

Policy Name:	Corneal Cross-Linking
Effective Date:	4/17/2023

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member’s plan document for other specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Conventional and accelerated corneal cross-linking **is COVERED** for the treatment of keratoconus and corneal ectasia.

Conventional and accelerated corneal cross-linking is considered investigative and unproven, and therefore **NOT COVERED** for all other indications. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Conventional and accelerated corneal cross-linking is considered investigative and unproven, and therefore **NOT COVERED** when combined with other procedures, also known as CXL-plus (e.g. intrastromal corneal ring segments (INTACS) or photorefractive keratectomy or phakic intraocular lens implantation. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes.

Transepithelial and partial epithelium-off corneal cross-linking is considered investigative and unproven, and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Description

Keratoconus is the most common corneal degenerative disorder. In keratoconus, collagen fibers within the cornea weaken and no longer maintain the normal round shape of the cornea. Consequently, the cornea bulges outward, steepens, and develops a progressive conical shape. This abnormal shape prevents light entering the eye from focusing directly on the retina, resulting in irregular astigmatism and progressive myopia or visual loss.

Corneal ectasia is caused by irregularities in the cornea that lead to disturbances of vision as a result of astigmatism. Corneal ectasia refers to a group of conditions, most notably keratoconus, but can also be related to irregular astigmatism that can develop after a patient undergoes refractive surgery (LASIK or PRK). In both cases, the cornea can continue to bulge, leading to a worsening of vision for the patient.

Corneal cross-linking (CXL) is a procedure that combines the use of ultraviolet (UV) light and riboflavin (vitamin B2) eye drops to trigger a photochemical reaction that changes the cross-links between and within collagen fibers in the cornea. The drops are administered to a fully or partially de-epithelialized cornea or an intact cornea. The stiffening of the corneal tissue is hypothesized to strengthen and stabilize the cornea, thereby flattening the cornea into a more normal shape. This may slow or halt progression of keratoconus. Following the outpatient procedure, a bandage contact lens is generally applied.

Conventional CXL involves the removal of the epithelial layer of the cornea, and then the riboflavin eye drops are applied topically to the eye at intervals until the riboflavin can be seen in the anterior chamber of the eye. After adequate riboflavin absorption, the UV light is applied.

Accelerated CXL is similar to conventional CXL, but the UV exposure time is decreased by increasing the irradiance.

Transepithelial CXL is performed without epithelial removal. This is done in an effort to reduce patient discomfort and possible greater infection risk compared with conventional CXL approach.

Partial epithelium-removal CXL is performed by partially removing the epithelium in an effort to reduce corneal damage and promote faster reepithelialization.

Topography-guided corneal cross-linking (TG-CXL) TG-CXL is performed using a customized, patient-specific UVA irradiation pattern that superimposes concentric circular zones over the keratoconic cone region of the corneal. These zones are centered on the maximum posterior elevation and receive varying amounts of energy depending on the severity of the curvature, with higher levels of energy being delivered to the innermost zones compared with outmost zones.

FDA Approval

Corneal cross-linking is a procedure and therefore not subject to FDA regulation. However, any medical devices, drugs or tests used as part of the procedure may be subject to FDA regulation.

On April 15, 2016, FDA approved the combination product Photrexa (riboflavin 5-phosphate ophthalmic solution) and Photrexa Viscous (riboflavin 5-phosphate in 20% solution) for use with the KXL UV-A Light system in corneal cross-linking for treatment of progressive keratoconus. On July 15, 2016 the indication was expanded to include corneal ectasia following refractive surgery.

Currently, Glaukos' iLink (formerly known as Avedro's) is the only cross-linking device approved by the U.S. Food and Drug Administration. The iLink system incorporates two unique riboflavin formulations, Photrexa Viscous (riboflavin 5-phosphate in 20% dextran ophthalmic solution) and Photrexa (a hypo-osmolar composition that can be used to swell a thin cornea) and a UV light source.

Prior Authorization

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below 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.

CPT Codes

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

Original Effective Date: 5/1/2017

Re-Review Date(s): 2/19/2020
2/15/2023

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