Reference number(s)
4545-A

Jurisdiction Specific Medicare Part B Luxturna

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Luxturna	voretigene neparvovec-rzyl

Indications

Covered uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- Retinitis pigmentosa
- Leber congenital amaurosis

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Exclusions

Coverage will not be provided for members with 2 pathogenic or likely pathogenic mutations involving only 1 copy of the RPE65 gene (cis configuration).

Prescriber Specialties

The requested drug must be administered by a qualified vitreoretinal surgeon with evidence of completion of the manufacturer's surgical and pharmacy training program for the appropriate storage, handling, and administration of the requested drug.

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Coverage Criteria

Retinitis Pigmentosa[1,2]

Authorization of 1 month for a single dose of the requested drug (1.5×10^{11} vector genomes) per eligible eye, per lifetime may be granted for the treatment of retinitis pigmentosa when both of the following are met:

- The member has a confirmed biallelic RPE65 mutation.
- Treatment of the contralateral eye will occur no sooner than 6 days and no later than 18 days after treatment of the first eye

Leber Congenital Amaurosis[1,2]

Authorization of 1 month for a single dose of the requested drug (1.5×10^{11} vector genomes) per eligible eye, per lifetime may be granted for the treatment of Leber congenital amaurosis when both of the following are met:

- The member has a confirmed biallelic RPE65 mutation.
- Treatment of the contralateral eye will occur no sooner than 6 days and no later than 18 days after treatment of the first eye

References

1. Voretigene Neparvovec-rzyl LCD (L37863) Version 6. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed December 9, 2025.
2. Billing and coding: voretigene neparvovec-rzyl (A56419) Version 8. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed December 9, 2025.
3. Luxturna [package insert]. Philadelphia, PA. Spark Therapeutics; May 2022.

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