Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Epioxa™ (riboflavin 5'-phosphate ophthalmic solution)

Effective: August 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☐ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☐ Tufts Health One Care-- A dual-eligible product; Fax 617-673-0956

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Keratoconus is a progressive corneal ectatic disorder characterized by thinning and weakening of the cornea, resulting in irregular astigmatism, visual distortion, and gradual loss of visual acuity. The condition typically begins during adolescence or early adulthood and often progresses most rapidly in younger patients; if left untreated, continued disease progression may lead to significant visual impairment and, in advanced cases, the need for corneal transplantation. Corneal collagen cross-linking is a photochemical procedure approved by the U.S. Food and Drug Administration (FDA) for the treatment of progressive keratoconus.

Food and Drug Administration (FDA) Approved Indications:

- EPIOXA HD and EPIOXA are photo enhancers indicated for use in epithelium-on corneal collagen cross-linking for the treatment of keratoconus in adults and pediatric patients aged 13 years and older, in conjunction with the O_2n System and the Boost Goggles. The O_2n System is a UV-A light delivery device for epithelium-on corneal collagen cross-linking, and the Boost Goggles is a supplemental oxygen delivery device designed to maintain a high-oxygen environment at the corneal surface during treatment.

Clinical Guideline Coverage Criteria

The Plan may cover Epioxa when all the following clinical criteria is met:

1. The Member is age 13 years of age or older; **and**
2. The Member has been diagnosed with keratoconus; **and**
3. The procedure is performed by an ophthalmologist experienced in the management of keratoconus; **and**
4. Epioxa is used as part of an epithelium-on corneal collagen cross-linking procedure in conjunction with both the O2n™ System and the Boost Goggles®.

Limitations

The Plan will not cover Epioxa under any of the following conditions:

- Any indications other than those outlined above.
- Treatment with Epioxa for Members under 13 years of age.
- Use outside of the FDA-approved Epioxa corneal collagen cross-linking procedure.
- Use without the O2n™ System and Boost Goggles®.
- Epioxa is limited to a single treatment per affected eye.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2789	Riboflavin 5'-phosphate, ophthalmic solution (Epioxa HD/Epioxa), up to 2 ml

References:

1. Epioxa HD and Epioxa. [package insert]. Aliso Viejo, CA: Glaukos Corporation; October 2025.
2. Beckman KA, Parkhurst GD, Lee JH, Al-Mohtaseb ZN, Greenwood MD, Armijo M, Smith V, Leone EH, Kothe AC, Navratil T. Randomized, Controlled Study to Evaluate the Safety and Efficacy of Oxygen-Enriched Epithelium-On Corneal Cross-Linking for the Treatment of Keratoconus. Ophthalmol Ther. 2026 Apr;15(4):1463-1484. doi: 10.1007/s40123-026-01364-7. Epub 2026 Mar 13. PMID: 41824263; PMCID: PMC13046903.
3. Glaukos Corporation. A Phase III, Multi-center Study to Evaluate the Safety and Efficacy of Epithelium-on Corneal Collagen Cross-linking in Eyes With Progressive Keratoconus. ClinicalTrials.gov identifier: NCT03442751. ClinicalTrials.gov. Updated January 30, 2024. Accessed July 8, 2026. https://clinicaltrials.gov/study/NCT03442751.
4. Porter D. Corneal cross-linking. American Academy of Ophthalmology. www.aao.org. Published December 2, 2025. Accessed July 8, 2026. Available at: https://www.aao.org/eye-health/treatments/corneal-cross-linking-2.
5. Asbell PA, Petratos T, et al. Keratoconus. In: Karakus S, ed. EyeWiki. American Academy of Ophthalmology. Reviewed August 13, 2024. Accessed July 8, 2026. https://eyewiki.aao.org/Keratoconus#Management.
6. Keratoconus. UpToDate.com/login [via subscription only]. Published May 31, 2024. Updated April 1, 2026. Accessed May 27, 2026.

Approval And Revision History

July 15, 2026: Reviewed by the Medical Policy Approval Committee (MPAC), effective August 1, 2026.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.