AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Luxturna™ (voretigen neparvovec-rzy) Subretinal Injection **(J3398) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

NOTE: Luxturna™ should ONLY be administered in a surgical suite under controlled aseptic conditions by a surgeon experienced in performing intraocular surgery.

Dosing Limits

A. Quantity Limit (max daily dose) [NDC 71394-0065-01 or 71394-0415-01]:
- N/A

B. Max Units (per dose and over time) [HCPCS Unit]:
- 150 billable units per eye
- If both eyes are to be treated, Luxturna must be administered to each eye on separate days at least 6 days apart

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Length of Authorization: 3 months or as determined by review

One dose per eye/per lifetime. Coverage cannot be renewed

- ❑ Member is at least 1 year of age or older
- ❑ Prescribed and administered by an ophthalmologist or retinal surgeon at an Ocular Gene Therapy Treatment Center authorized by Spark Therapeutics
- ❑ Member has a confirmed diagnosis of a biallelic RPE65 mutation-associated retinal dystrophy
- ❑ Member has sufficient viable retinal cells as determined by treating physician through optical coherence tomography (OCT) imaging and/or ophthalmoscopy indicating **ONE** of the following:
  - ❑ An area of retinal thickness >100 microns within the posterior pole
  - ❑ ≥ 3-disc areas of the retina without atrophy or pigmentary degeneration within the posterior pole
  - ❑ Any remaining visual field within 30 of fixation as measured by III4e isopter or equivalent
- ❑ Member has **NOT** had intraocular surgery within the past six months
- ❑ Member has **NOT** previously received subretinal administration of a gene therapy vector, or Luxturna into the intended eye

Medication being provided by a Specialty Pharmacy – Proprium Rx

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

***Approved by Pharmacy and Therapeutics Committee:** ~~7/18/2019;~~ **9/26/2024**
REVISED/UPDATED/REFORMATTED: ~~10/12/2019;~~ **10/15/2024**