

Clinical Review Criteria Related to Corneal Cross-Linking:

Line of Business: Corporate Comm – FF Comm - SF Medicare Medicaid MedSupp

Definitions:

- Keratoconus: Progressive, non-inflammatory eye disease characterized by a cone-like shape to the cornea versus the normally round cornea. Cornea begins to bulge and the cone shape deflects light that enters the eye on its way to the light sensitive retina which results in distorted vision, or blurred vision and light sensitivity. Generally, a bilateral disease.
- Conventional (epithelium off) corneal collagen cross-linking (CXL) is treatment that involves debriding of the most superficial layer of the cornea (epithelium) prior to applying medicated drops that contain riboflavin (vitamin B2) to the eye which is then followed by exposure to ultraviolet light. Only treatment approved by U.S. Food and Drug Administration (FDA).

Policy:

Medical Criteria Disclaimer

Property of Health New England. All rights reserved. The treating physician or primary care provider must submit to Health New England the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Health New England will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how Health New England determines whether certain services or supplies are medically necessary. Health New England established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). Health New England expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by Health New England, as some programs exclude coverage for services or supplies that Health New England considers medically necessary. If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage and Medicaid members. Health New England has adopted the herein policy in providing management, administrative and other services to its Health Plan.

Description: Corneal Cross-Linking

Per Hayes: CXL uses a combination of riboflavin (vitamin B2) eye drops, absorbed throughout the cornea stroma, with ultraviolet A (UVA) radiation to trigger a photochemical reaction that changes the cross-links between and within collagen fibers in the corneal stroma. This is believed to strengthen and increase the biomechanical stiffness of the corneal stroma, thereby flattening the steepened cornea into a more normal shape so that vision improves.

Different approaches to remove or penetrate the corneal epithelium and different UVA light intensities have given rise to a variety of CXL approaches. Conventional CXL (C-CXL) involves

removing the epithelium, after which riboflavin drops are applied to the cornea and the UVA irradiation is performed, typically for 30 minutes at an intensity of 3 milliwatts per square centimeter (mW/cm²).

I. For Commercial Policies only: Corneal cross-linking, Conventional, epithelium-off, corneal collagen crosslinking (C-CXL) using a U.S. Food and Drug Administration (FDA) approved drug/device system (e.g., Photrexa® Viscous or Photrexa® with the KXL® System) is considered medically necessary for the treatment of one of the following:

A. Progressive keratoconus diagnosed by keratometry and corneal mapping

II. Criteria for approval includes all of the following:

A. Age 14-65 years of age; AND

B. Progressive deterioration in vision due to keratoconus; AND

C. Either one of the following vision changes in the past 12-24 months

1. Increase of 1.00 diopters or more in the steepest keratometry measurement, OR

2. A reduction of uncorrected visual acuity or best spectacle corrected visual acuity by 1 line

D. Absence of visual disturbance from another eye disease or significant central corneal opacity; AND

E. Corneal cross linking is ONLY for treatment of progressive keratoconus; for all other indications this procedure is investigational; AND

F. Non-pregnant individuals; AND

G. Corneal thickness of at least 400 microns or more AND

H. No history of systemic or corneal disease that may interfere the healing after the procedure (i.e., chemical injury or history of delayed epithelial healing.

III. Required Documentation:

A. MD documentation of progressive keratoconus and absence of contraindications for the procedure

IV. What is Not Covered/Contraindicated:

Note: Procedure not covered under Medicare or Medicaid, below only applies to commercial policies

A. Corneal thickness of <400 microns for the C-CXL protocol

- B. CXL with Intacs
- C. Prior herpetic infection (because viral reactivation may occur)
- D. Concurrent infection
- E. Severe corneal scarring or opacification
- F. History of poor epithelial wound healing
- G. Severe ocular surface disease (e.g., dry eye)
- H. Autoimmune disorders
- I. Not covered under Medicare
- J. The following collagen cross-linking procedures are experimental/investigational and are not covered, including, but not limited to:
 1. Transepithelial corneal cross-linking (T-CXL)
 2. Accelerated corneal cross-linking (A-CXL)
 3. Topography-guided corneal cross-linking (TG-CXL) or partial epithelium-off corneal cross-linking (P-CXL)

CPT Codes:

0402T: Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)

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