MassHealth Luxturna Monitoring Program

Luxturna (voretigene neparvovec-rzyl) will require prior authorization (PA) and will be managed by the Luxturna Monitoring Program.

Agent	Food and Drug Administration (FDA)-approved Indications and Limitations of Use
Luxturna (voretigene neparvovec-rzyl)	• Treatment of patients with confirmed biallelic retinal pigment epithelial 65 kDa protein (RPE65) mutation-associated retinal dystrophy.

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. Patients must have viable retinal cells as determined by the treating physician. Patients with biallelic RPE65 mutations have progressive rod and cone degeneration. Luxturna is administered as a subretinal injection and is designed to deliver a normal copy of the gene encoding human RPE65 to retinal pigment epithelial cells, resulting in transduction of some cells with functional cDNA and providing the potential to restore the visual cycle.

Luxturna Monitoring Program

Luxturna (voretigene neparvovec-rzyl) will require PA. This therapy is administered to each eye by subretinal injection on separate days no fewer than six days apart. The durability of response is currently unknown given the recent FDA-approval of these agents. As such, MassHealth Drug Utilization Review (DUR) will be reaching out to prescribers approximately 90 days after the second retinal surgery date to verify clinical effectiveness and at ongoing intervals for long-term monitoring of sustained response.

Following PA approval, MassHealth DUR will outreach to the prescriber to inform of the Luxturna Monitoring Program and fax information to assist prescribers reporting member outcomes following administration of Luxturna.

Approximately 90 days following the second retinal surgery, the prescriber will need to submit medical records confirming the dates or surgery and documenting the initial response to therapy (e.g., full-field light sensitivity threshold [FST] scores).

DUR will be outreaching at ongoing intervals in order to conduct long term monitoring for Luxturna. Prescribers will inform DUR at these intervals whether the member continues to have ongoing response or has relapsed.

1. Luxturna [package insert] Philadelphia (PA): Spark Therapeutics; 2017 Dec.
2. Reape KZ, Chung DC, Schaefer G, et al. Natural history of individuals with retinal degeneration due to biallelic mutations in the RPE65 gene. Poster presented at: the Association for Research in Vision and Ophthalmology Annual Meeting; May 7-11, 2017; Baltimore, MD.