Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 174.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Luxturna (voretigene-neparvovec-rzyl)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Luxturna (voretigene-neparvovec-rzyl)

II. Purpose/Objective:
To provide a policy of coverage regarding Luxturna (voretigene-neparvovec-rzyl)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Luxturna (voretigene-neparvovec-rzyl) is an adeno-associated virus vector-based gene therapy that delivers a normal copy of the gene encoding human retinal pigment epithelial 65 kDa protein (RPE65) to retinal cells thus augmenting reduced or absent levels of biologically active RPE65. The RPE65 gene mutations lead to reduced or absent levels of RPE65 isomerohydrolase activity, blocking the visual cycle and ultimately impairing vision.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Luxturna (voretigene-neparvovec-rzyl) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Prescription written by or in consultation with a retinal specialist **AND**
- Medical record documentation that the patient is ≥ 12 months of age **AND**
- Medical record documentation of diagnosis of biallelic RPE65 mutation-associated retinal dystrophy confirmed via genetic testing **AND**
- Medical record documentation that the member has sufficient viable retinal cells, defined as ONE of the following:
    - An area of retina within the posterior pole of > 100 micron thickness as shown on optical coherence tomography
    - ≥ 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole based on ophthalmoscopy
    - Remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent

AUTHORIZATION DURATION: One-time authorization for one (1) treatment per eye per lifetime

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Luxturna [prescribing information]. Philadelphia, PA: Spark Therapeutics Inc; May 2022.
2. Russell S, Bennett J, Wellman JA, et al. Efficacy and safety of voretigene neparvovec (AAV2-hRPE65v2) in patients with RPE65 -mediated inherited retinal dystrophy: a randomised, controlled, open-label, phase 3 trial. The Lancet; 2017 Aug 26. 390(10097):849-860 [cited 2023 Dec 26]. Available from: https://www.clinicalkey.com/#!/content/playContent/1-s2.0-S0140673617318688?returnurl=https:%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS0140673617318688%3Fshowall%3Dtrue&referrer=https:%2F%2Fpubmed.ncbi.nlm.nih.gov%2F

This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/15/18

Revised: 12/15/22 (LOB carve out, Medicaid PARP statement), 12/5/23 (Medicaid business segment, references), 11/26/24 (LOB table, taglines)

Reviewed: 4/22/19, 1/1/20, 1/1/21, 12/17/21

MA UM Committee approval: 12/31/23, 12/31/24

DHS PARP approval: 1/15/25