

## Medical Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☒ **Commercial** ☒ **Commercial Individual (PPACA)** ☐ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

**Luxturna**<sup>TM</sup> (voretigene neparvovec-rzyl)

### Member

Last Name: \_\_\_\_\_ First Name: \_\_\_\_\_  
 ID #: \_\_\_\_\_ DOB: \_\_\_\_\_ Gender: \_\_\_\_\_  
 Primary Care Physician: \_\_\_\_\_  
 Requesting Provider: \_\_\_\_\_ Prov. Phone: \_\_\_\_\_ Prov. Fax: \_\_\_\_\_  
 Provider Address: \_\_\_\_\_  
 Provider NPI: \_\_\_\_\_ Contact Name: \_\_\_\_\_  
 Date: \_\_\_\_\_

### Product Information

Drug product: ☐ Luxturna intraocular suspension **Start date** (or date of next dose): \_\_\_\_\_  
**Date of last dose** (if applicable): \_\_\_\_\_  
**Dosing frequency:** \_\_\_\_\_  
 Place of administration: ☐ Provider's office  
☐ Outpatient infusion center Center name: \_\_\_\_\_  
☐ Home infusion Agency name: \_\_\_\_\_  
 Billing: ☐ Physician buy and bill  
☐ Preferred specialty vendor  
☐ Other: \_\_\_\_\_  
 ICD code(s): \_\_\_\_\_

### Precertification Requirements

**Before this drug is covered, documentation must be submitted to support that the patient meets all of the following requirements:**

- 1) Must be age 12 months or older.
- 2) Must be prescribed by an ophthalmologist or retinal surgeon.
- 3) Diagnosis of biallelic RPE65 mutation-associated retinal dystrophy (confirmed by genetic testing). Pathogenic and/or likely pathogenic classification of the RPE65 mutations has been affirmed within the last 12 months.
- 4) Sufficient viable retinal cells as determined by optical coherence tomography (OCT) and/or ophthalmoscopy with an area of retina within the posterior pole of greater than 100 µm thickness.
- 5) Member has not previously received Luxturna or another RPE65 gene therapy.

**Note:** Authorization for indications not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the drug's use for the identified indication.

## Priority Health Precertification Documentation

### A. What condition is this drug being requested for?

☐ Biallelic RPE65 mutation-associated retinal dystrophy (documentation of genetic test must be submitted to Priority Health)

☐ Other – the patient's condition is: \_\_\_\_\_

Rationale for use: \_\_\_\_\_

### B. Does the member have sufficient viable retinal cells (e.g. area within posterior pole of > 100 µm thickness) as confirmed by optical coherence tomography (OCT)?

☐ Yes

☐ No; rationale for use: \_\_\_\_\_

\_\_\_\_\_

### C. Is the request provider an ophthalmologist or retinal surgeon?

☐ Yes

☐ No; Rationale for use: \_\_\_\_\_

\_\_\_\_\_

### D. Has the member previously received Luxturna or other RPE65 gene therapy?

☐ No

☐ Yes; Rationale for use: \_\_\_\_\_

\_\_\_\_\_

## Additional information

Luxturna will only be authorized in accordance with FDA-approved dosing for retinal dystrophy as the safety and effectiveness of repeat administration have not been evaluated (**one treatment per eye per lifetime**). Luxturna will not be authorized for use in patients previously treated with Luxturna or another RPE65 gene therapy.

Physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s).

Coverage of Luxturna is dependent on member's eligibility and benefit plan documents. Benefit coverage is effective no sooner than January 1, 2021.