

Pharmacy Policy

Luxturna

Policy Number: 9.904

Version Number: 2.0

Version Effective Date: 3/1/2022

Product Applicability <input type="checkbox"/> All Plan+ Products	
Well Sense Health Plan <input type="checkbox"/> New Hampshire Medicaid	Boston Medical Center HealthNet Plan <input checked="" type="checkbox"/> MassHealth - MCO <input checked="" type="checkbox"/> MassHealth - ACO <input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct <input type="checkbox"/> Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Luxturna (voretigene neparovec-rzyl)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Lifetime limit of one treatment per eye has been met.
Required Medical Information	Documentation of the following: 1. Must have diagnosis of biallelic RPE65 mutation-associated retinal dystrophy, evidenced by the blueprint genetics retinal dystrophy panel; AND 2. Prescriber must document patients have viable retinal cells.
Age Restriction	12 months of age or older
Prescriber Restriction	Prescribed and administered by ophthalmologist or retinal surgeon with experience providing sub-retinal injections

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Coverage Duration	Initial: 28 days
--------------------------	------------------

Applicable Coding:

Code	Medication
J3398	Luxturna (voretigene neparovvec)

Clinical Background Information and References

1. LUXTURNA (voretigene neparovvec-rzyl) prescribing information. Philadelphia, PA. Spark Therapeutics, Inc. December 2017. Accessed Oct 2021.
2. Luxturna drug information. UpToDate. Waltham, MA: UpToDate Inc. <https://www.uptodate.com> Accessed Oct, 2021.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.081 Luxturna policy retired, new policy created	1/1/2021	P&T Committee
11/11/2021	No recommended changes.	3/1/2022	P&T Committee

Next Review Date

2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

* *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.