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 ❒ Inpatient ❒ Distributor: Accredo Specialty Pharmacy ❒

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	❒

Please check off that the patient meets ALL the following criteria:	
Is adult (age <65 years) or child (age ≥3 years)	❒
Genetic test confirming presence of bilallelic RPE65 pathogenic or likely pathogenic variant(s): • 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.	❒
Presence of viable retinal cells as determined by treating physicians as assessed by optical coherence tomography imaging and/or ophthalmoscopy:	
• An area of retina within the posterior pole of >100 µm thickness shown on optical coherence tomography	❒

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

CONTRAINDICATIONS

Please check off that the patient DOES NOT HAVE ANY of the following contraindications:	
• Pregnancy.	❒
• Breastfeeding.	❒
• Use of prescription retinoid compounds or precursors that could potentially interact with the biochemical activity of the RPE65 enzyme within the past 3 months.	❒
• Prior intraocular surgery within the past 3 months.	❒
• 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).	❒

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	
		❒
		❒

Providers should enter other relevant code(s) below:

Code	Description	
		❒
		❒