CONDUENT

Drug Monograph

Drug/Drug Class:	**Luxturna™ (voretigene neparvovec-rzyl) suspension for subretinal injection/ Gene Therapy**
Prepared for:	MO HealthNet
Prepared by:	Conduent

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose:	The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be made available on an open access basis to prescribers, require a clinical edit or require prior authorization for use.
Dosage Forms:	Luxturna™ is now available as one single-dose vial that contains 5 x 10^{12} vector genomes per ml in 0.5 ml extractable volume.
Manufacturer:	Spark Therapeutics, Inc., Philadelphia, PA 19104
Indications:	Luxturna™ is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physician.
Costs:	$423,300 per treatment eye for Luxturna™. Maximum Allowable Cost
Summary of Findings:	The Division recommends adding this drug to the current gene therapy clinical edit.
Status Recommendation:	☐ Prior Authorization (PA) Required ☒ Clinical Edit ☐ Fiscal Edit ☐ PDL
Type of PA Criteria:	☐ Increased Risk of ADE ☐ Under Solicitation ☒ Appropriate Indications ☐ No PA Required

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