



## Corneal Cross-linking (CXL) Epithelium-off

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<b>State(s):</b> <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other:	<b>LOB(s):</b> <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid
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### Enterprise Policy

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*Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determination are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.*

### Background

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Corneal cross-linking (CXL) is an outpatient procedure designed to treat progressive keratoconus and corneal ectasia (and sometimes other conditions that cause similar weakening of the cornea). Keratoconus is a progressive eye disease characterized by deformation (becomes cone shaped) of the cornea. Corneal ectasia is a form of keratoconus that occurs after refractive surgery. The goal of CXL is to stop the cornea from getting thinner, weaker, and more irregular in shape.

The CXL procedure strengthens and stabilizes the cornea by creating new links between collagen fibers within the cornea. The two-step procedure applies liquid riboflavin (vitamin B2) to the surface of the eye immediately followed by a controlled exposure of the eye to ultraviolet light.

There are 2 basic types of corneal cross-linking: Epithelium-off CXL and Epithelium-on CXL. In the Epithelium-off CXL procedure the thin outer layer (epithelium) of the cornea is removed to allow the liquid riboflavin to more easily penetrate the corneal tissue. The Avedro system of corneal crosslinking is currently the only FDA approved method of Epithelium-off CXL.

Epithelium-on (transepithelial) corneal collagen cross-linkage (CXL) is considered experimental, investigational or unproven.

## Criteria

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### Commercial

#### Preauthorization is required

PacificSource considers Corneal Collagen Cross-linking (CXL)-Epithelium-off using riboflavin and ultraviolet a medically necessary treatment when ALL the following are met:

Diagnosis of progressive keratoconus OR corneal ectasia and **ONE** of the following:

- An increase of 1 diopter (D) in the steepest keratometry value.
- An increase of 1 D in regular astigmatism evaluated by subjective manifest refraction.
- A myopic shift (decrease in the spherical equivalent) of 0.50 D on subjective manifest refraction.
- A decrease  $\geq 0.1$  mm in the back optical zone radius in rigid contact lens wearers where other information was not available.
- Documented keratoconus by tomography in patients under the age of 25.

**Riboflavin (Photrexa)** is considered part of the cost of the Corneal Collagen Cross-linking (CXL) procedure and is not separately reimbursable.

#### Exclusions:

- PacificSource considers Corneal Collagen Cross-linking (CXL) using riboflavin and ultraviolet experimental, investigational or unproven for all other indications because its effectiveness for other indications has not been established.
- PacificSource considers Epithelium-on (transepithelial) Corneal Collagen Cross-linkage (CXL) experimental, investigational or unproven for keratoconus, keratectasia, and all other indications.

### Medicaid

This policy does not apply to PacificSource Community Solutions members. PacificSource Community Solutions follows Oregon Health Plan (OHP) Oregon Administrative Rules (OARs) 410-120-1200(2)(a)-(ff), 410-120-0000(137), 410-141-3825(1)(a-i), and considers Corneal Cross-linking (CXL) Epithelium-off not a covered benefit.

### Medicare

PacificSource Medicare follows CMS guidelines and criteria. In the absence of internal policy guidelines, CMS criteria, and evidence-based criteria, requests are reviewed on an individual basis for determination of coverage and medical necessity.

## Experimental/Investigational/Unproven

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PacificSource considers Epithelium-on (transepithelial) Corneal Collagen Cross-linkage (CXL), Topography-guided Corneal Cross-linking (TGCXL), and Partial Epithelium-off Corneal Cross-linking (P-CXL) experimental, investigational or unproven.

## Coding Information

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

**66999** Unlisted procedure, anterior segment of eye

**J2787** Drugs, unclassified injection

## Definitions

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**Corneal epithelium-** the outer layer of the cornea is five to seven cells thick and measures about 50 microns — making it slightly less than 10 percent of the thickness of the entire cornea. Epithelial cells are constantly being produced and sloughed off in the tear layer of the surface of the eye.

**Corneal stroma-** the middle layer of the cornea is approximately 500 microns thick, or about 90 percent of the thickness of the overall cornea. It is composed of strands of connective tissue called collagen fibrils. These fibrils are uniform in size and are arranged parallel to the cornea surface in 200 to 300 flat bundles called lamellae that extend across the entire cornea. The regular arrangement and uniform spacing of these lamellae is what enables the cornea to be perfectly clear.

**Covalent bond** – a chemical bond formed by the sharing of one or more electrons, especially pairs of electrons, between atoms in a molecule.

**Ectasia** or **Keratectasia** - is a serious long-term complication of laser in situ keratomileusis (LASIK) surgery and photorefractive keratectomy. It is similar to keratoconus, but occurs postoperatively and primarily affects older populations. It may result from unrecognized preoperative keratoconus or, less frequently, from the surgery itself. Similar to keratoconus, it is characterized by progressive thinning and steepening of the cornea, resulting in corneal optical irregularities and loss of visual acuity.

**Keratoconus** - a degeneration of the structure of the cornea in which the corneal surface thins and begins to bulge into a cone shape. This causes refractive error, which is usually a myopic shift and is often associated with irregular astigmatism, leading to visual impairment.

## References

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## Appendix

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**Policy Number:** [Policy Number]

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**Policy type:** Enterprise

**Author(s):**

**Depts:** Health Services

**Applicable regulation(s):**

**Commercial Ops:** 03/2021

**Government Ops:** 03/2021