



Corneal Cross-linking (CXL) Epithelium-off

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

Enterprise Policy

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

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.

Criteria

Commercial

Preauthorization is Required

PacificSource considers corneal collagen cross-linking (CXL)-epithelium-off using riboflavin and ultraviolet A medically necessary treatment for members with progressive keratoconus **OR** corneal ectasia. Progressive keratoconus and corneal ectasia are defined as having one or more 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 ≥ 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 A 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 Medicaid members. PacificSource Medicaid 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

Preauthorization is required.

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.

Coding Information

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

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

Bikbova G, et al. Standard corneal collagen crosslinking versus transepithelial iontophoresis-assisted corneal crosslinking, 24 months follow-up: randomized control trial. *Acta Ophthalmol*. 2016 Nov; 94(7): e600–e606 Accessed 03/19/2020. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5111766/>

Center for Medicare and Medicaid Services (CMS), Healthcare Common Procedure Coding System (HCPCS), application Summaries for Drugs, Biologicals and Radiopharmaceuticals, May 17, 2017, March 19, 2020

<https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2017-05-17-HCPCS-Application-Summary.pdf>

FDA Center for Drug Evaluation and Research, Photrexa Viscous and Photrexa and KXL System, April 15, 2016, Accessed March 19, 2020

<https://www.fda.gov/media/102962/download>

Hayes Medical Technology Directory. Corneal Cross-linking for Treatment of Keratoconus (comparative effectiveness review) Landsdale, PA: Hayes, Inc. February 15, 2018

Hayes-News Government. FDA approves First-in-Class Treatment of Progressive Keratoconus. Landsdale, PA: Hayes, Inc. April 20, 2016.

Hayes Search and Summary. Corneal Collagen Cross-Linking for Treatment of Lasik-related Ectasia. Landsdale, PA: Hayes, Inc. December 27, 2018

Hersh PS et al. United States Multicenter Clinical Trial of Corneal Collagen Crosslinking for Keratoconus Treatment. *Ophthalmology*. 2017 Sep;124(9):1259-1270. Accessed 2/28/2019, 3/19/2020 <https://www.ncbi.nlm.nih.gov/pubmed/28495149>

Mandathara PS et al. Outcome of Keratoconus Management: Review of the Past 20 Years' Contemporary Treatment Modalities. *Eye Contact Lens*. 2017 May;43(3):141-154. Accessed 2/28/2019, 03/19/2020

<http://www.ncbi.nlm.nih.gov/pubmed/27171132>

National Institute for Health and clinical Excellence (NICE). Photochemical corneal collagen cross-linkage using riboflavin and ultraviolet A for keratoconus and keratectasia. IPG466, September 2013
Accessed 3/19/2020

<https://www.nice.org.uk/guidance/ipg466/evidence>

Peyman A et al. Collagen cross-linking effect on progressive keratoconus in patients younger than 18 years of age: A clinical trial. [Adv Biomed Res](#). 2015; 4: 245. Accessed 2/28/2019, 3/19/2020

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4685639/>

Rush SW et al. Epithelium-off versus transepithelial corneal collagen crosslinking for progressive corneal ectasia: a randomized and controlled trial. *BMJ Journals* vol. 101, issue 4. Accessed 2/28/2019, 3/19/2020. <http://bjo.bmj.com/content/101/4/503.full>

Appendix

Policy Number: [Policy Number]

Effective: 4/23/2020

Next review: 4/1/2021

Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s): N/A

External entities affected: N/A
