



Updated: 10/2022
DMMA Approved: 11/2022

Request for Prior Authorization for Luxturna (voretigene neparvovec-rzyl)
Website Form – 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 μ m 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.

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 am to 7 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: <input type="checkbox"/> at a pharmacy OR <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

Prescribing Provider Signature

Date

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