HIGHMARK WHOLECARE

Updated: 05/2025
PARP Approved: 05/2025

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 pigmetosa (RP) including clinical features, funduscopic 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.

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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? ☐ Yes ☐ No	Date Medication Initiated:	

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)

Diagnosis:	ICD Code:

Does the member have confirmed RPE65 mutation in both alleles? ☐ Yes ☐ No

Is there clinical documentation confirming diagnosis of Leber congenital amaurosis (LCA) or Retinitis pigmetosa (RP) including clinical features, funduscopic appearance, and results of testing such as dark-adapted thresholds, Ganzfeld-flash electroretinography (ERG), and when appropriate, perimetry? ☐ Yes ☐ 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? ☐ Yes ☐ No

Does the member have viable retinal cells? Select all that apply to the member:
- ☐ Area of retina within the posterior pole of greater than 100 µm 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

Which eye is being treated? ☐ Left ☐ Right ☐ Both

Has the member previously received treatment with voretigene neparvovec-rzyl in the requested eye(s)? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date