Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Luxturna (voretigene neparvovec-rzyl)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***May 2018***

Last P & T Committee Approval Date: May 2018

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Luxturna (voretigene neparvovec-rzyl).

Luxturna (voretigene neparvovec-rzyl) is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

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The drug, Luxturna (voretigene neparvovec-rzyl), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must have inherited retinal dystrophy with biallelic RPE65 mutation
  - Must be confirmed by genetic testing
- Must be at least 1 year old
- Must have viable retinal cells as determined by the treating physician

Reauthorization Criteria:

Reauthorization is not allowed for this one-time treatment.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 month (1 treatment)
Reauthorization	N/A

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

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

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	*05/18*

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