OPTIMA HEALTH PLAN

PHARMACY/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 1-844-688-1550**. 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 will 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 **(Medical) (J-3398)**

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

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength/Month: _____

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

Diagnosis: _____ **ICD Code:** _____

❑ 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.

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.

INITIAL AUTHORIZATION: ONE DOSE PER EYE/PER LIFETIME. RENEWAL IS NOT AUTHORIZED

❑ Has member received Luxturna™ in the past? ❑ **Yes** ❑ **No**

- ❑ **Yes**, in the same eye **(Provide details and progress notes with date and time stamp.)**
- ❑ **Yes**, but in the other eye only **(Provide details and progress notes with date and time stamp.)**
- ❑ **No**
- ❑ **Unknown**

MEDICAL INFORMATION. Supportive documentation must be provided for all answers below or request may be delayed or denied.

1. Does member have vision loss due to inherited retinal dystrophy? ❑ **Yes** ❑ **No**

(Continued on next page)

AND

2. Did member undergo genetic testing?

   ❑ **Yes** – include a copy of the test results ❑ **No** – denial of drug

   If **YES:**

   a) Did genetic testing confirm biallelic mutation of the RPE65 gene (two confirmed pathogenic or likely pathogenic loss of function variants)? ❑ **Yes** ❑ **No**

   AND

   b) Indicate which of the following genetic test was performed to confirm biallelic pathogenic and/or likely pathogenic RPE65:

      ❑ Single-gene test ❑ None listed

      Provide the date of the test: _____

3. Are the RPE65 gene mutations classifications based on the ACMG standards and guidelines for the interpretation of sequence variants (2015)? ❑ **Yes** ❑ **No**

   Which eye is being treated? ❑ Left Eye ❑ Right Eye ❑ Both Eyes

   If both eyes, does prescriber agree that the initial eye's injection and the second eye's injection will be administered at least six days apart?) ❑ **Yes** ❑ **No**

4. Does member have sufficiently viable retinal cells as determined by optical coherence tomography (OCT) and/or ophthalmoscopy? ❑ **Yes** ❑ **No** (denial of drug)

   If **YES**, does the optical coherence tomography (OCT) and/or ophthalmoscopy show any of the following? **(Check and provide documentation of at least one of the below.)**

   ❑ Area of retina within the posterior pole of greater than 100 μm thickness per OCT

   OR

   ❑ At least 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole

   AND

   ❑ Visual field within 20 degrees in any meridian as measured by III4e isopter **OR** equivalent in both eyes

   OR

   ❑ Visual acuity worse than 20/60 in **both** eyes

(Continued on next page; signature page is required to process request.)

(Please ensure signature page is attached to form.)

For urgent reviews: Practitioner should call Optima Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Optima'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.

Member Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee:** 7/18/2019
REVISED/UPDATED: 10/12/2019