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Medical Policy:	II-207-001
Topic:	Corneal Collagen Cross-Linking
Section:	Medicine
Effective Date:	August 6, 2018
Issue Date:	August 6, 2018
Last Reviewed:	April 2018

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Corneal collagen cross-linking (CXL) is a photochemical procedure being evaluated to stabilize the cornea in patients with progressive keratectasia, a protrusion of a thin, scarred cornea. Keratectasia can occur due to keratoconus, pellucid marginal degeneration, or as an iatrogenic keratoconus secondary to refractive surgery. CXL may also have anti-edematous and antimicrobial properties.

Corneal collagen cross-linking (CXL) is performed with the photosensitizer riboflavin (vitamin B2) and ultraviolet A (UV-A) irradiation. A common CXL protocol, epithelium-off CXL, removes about 8 mm of the central corneal epithelium under topical anesthesia to allow better diffusion of the photosensitizer riboflavin into the stroma. The interaction of riboflavin and UV-A causes the formation of additional covalent bonds (cross-linking) between collagen molecules, resulting in stiffening of the cornea. Theoretically, use of the homogeneous light source in conjunction with riboflavin protects deeper eye structures (e.g. endothelium, anterior chamber, iris, lens, retina) from a UV dose that is above the cytotoxic threshold. Epithelium-on CXL, a procedure in which the corneal epithelial surface is left primarily intact, is less commonly employed. CXL-plus combines the CXL procedure with other procedures such as implantation of intrastromal corneal ring segments, photorefractive keratectomy (PRK) or phakic intraocular lens implantation.

In 2016, the U.S. Food and Drug Administration (FDA) approved a riboflavin ophthalmic solution, Photrexa® Viscous and Photrexa®, in combination with the company's particular UVA irradiation device, marketed as the KXL® System, for use in the epithelial-off corneal cross-linking for the treatment of progressive keratoconus and corneal ectasia following refractive surgery.

*This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances may warrant individual consideration, based on review of applicable medical records.*

**Policy Position** Coverage is subject to the specific terms of the member's benefit plan.

**I. Epithelium-off** corneal collagen cross linking using riboflavin and ultraviolet A may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when BOTH of the following criteria are met:

- ONE of the following conditions:
  - Progressive keratoconus; or
  - Corneal ectasia (keratectasia) after refractive surgery; **AND**
- **Failed conservative treatment (e.g., spectacle correction, rigid contact lenses)**

**II. Epithelium-on** (transepithelial) corneal collagen cross-linking is considered **EXPERIMENTAL/INVESTIGATIVE** for all indications, including but not limited to

keratoconus and corneal ectasia (keratectasia), due to the lack of evidence demonstrating an impact on improved health outcomes.

III. ANY type of collagen cross-linking is considered

**EXPERIMENTAL/INVESTIGATIVE** in all other situations due to the lack of evidence demonstrating an impact on improved health outcomes, including but not limited to:

- Collagen cross-linking for treatment of infectious keratitis
- Corneal collagen cross-linking-plus (CXL-plus) combination procedures.

### Procedure Codes

0402T

### Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

- Clinical notes describing ALL of the following:
  1. Ocular condition for which corneal collagen cross-linking is proposed
  2. Conservative treatment measures and response
  3. Method of corneal collagen cross-linking proposed (epithelium-off or epithelium-on)

### Link to Commercial Pre-Authorization Form:

[https://www.bluecrossmn.com/healthy/public/portalcomponents/PublicContentServlet?contentId=P11GA\\_12956557](https://www.bluecrossmn.com/healthy/public/portalcomponents/PublicContentServlet?contentId=P11GA_12956557)

## Denial Statements

No additional statements.

## Links

*Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.*

*Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.*

*For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.*

*Blue Cross and Blue Shield of Minnesota reserves the right to revise, update and /or add to its medical policies at any time without notice. Codes listed on this policy are included for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. These guidelines are the proprietary information of Blue*

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