JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP023
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		Review Date	01/15/2020
	Subject **Luxturna**	*Revision Date*	11/10/2021
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Luxturna

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I. POLICY

Luxturna (Voretigene neparvovec-rzyl) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

Luxturna may be approved for patients, who meet ALL of the following:

1. The patient is greater than 3 and less than 65 years of age
2. Documentation has been provided showing the following:
   a. Diagnosis of Biallelic RPE65 mutation-associated retinal dystrophy
   b. Diagnosis has been confirmed by generic testing
   c. Patient has sufficient viable retinal cells as determined by treating physicians as assessed by optical coherence tomography imaging:
      i. An area of retina within the posterior pole of >100 µm thickness shown on optical coherence tomography
   d. Baseline full-field light sensitivity threshold (FST) testing with results for each eye
   e. No prior intraocular surgery within the past 6 months
   f. The prescriber is an ophthalmic surgeon who will be administering Luxturna in a certified treatment center

III. AUTHORIZATION PERIOD/LIMITATIONS

Luxturna may approve for a one-time injection in each eye once in a lifetime.

No approval extensions will be authorized.

IV. EXCLUSIONS

Luxturna will not be covered for the following:

1. Patients with malignancies for which treatment could affect CNS function, such as:
   a. Leukemia with CNS or optic nerve involvement

b. Conditions involving Orbital radiotherapy

2. Patients will diabetes or sickle cell disease with advanced retinopathy (such as macular edema, or proliferative changes)
3. Patients with congenital or acquired immunodeficiency
4. Patients that are pregnant or breastfeeding
5. Any diagnosis that is considered investigational

V. RECOMMENDED DOSE

Luxturna will be approved up to a maximum of 1 dose of 1.5×10^{11} vector genonomes (vg) administered by subretinal injection in a total volume of 0.3 mL per eye.

VI. REFERENCES

1. Luxturna [prescribing information]. Philadelphia, PA: Spark Therapeutics Inc; 2017 December

VII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
10/17/2018	Policy Creation
01/15/2020	No policy changes-presented policy for USFHP adoption effective 3/1/2020
11/10/2021	Removed Priority Partners as an applicable LOB

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