# Keratoconus Surgical Treatments

Humana®

**Effective Date:** 07/25/2024
**Revision Date:** 07/25/2024
**Review Date:** 07/25/2024
**Policy Number:** HUM-0314-019
**Line of Business:** Commercial

## Medical Coverage Policy

### Table of Contents





## Related Medical/Pharmacy Coverage Policies

None

## Description

Keratoconus is a noninflammatory degenerative eye condition characterized by progressive steepening and thinning of the normally round cornea into a cone shape. These changes lead to decreased visual acuity (distorted or blurred vision) and sensitivity to light or glare. The condition typically presents itself during adolescence or early adulthood. Although keratoconus usually affects both eyes, it may occur in one eye first or be more severe in one eye than the other. Initial interventions generally include glasses or soft contact lenses, but as keratoconus progresses, an individual may require fitting with rigid gas permeable or other types of contact lenses. **(Refer to Coverage Limitations section)**

Treatments for keratoconus include, but may not be limited to:

**Conventional (epithelium-off, epi-off) corneal collagen cross-linking (CXL)** involves debriding the most superficial layer of the cornea (corneal epithelium) prior to the application of medicated drops containing riboflavin (vitamin B2) to the eye followed by exposure to ultraviolet (UV) light. The procedure strengthens the bonds between collagen fibers in the cornea, thereby improving its shape and halting the progression of

keratoconus. The proprietary iLink procedure consists of the US Food & Drug Administration (FDA)-approved medications Photrexa and Photrexa Viscous when used in conjunction with the UVA-emitting KXL system.

**Intrastromal corneal ring segments (Intacs)** are clear, micro-thin ophthalmic medical devices designed to reduce or eliminate nearsightedness and astigmatism as well as avoid corneal transplantation. The rings are surgically inserted and rest between layers of tissue in the cornea, outside the central optical zone, flattening the curvature of the cornea to restore functional vision and contact lens tolerance. Intacs may be removed and replaced with ring segments of different thickness if the eyes change after the original surgery.

A **deep anterior lamellar keratoplasty (DALK)** procedure retains approximately five percent of the original cornea and replaces the rest with donor tissue. The individual's own endothelium (lining of the cornea's inner surface) is retained, thereby reducing the risk of graft rejection.

**Full thickness corneal transplantation (penetrating keratoplasty)** is the treatment of choice when keratoconus has progressed, and other interventions are no longer helpful or are not an option. During surgery, the diseased cornea is removed and replaced with a donor cornea. Prior to the availability of CXL and Intacs, keratoplasty was considered the standard treatment for keratoconus.

Other proposed treatments for keratoconus include, but may not be limited to:

**Accelerated corneal collagen cross-linking (CXL)** is similar to conventional CXL but is performed by using a higher UV light dose and decreasing the total exposure time. **(Refer to Coverage Limitations section)**

**Combination therapy** using **Intacs** to flatten the cornea and **CXL** to halt disease progression is under study. **(Refer to Coverage Limitations section)**

**Endothelial keratoplasty** refers to a partial thickness keratoplasty that removes the unhealthy endothelium and replaces it with donor tissue. **(Refer to Coverage Limitations section)**

**Transepithelial (epithelium-on, epi-on) corneal collagen cross-linking (CXL)** is similar to conventional CXL but is performed without removing the most superficial layer of the cornea (corneal epithelium) prior to the administration of eye drops. **(Refer to Coverage Limitations section)**

## Coverage Determination

**Corneal Collagen Cross-Linking (CXL)**
Humana members may be eligible under the Plan for **conventional (epithelium-off, epi-off) CXL** when the following criteria are met:

- Diagnosis of progressive keratoconus; **AND**

- Any one or more of the following vision changes within the preceding 12 months:

- Increase of 1.00 diopter (D) or more in the steepest keratometry measurement; **OR**
- Increase of mean keratometry of 0.7 D or more; **OR**
- Thinning of corneal pachymetry of 10 microns or more; **OR**
- Reduction in uncorrected visual acuity or best spectacle corrected visual acuity by more than one line;

**AND** both of the following[23]:

- Clear central cornea (without scarring or disease); **AND**
- Corneal thickness of at least 400 microns at the time of treatment

**Intrastromal Corneal Ring Segments (Intacs)**
Humana members may be eligible under the Plan for **Intacs** when the following criteria are met:

- Diagnosis of keratoconus with progressive deterioration of vision; **AND**
- Inadequate vision correction with eyeglasses or contacts; **AND**
- Corneal transplantation is the ONLY alternative to Intacs for improving vision; **AND**
- 21 years of age or older; **AND**
- Clear central cornea; **AND**
- Corneal thickness of 450 microns or more at the proposed incision site

**Deep Anterior Lamellar Keratoplasty (DALK)**
Humana members may be eligible under the Plan for **deep anterior lamellar keratoplasty (DALK)** for keratoconus when the following criteria are met:

- Absence of contraindications; **AND**
- Disease involving the anterior 95% of corneal thickness with normal endothelium; **AND**
- Other treatment options (eg, conventional CXL, Intacs) have failed or are not indicated

**Full Thickness Corneal Transplantation (Penetrating Keratoplasty)**
Humana members with keratoconus may be eligible under the Plan for **full thickness corneal transplantation (penetrating keratoplasty)** when other treatment options (conventional CXL, Intacs, DALK) have failed or are not indicated.

