrophy with confirmed RPE65 mutation in both alleles confirmed by both of the following:
  - Clinical documentation confirming diagnosis of Leber congenital amaurosis (LCA) or Retinitis pigmentosa (RP) including clinical features, funduscopy appearance, and results of testing such as dark-adapted thresholds, Ganzfeld-flash electroretinography (ERG), and when appropriate, perimetry.
  - Documentation of positive genetic test result confirming a biallelic pathogenic or likely pathogenic RPE65 mutation (homozygote or compound heterozygote) by a CLIA-approved mutational test.
- Must be prescribed by or in consultation with an ophthalmologist
- Must have viable retinal cells as determined by at least one of the following:
  - Area of retina within the posterior pole of greater than 100 µm thickness per OCT
  - At least 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole
  - Remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent
- Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Has not previously received treatment with voretigene neparvovec-rzyl in the requested treatment eye(s)
- **Initial Duration of Approval:** 1 injection per eye (1 month)
- **Reauthorization criteria**
  - None – one time use

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

**LUXTURNA  
PRIOR AUTHORIZATION FORM**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049

If needed, you may call to speak to a Pharmacy Services Representative. **PHONE:** (800) 392-1147 Mon – Fri 8:30am to 5:00pm

**PROVIDER INFORMATION**

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

**MEMBER INFORMATION**

Member Name:	DOB:
Member ID:	Member weight:      Height:

**REQUESTED DRUG INFORMATION**

Medication:	Strength:
Directions:	Quantity:      Refills:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No      Date Medication Initiated:	

**Billing Information**

This medication will be billed: <input type="checkbox"/> at a pharmacy <b>OR</b> <input type="checkbox"/> medically, JCODE: _____
Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's office <input type="checkbox"/> Member's home <input type="checkbox"/> Other

**Place of Service Information**

Name:	NPI:
Address:	Phone:

**MEDICAL HISTORY (Complete for ALL requests)**

Diagnosis:	ICD Code:
Does the member have confirmed RPE65 mutation in both alleles? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Is there clinical documentation confirming diagnosis of Leber congenital amaurosis (LCA) or Retinitis pigmentosa (RP) including clinical features, funduscopy appearance, and results of testing such as dark-adapted thresholds, Ganzfeld-flash electroretinography (ERG), and when appropriate, perimetry? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Is there documentation of positive genetic test result confirming a biallelic pathogenic or likely pathogenic RPE65 mutation (homozygote or compound heterozygote) by a MoIDX-approved mutational test? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Does the member have viable retinal cells? Select all that apply to the member: <input type="checkbox"/> Area of retina within the posterior pole of greater than 100 µm thickness per optical coherence tomography (OCT) <input type="checkbox"/> At least 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole <input type="checkbox"/> Remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent	
Which eye is being treated? <input type="checkbox"/> Left <input type="checkbox"/> Right <input type="checkbox"/> Both	
Has the member previously received treatment with voretigene neparvovec-rzyl in the requested eye(s)? <input type="checkbox"/> Yes <input type="checkbox"/> No	

**SUPPORTING INFORMATION or CLINICAL RATIONALE**

<b>Prescribing Provider Signature</b>	<b>Date</b>