Medical Policy

BlueCross BlueShield Kansas
An Independent licensee of the Blue Cross Blue Shield Association

Title: Luxturna

Professional / Institutional
Original Effective Date: December 26, 2025
Latest Review Date: July 23, 2026
Current Effective Date: July 23, 2026

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

Indication	Dose
Biallelic RPE65 mutation-associated retinal dystrophy	**For subretinal injection only.** Preparing for Administration: • Luxturna should be administered in the surgical suite under controlled aseptic conditions by a surgeon experienced in performing intraocular surgery. • Dilate the eye, give adequate anesthesia to the patient, and administer a topical broad spectrum microbiocide. • Complete a vitrectomy. • Do not administer Luxturna in the immediate vicinity of the fovea. Luxturna Injection: • Under direct visualization, administer Luxturna into the affected eye [1.5×10^{11} vector genomes (vg) in a total volume of 0.3 mL].

Indication	Dose
	• Perform subretinal administration of Luxturna to each eye on separate days within a close interval, but no fewer than 6 days apart. • Recommend systemic oral corticosteroids equivalent to prednisone at 1 mg/kg/day (maximum of 40 mg/day) for a total of 7 days (starting 3 days before administration of Luxturna to the first eye) and followed by tapering the dose during the following 10 days. The same corticosteroid dosing regimen applies for the administration of Luxturna to the second eye. If the corticosteroid taper following Luxturna administration to the first eye is not complete three days prior to the planned Luxturna administration to the second eye, then the corticosteroid regimen for the second eye replaces the taper for the first eye.

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

I. Length of Authorization

- Initial: Prior authorization validity will be provided for one dose per eye
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 150 billable units for one dose per eye

III. Initial Approval Criteria [1,2]

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax. Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Prior authorization validity is provided in the following conditions:

- Patient is at least 12 months of age; **AND**
- Patient must have an adequate washout period, defined as a minimum of 3 months, from retinoid therapies prior to receipt of voretigene neparvovec-rzyl; **AND**
- Patient has not had intraocular surgery within six months; **AND**
- Patient has not previously received subretinal administration of a gene therapy vector, or Luxturna, into the intended eye; **AND**

Retinal Dystrophy † Φ [1,2]

- Patient has a definitive diagnosis confirming biallelic *RPE65* mutation-associated retinal dystrophy; **AND**
- Patient must have viable retinal cells as determined by non-invasive means, such as optical coherence tomography (OCT) and/or ophthalmoscopy indicating one or more of the following:
  - An area of retina within the posterior pole of >100 µm thickness shown on OCT
  - ≥ 3-disc areas of retina without atrophy or pigmentary degeneration within the posterior pole
  - Remaining visual field within 30 degrees of fixation as measured by an III4e isopter or equivalent

† FDA Approved Indication(s); ǂ Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1]

- Duration of authorization has not been exceeded *(refer to Section I)*.

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CLINICAL RATIONALE

See package insert for FDA preshttps://dailymed.nlm.nih.gov/dailymed/index.cfm

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

HCPCS code:

- J3398 – Injection, voretigene neparvovec-rzyl, 1 billion vector genomes; 1 billable unit = 10^9 vector genomes
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NDC:

- Luxturna carton (one single-dose vial of Luxturna and two vials of diluent): 71394-0415-xx

REVISIONS	
Posted: 11-26-2025 Effective: 12-26-2025	New medical policy added to the bcbsks.com web site. Policy is maintained by Prime Therapeutics LLC.
Posted: 06-23-2026 Effective: 07-23-2026	Updated Length of Authorization: • Removed: "Coverage will be provided for one does and may not be renewed" • Added: "Initial: Prior authorization validity will be provided initially for one dose." And "Renewal: Prior authorization validity may NOT be renewed." Initial Approval Criteria • Added o Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax. Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines • Removed o Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e. genetic and mutational

REVISIONS	
	testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax • Change 'coverage' to 'Prior authorization validity' Updated Reference Section
	Policy is maintained by Prime Therapeutics LLC.

REFERENCES

1. Luxturna [package insert]. Philadelphia, PA; Spark Therapeutics, Inc., May 2022. Accessed December 2025.
2. Russell S, Bennett J, Wellman JA, et al. Efficacy and safety of voretigene neparvovec (AAV2-hRPE65v2) in patients with RPE65-mediated inherited retinal dystrophy: a randomised, controlled, open-label, phase 3 trial. Lancet. 2017 Aug 26;390(10097):849-860. doi: 10.1016/S0140-6736(17)31868-8. Epub 2017 Jul 14. Erratum in: Lancet. 2017 Aug 26;390(10097):848.
3. Palmetto GBA. Local Coverage Article: Billing and Coding: Voretigene Neparvovec-rzyl (Luxturna®) (A56419). Centers for Medicare & Medicaid Services, Inc. Updated on 04/10/2023 with effective date of 04/20/2023. Accessed December 2025.