SmartPA Criteria Proposal

Drug/Drug Class:	Luxturna Clinical Edit
First Implementation Date:	April 18, 2019
Proposed Date:	June 16, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Luxturna® (voretigene neparvovec-rzyl)

Why Issue Selected: Luxturna® is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic *RPE65* mutation-associated retinal dystrophy, an inherited form of vision loss. Biallelic *RPE65* mutation-associated retinal dystrophy affects approximately 1,000 to 2,000 patients in the United States. Mutations in the *RPE65* gene lead to reduced or absent concentrations of RPE65 isomerohydrolase activity, blocking the visual cycle and resulting in impaired vision. Vision loss often begins during childhood or adolescence and ultimately progresses to complete blindness. Luxturna is a live, non-replicating adeno-associated virus serotype 2 which has been genetically modified to express the human *RPE65* gene; it delivers a normal copy of the gene to the cells of the retina, allowing normal protein production to facilitate phototransduction and restoration of vision loss. Luxturna is administered by subretinal injection performed in each eye on separate days within a close interval, but no fewer than 6 days apart. Premedication with a short course of oral corticosteroids is required prior to administration to prevent potential immune reaction. Due to the high cost and specific approved indication, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Luxturna.

Program-Specific Information:

Date Range FFS 4-1-2021 to 3-31-2022			
Drug	**Claims**	**Cost per vial**	**Cost per therapy**
LUXTURNA VIAL	0	$423,300.00 MAC	$846,600.00 MAC

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

Data Sources:
☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Luxturna® (voretigene neparvovec-rzyl)
- Age range: All appropriate MO HealthNet participants aged 12 months or older

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Approval Criteria

- Prescribed by or in consultation with an ophthalmologist or other specialist in the treated disease state **AND**
- Participant has vision loss due to biallelic *RPE65* mutation-associated retinal dystrophy as confirmed through genetic testing **AND**
- Participant has viable retinal cells as determined by the provider **AND**
- Claim does not exceed 2 doses (1 dose per eye) per lifetime

Denial Criteria

- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:	X	Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
Rule Type: CE

Default Approval Period

30 days

References

- LUXTURNA (voretigene neparvovec-rzyl) intraocular suspension for subretinal injection [package insert]. Philadelphia, PA: Spark Therapeutics, Inc.; December 2019.
- Clinical Pharmacology. Voretigene Neparvovec: LUXTURNA. Accessed May 16, 2022.
- IPD Analytics. Ophthalmics: Rare Ophthalmic Conditions. Accessed May 16, 2022.

DRAFT

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