CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Luxturna (voretigene neparvovec-rzyl) intraocular suspension for subretinal injection
BILLING CODE	TBD
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 1 Luxturna carton per eye for lifetime
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Luxturna (voretigene neparvovec-rzyl) intraocular suspension for subretinal injection is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

BIALLELIC RPE65 MUTATION-ASSOCIATED RETINAL DYSTROPHY

For **initial** authorization:

1. Member is 3 years of age or older; AND
2. Medication must be prescribed by ophthalmologist or retinal surgeon; AND
3. Member has confirmed diagnosis of biallelic RPE65 mutation-associated retinal dystrophy by genetic testing in a CLIA-certified laboratory; AND
4. Member has baseline multi-luminance mobility testing (MLMT) score documented in chart notes; AND
5. Member has sufficient viable retinal cells as determined by retinal thickness on spectral domain optical coherence tomography (>100 microns within the posterior pole); AND
6. Member's visual acuity is 20/60 or worse (both eyes) and/or visual field less than 20 degrees in any meridian as measured by a III4e isopter or equivalent (both eyes); AND
7. Member was not previously treated with RPE65 gene therapy.
8. **Dosage allowed:** 1.5×10^{11} vector genomes (vg), administered by subretinal injection in a total volume of 0.3 mL for each eye. Administration of Luxturna to each eye must be performed on separate days within a close interval, but not fewer than 6 days.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Medication will not be reauthorization for continuous use.

CareSource considers Luxturna (voretigene neparvovec-rzyl) intraocular suspension for subretinal injection not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
08/27/2018	New policy for Luxturna created.

References:

1. Luxturna [package insert]. Philadelphia, PA; Spark Therapeutics, Inc.: 2017.

2. Maguire AM, Simonelli F, Pierce EA, at el. Safety and efficacy of gene transfer for Leber's congenital amaurosis. N Engl J Med. 2008 May 22;358(21):2240-8. doi: 10.1056/NEJMoa0802315. Epub 2008 Apr 27.
3. Bennett J, Wellman J, Marshall KA, at el. Safety and durability of effect of contralateral-eye administration of AAV2 gene therapy in patients with childhood-onset blindness caused by RPE65 mutations: a follow-on phase 1 trial. Lancet. 2016 Aug 13;388(10045):661-72. doi: 10.1016/S0140-6736(16)30371-3. Epub 2016 Jun 30.
4. Russell S, Bennett J, Wellman JA, at el. Efficacy and safety of voretigene neparvovec (AAV2-hRPE65v2) in patients with RPE65-mediated inherited retinal dystrophy: a randomised, controlled, open-label, phase 3 trial. Lancet. 2017 Aug 26;390(10097):849-860. doi: 10.1016/S0140-6736(17)31868-8. Epub 2017 Jul 14.
5. Ameri H. Prospect of retinal gene therapy following commercialization of voretigene neparvovec-rzyl for retinal dystrophy mediated by RPE65 mutation. J Curr Ophthalmol. 2018 Feb 16;30(1):1-2.

Effective date: 09/07/2018
Revised date: 08/27/2018