Luxturna

Luxturna (Voretigene Neparvovec-rzyl) J3398

Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ Inherited Retinal Dystrophy Due to Biallelic RPE65 Mutations

- ☐ Patient has confirmed diagnosis of inherited retinal dystrophy (e.g., Leber congenital amaurosis, retinitis pigmentosa) AND
- ☐ Genetic testing confirms biallelic RPE65 mutations from CLIA-certified laboratory AND
- ☐ Patient has sufficient viable retinal cells as determined by:
  - ☐ OCT demonstrating retained retinal structure AND
  - ☐ Visual function testing (multi-luminance mobility testing or comparable assessment) showing measurable visual impairment AND
- ☐ Patient is at least 12 months of age AND
- ☐ No prior treatment with Luxturna or other gene therapy for RPE65-mediated disease AND
- ☐ Prescribed by or in consultation with retinal specialist at qualified treatment center

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Patient had an **adequate response** or **significant improvement** while on this medication.

☐ Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Luxturna Prior Authorization

Drug Name(s):
LUXTURNA **VORETIGENE NEPARVOVEC-RZYL**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan, in accordance with the Label.
- Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:
N/A

Prescriber Restrictions:
Ophthamologist or other related specialist

Coverage Duration:
Approval will be for 6 months

FDA Indications:
Luxturna

- Retinal dystrophy, In patients with viable retinal cells and confirmed biallelic RPE65 mutation

Off-Label Uses:
N/A

Age Restrictions:
Indicated for patients 12-months and older.

Other Clinical Consideration:
N/A

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/CS/0C47D8/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/B5FC7C/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932398&contentSetId=100&title=Voretigene+Neparvovec-rzyl&servicesTitle=Voretigene+Neparvovec-rzyl&brandName=Luxturna&UserMdxSearchTerm=Luxturna#