



MASSACHUSETTS

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Gene Therapy for Inherited Retinal Dystrophy – Luxturna Prior Authorization Request Form #926

Medical Policy #911 Gene Therapy for Inherited Retinal Dystrophy - Luxturna

Please use this form to assist in identifying members who meet Blue Cross Blue Shield of Massachusetts' (BCBSMA's) medical necessity criteria for Luxturna therapy. For members who do not meet the criteria, submit a letter of medical necessity with a request for [Clinical Exception \(Individual Consideration\)](#).

Once completed, please fax to: 888-973-0726

CLINICAL DOCUMENTATION

Copies of clinical documentation that supports the medical necessity criteria for [Luxturna](#) must be submitted with this form. If the patient does not meet all the criteria listed below, please submit a letter of medical necessity explaining why an exception is justified.

| Patient Information | |
|---------------------|--|
| Patient Name: | Today's Date: |
| BCBSMA ID#: | Date of Treatment: |
| Date of Birth: | Place of Service: Outpatient <input type="checkbox"/> Inpatient <input type="checkbox"/> |
| | Distributor: Accredo Specialty Pharmacy <input type="checkbox"/> |

| Physician Information | Facility Information |
|-----------------------|----------------------|
| Name: | Name: |
| Address: | Address: |
| Phone #: | Phone #: |
| Fax#: | Fax#: |
| NPI#: | NPI#: |

| Please check off if the patient has the following diagnosis: | |
|--|--------------------------|
| Vision loss due to biallelic RPE65 or likely pathogenic variant-associated retinal dystrophy | <input type="checkbox"/> |

| Please check off that the patient meets <u>ALL</u> the following criteria: | |
|---|--------------------------|
| Is adult (age <65 years) or child (age ≥3 years) | <input type="checkbox"/> |
| Genetic test confirming presence of bilallelic RPE65 pathogenic or likely pathogenic variant(s): <ul style="list-style-type: none"> • Single RPE65 pathogenic or likely pathogenic variant found in the homozygous state • Two RPE65 pathogenic or likely pathogenic variants found in the trans configuration (compound heterozygous state) by segregation analysis. | <input type="checkbox"/> |
| Presence of viable retinal cells as determined by treating physicians as assessed by optical coherence tomography imaging and/or ophthalmoscopy: <ul style="list-style-type: none"> • An area of retina within the posterior pole of >100 μm thickness shown on optical coherence tomography | <input type="checkbox"/> |

| | |
|--|--------------------------|
| OR | |
| • ≥3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole OR | <input type="checkbox"/> |
| • Any remaining visual field within 30° of fixation as measured by III4e/V4e isopter equivalent OR | <input type="checkbox"/> |
| • Measureable full-field light sensitivity threshold (FST). | <input type="checkbox"/> |

CONTRAINDICATIONS

| Please check off that the patient DOES NOT HAVE ANY of the following contraindications: | |
|--|--------------------------|
| • Pregnancy. | <input type="checkbox"/> |
| • Breastfeeding. | <input type="checkbox"/> |
| • Use of prescription retinoid compounds or precursors that could potentially interact with the biochemical activity of the RPE65 enzyme within the past 3 months. | <input type="checkbox"/> |
| • Prior intraocular surgery within the past 3 months. | <input type="checkbox"/> |
| • Preexisting eye conditions or complicating systemic diseases that would eventually lead to irreversible vision loss and prevent the patient from receiving full benefit from Voretigene neparvovec-rzyl (eg, leukemia with central nervous system/optic nerve involvement, severe diabetic retinopathy). | <input type="checkbox"/> |

| HCPCS Codes | Code Description |
|--------------------|---|
| C9399 | Unclassified drugs or biological |
| J3398 | Injection, voretigene neparvovec-rzyl, 1 billion vector genomes |
| J3490 | Unclassified drugs |
| J3590 | Unclassified biologics |

Providers should enter the relevant diagnosis code(s) below:

| Code | Description | |
|-------------|--------------------|--------------------------|
| | | <input type="checkbox"/> |
| | | <input type="checkbox"/> |

Providers should enter other relevant code(s) below:

| Code | Description | |
|-------------|--------------------|--------------------------|
| | | <input type="checkbox"/> |
| | | <input type="checkbox"/> |