Policy Number: RX.PA.089.MPC
Revision Date: 02/2024

RX.PA.089.MPC Luxturna (voretigene neparvovec-rzyl)

The purpose of this policy is to define the prior authorization process for Luxturna® (voretigene neparvovec-rzyl).

Luxturna® (voretigene neparvovec-rzyl) is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.

PROCEDURE

A. Initial Authorization Criteria

1. Retinal Dystrophy

- Member must be ≥ 12 months old;
- Must have a diagnosis of biallelic RPE65 mutation associated-retinal dystrophy
  - Genetic testing required to confirm biallelic mutations of the RPE65 gene
- Member must have viable retinal cells in each eye assessed by optical coherence tomography (OCT) and/or ophthalmoscopy that indicates at least ONE of the following:
  - Area of retina within the posterior pole greater than 100 µm thickness
    OR
  - Greater than or equal to 3-disc areas of retina without atrophy or pigmentary degeneration within the posterior pole
    OR
  - Remaining visual field within 30 degrees of fixation as measured by III4e isopter or equivalent
- Visual acuity worse than 20/60 in both eyes and/or visual field less than 20 degrees in any meridian measured by III4e isopter or equivalent
- Prescriber attests that member will have a washout period of at least 3 months from retinoid therapies
- Prescriber attests that the member has not had intraocular surgery within the last 6 months
- Must be prescribed by an ophthalmologist;
- Prescriber attests that the member has not received prior treatment with Luxturna in the treatment eye
- Luxturna dose must not exceed 1.5×10^{11} vector genomes (vg) per eye
- Luxturna is restricted to a single authorization for an injection into each eye per lifetime

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Luxturna will be considered investigational or experimental for any other use and will not be covered.

D. Reauthorization Criteria:

Luxturna is not eligible for reauthorization.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	1 injection per eye
Reauthorization	N/A

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APPLICABLE CODES:	
CODE	**DESCRIPTION**
J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genome

REFERENCES

1. Luxturna [package insert]. Philadelphia, PA: Spark Therapeutics, Inc.; May 2022.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/2024*
New policy	*10/2023*