



Updated: 04/2024  
DMMA Approved: 04/2024

**Request for Prior Authorization for Luxturna (voretigene neparvovec-rzyl)**  
**Website Form – [www.highmarkhealthoptions.com](http://www.highmarkhealthoptions.com)**  
**Submit request via: Fax - 1-855-476-4158**

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.

### **Luxturna Prior Authorization Criteria:**

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  $\mu\text{m}$  thickness per optical coherence tomography (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.

**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 Health Options Pharmacy Services. **FAX: (855) 476-4158**

If needed, you may call to speak to a Pharmacy Services Representative. **PHONE: (844) 325-6251 Mon – Fri 8:00 am to 7:00 pm**

**PROVIDER INFORMATION**

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
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:	
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No	

**Billing Information**

This medication will be billed:  at a pharmacy **OR**  medically, JCODE: \_\_\_\_\_

Place of Service:  Hospital     Provider's office     Member's home     Other

**Place of Service Information**

Name:	NPI:
Address:	Phone:

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

<b>Diagnosis:</b>	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	
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 treatment eye(s)? <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	

**SUPPORTING INFORMATION or CLINICAL RATIONALE**


**Prescribing Provider Signature**

**Date**

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