Updated: 03/2019
PARP Approved: 04/2019

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:

- The member must be at least 1 year old
- Must have a diagnosis of retinal dystrophy with confirmed RPE65 mutation in both alleles
- Must be prescribed by or in consultation with an ophthalmologist
- Must have visual acuity worse than 20/60 in both eyes or visual field less than 20 degrees in any meridian
- Must have viable retinal cells as determined by the treating physician
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **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.

Gateway Health

Updated: 03/2019
PARP Approved: 04/2019

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 Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Frequency:	Duration:	
Is the member currently receiving requested medication? ☐ Yes ☐ No		Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a 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:

☐ Retinal Dystrophy
☐ Other: _____ ICD-10 Code: _____

Does the member have confirmed RPE65 mutation in both alleles? ☐ Yes ☐ No
Which eye is being treated? ☐ Left ☐ Right ☐ Both
Is visual acuity worse than 20/60 in both eyes or visual field less than 20 degrees in any meridian? ☐ Yes ☐ No
Does the member have viable retinal cells? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date