**Penetrating keratoplasty for conditions other than keratoconus (eg, corneal degenerations/dystrophies, keratitis, trauma) is generally considered medically necessary and is not subject to the criteria within this medical coverage policy.**

## Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **conventional (epithelium-off, epi-off) CXL, Intacs or full thickness corneal transplantation (penetrating keratoplasty)** for any indications other than those listed above. All other indications are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **deep anterior lamellar keratoplasty (DALK)** for any indications other than those listed above, or in the presence of the following contraindications:

- Conditions relating to endothelial dysfunction or loss (eg, pseudophakic bullous keratopathy, iridocorneal endothelial syndrome); **OR**

- Posterior corneal dystrophies (eg, Fuchs' corneal endothelial dystrophy, posterior polymorphous corneal dystrophy, congenital hereditary endothelial dystrophy)

This is considered experimental/investigational as it is not identified as widely used and generally accepted for any other proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for the following procedures for keratoconus:

- Any CXL method other than conventional (epithelium-off, epi-off) (eg, accelerated protocol, transepithelial [epithelium-on, epi-on]); **OR**

- CXL in conjunction with Intacs; **OR**

- Endothelial keratoplasty

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the plan for:

- Correction of refractive errors; **OR**
- Fitting or purchase of contact lenses or eyeglasses; **OR**
- Refractive surgeries; **OR**
- Treatment for complications of noncovered elective procedures (corneal ectasia post-LASIK surgery)

These are generally excluded by certificate. In the absence of a certificate exclusion, these would be considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

## Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

| CPT® Code(s) | Description | Comments |
|---|---|---|
| 65710 | Keratoplasty (corneal transplant); anterior lamellar | |
| 65730 | Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia) | |
| 65750 | Keratoplasty (corneal transplant); penetrating (in aphakia) | |
| 65755 | Keratoplasty (corneal transplant); penetrating (in pseudophakia) | |
| 65756 | Keratoplasty (corneal transplant); endothelial | **Not Covered if performed for the treatment of keratoconus** |
| 65785 | Implantation of intrastromal corneal ring segments | |
| 66999 | Unlisted procedure, anterior segment of eye | **Not Covered if used to report any procedure outlined in Coverage Limitations section** |
| **CPT® Category III Code(s)** | **Description** | **Comments** |
| 0402T | Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (Report medication separately) | |
| **HCPCS Code(s)** | **Description** | **Comments** |
| No code(s) identified | | |

## References

1. American Academy of Ophthalmology (AAO). Ophthalmic Technology Assessment. Deep anterior lamellar keratoplasty as an alternative to penetrating keratoplasty. https://www.aao.org. Published January 2011.

2. American Academy of Ophthalmology (AAO). Preferred Practice Pattern. Corneal ectasia. https://www.aao.org. Published September 2023.

3. American Academy of Ophthalmology (AAO). Preferred Practice Pattern. Refractive surgery. https://www.aao.org. Published September 9, 2022.

4. ClinicalKey. Choi M, Donnenfeld E. Collagen crosslinking for keratoconus. In: Mannis M, Holland E. *Cornea*. 5th ed. Elsevier; 2022:1539.e1-1546. https://www.clinicalkey.com.

5. ClinicalKey. Moss A. Outcomes of anterior lamellar keratoplasty. In: Mannis M, Holland E. *Cornea*. 5th ed. Elsevier; 2022:1273.e1-1276. https://www.clinicalkey.com.

6. ClinicalKey. Nijm L, Mannis M, Damani M, Holland E. The evolution of contemporary keratoplasty. In: Mannis M, Holland E. *Cornea.* 5th ed. Elsevier; 2022:1147.e1-1154. https://www.clinicalkey.com.

7. ClinicalKey. Sajjad A, Sugar J, Kang K. Keratoconus and other ectasias. In: Yanoff M, Duker J. *Ophthalmology*. 6th ed. Elsevier; 2023:233-236.e1. https://www.clinicalkey.com.

8. ClinicalKey. Santiago MR. Corneal cross-linking. In: Yanoff M, Duker J. *Ophthalmology*. 6th ed. Elsevier; 2023:127-130.e1. https://www.clinicalkey.com.

9. ClinicalKey. Sarnicola C, Sarnicola E, Sarnicola V, Anwar M. Indications for anterior lamellar keratoplasty. In: Mannis M, Holland E. *Cornea.* 5th ed. Elsevier; 2022:1243.e1-1249.e1. https://www.clinicalkey.com.

10. ClinicalKey. Tognon T, Campos M. Intrastromal corneal ring segments. In Mannis M, Holland E. *Cornea*. 5th ed. Elsevier; 2022:1765.e1-1777. https://www.clinicalkey.com.

11. Cochrane Library. Database of Systematic Reviews. Deep anterior lamellar keratoplasty versus penetrating keratoplasty for treating keratoconus. https://www.cochranelibrary.com. Published July 22, 2014.

12. Cochrane Library. Database of Systematic Reviews. Transepithelial versus epithelium-off corneal crosslinking for progressive keratoconus. https://www.cochranelibrary.com. Published April 2021.

13. ECRI Institute. Clinical Evidence Assessment. Partial-thickness keratoplasty for treating keratoconus. https://www.ecri.org. Published June 2, 2016. Updated April 25, 2022.

14. ECRI Institute. Hotline Response (ARCHIVED). Corneal collagen cross-linking for treating keratoconus and corneal ectasia. https://www.ecri.org. Published January 10, 2018. Updated February 12, 2019.

15. ECRI Institute. Product Brief (ARCHIVED). Intacs corneal implants (Additional Technology, