



**Easy Choice Health Plan**

**Missouri Care**

**'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona**

**OneCare (Care1st Health Plan Arizona, Inc.)**

**Staywell of Florida**

**WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)**

**WellCare Prescription Insurance**

**WellCare Texan Plus (Medicare – Dallas & Houston markets)**

**Luxturna**

**Policy Number: HS-331**

**Original Effective Date: 3/1/2018**

**Revised Date(s): 5/3/2018**

## APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

## DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on [www.wellcare.com](http://www.wellcare.com). Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

## BACKGROUND

On December 19, 2017 The US Food and Drug Administration (FDA) approved Luxturna (voretigene neparvovec-rzyl), a new gene therapy to treat a rare form of inherited vision loss that can lead to blindness. Luxturna is indicated for adults and children greater than 12 months of age with confirmed biallelic RPE65 mutation–associated retinal dystrophy.<sup>1</sup>

Biallelic RPE65 mutation–associated retinal dystrophy is a retinal disease caused by mutations in both copies of the RPE65 gene. It affects between 1000 and 2000 people each year in the United States and diagnosis can only be confirmed by genetic testing.<sup>1,2</sup> The purpose of the RPE65 gene is to facilitate the creation of a protein required for normal vision. The protein is part of a multi-step process which converts light entering the eye into electrical signals that are transmitted to the brain.<sup>3</sup> When there are mutations and the process is blocked, the visual cycle is interrupted and results in vision loss. Luxturna sends a functional copy of the RPE65 gene directly to retinal cells, which can then

produce the normal protein to restore vision. The functioning gene has the potential to make the visual cycle work properly again.<sup>1,2</sup>

Luxturna prescribing information suggests the recommended dose of Luxturna for each eye to be  $1.5 \times 10^{11}$  vector genomes(vg), administered by subretinal injection in a total volume of 0.3mL. The medication should be administered to each eye on separate days within a close interval but no fewer than 6 days apart. Systematic oral corticosteroids equivalent to prednisone are recommended for a total of 7 days beginning 3 days before administration and followed by a tapering dose during the next 10 days.<sup>4</sup>

Luxturna can only be administered at Ocular Gene Therapy Treatment Centers.<sup>2</sup>

According to the FDA release the most commonly reported adverse reactions were conjunctival hyperemia, cataract, increased intraocular pressure, and retinal tear.<sup>1</sup>

## POSITION STATEMENT

### Applicable To:

- Medicaid – All Markets
- Medicare – All Markets

### Exclusions

1. Members who have previously received *RPE65* gene therapy in intended eye.
2. Members under the age of 12 months.

### Coverage

Luxturna is **considered medically necessary** for members with Inherited Retinal Dystrophies (IRD) caused by mutations in the *RPE65* gene and a covered benefit when all of the following criteria apply:

1. Patient is greater than 12 months of age; **AND**,
2. Member has a confirmed diagnosis of biallelic *RPE65* mutation-associated retinal dystrophy as determined by genetic testing for biallelic mutation of the *RPE65* gene; **AND**,
3. The member has viable retinal cells as determined by the treating physicians - This can be determined by non-invasive means, such as optical coherence tomography (OCT) and/or ophthalmoscopy; **AND**,
4. Treatment with Luxturna must be done separately in each eye on separate days, with at least six days between surgical procedures; **AND**,
5. Luxturna must be administered by a surgeon experienced in performing intraocular surgery; **AND**,
6. The member must not have had treatment with Luxturna previously in the intended eye; **AND**,
7. The facility, at which Luxturna is administered, must be appropriately certified to do so.

## CODING

### Covered CPT Codes

- 67036** Vitrectomy, mechanical, pars plana approach  
**67299** Unlisted procedure, posterior segment

### Covered HCPCS Code

- C9032** Injection, voretigene neparvovec – rzyl, 1 billion vector genome

### Covered ICD-10 Codes – *This list may not be all inclusive.*

- H35.50** Unspecified hereditary retinal dystrophy  
**H35.52** Pigmentary retinal dystrophy  
**H35.54** Dystrophies primarily involving the retinal pigment epithelium

### Modifiers

-RT, -LT

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

## REFERENCES

1. Frellick, M. FDA Approves Novel Gene Therapy for Rare Form of Vision Loss. Medscape Web site [https://www.medscape.com/viewarticle/890366?nlid=119685\\_3901&src=wnl\\_newsalt\\_171219\\_MSCPEDIT&uac=213422HK&impID=1513201&faf=1](https://www.medscape.com/viewarticle/890366?nlid=119685_3901&src=wnl_newsalt_171219_MSCPEDIT&uac=213422HK&impID=1513201&faf=1). Published December 19, 2017. Accessed February 15, 2018.
2. About Luxturna (voretigene neparvovec-rzyl). Luxturna Web site <https://luxturna.com/about-luxturna>. Published 2017. Accessed February 15, 2018.
3. RPE65 gene. Genetics Home Reference Website <https://ghr.nlm.nih.gov/gene/RPE65#resources>. Published August 2010. Accessed February 15, 2018.
4. Highlights of prescribing information. Spark Therapeutics Web site [http://sparktx.com/luxturna\\_us\\_prescribing\\_information](http://sparktx.com/luxturna_us_prescribing_information). Published 2017. Accessed February 15, 2018.
5. New York State Medicaid will begin covering voretigene neparvovec-rzyl (Luxturna). New York State Medicaid Update - March 2018 Volume 34 - Number 3. [https://www.health.ny.gov/health\\_care/medicaid/program/update/2018/2018-03.htm#luxturna](https://www.health.ny.gov/health_care/medicaid/program/update/2018/2018-03.htm#luxturna). Accessed April 13, 2018.

## MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
5/3/2018	<ul style="list-style-type: none"><li>• Approved by MPC. Updates made to criteria to match NY Medicaid coverage update.</li></ul>
3/1/2018	<ul style="list-style-type: none"><li>• Approved by MPC. New.</li></ul>