Reference number(s)
2457-A

STANDARD MEDICARE PART B MANAGEMENT

Luxturna (voretigene neparvovec-rzyl)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Luxturna is 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(s).

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. REQUIRED INFORMATION

Testing or analysis confirming a genetic diagnosis of biallelic RPE65 gene mutations.

III. CRITERIA FOR INITIAL APPROVAL

Biallelic RPE65 mutation-associated retinal dystrophy
Authorization of 1 month may be granted for treatment of biallelic RPE65 mutation-associated retinal dystrophy when all of the following criteria are met:

A. The member has not received a previous treatment course of Luxturna.
B. The member has viable retinal cells in both eyes as determined by retinal thickness on spectral domain optical coherence tomography, fundus photography, and clinical examination.
C. The member must have either of the following in both eyes:
    1. Visual acuity of 20/60 or worse.
    2. Visual field less than 20 degrees in any meridian.

IV. REFERENCES

1. Luxturna [package insert]. Philadelphia, PA: Spark Therapeutics, Inc.; December 2017.
2. Russel S, Bennett J, Wellman JA, et al. Efficacy and safety of voretigene neparvovec (AAV2-hRPE65v2) in patients with RPE65-mediated inherited retinal dystrophy: a randomized, controlled, open-label phase 3 trial. *Lancet 2017*; 390:849-860.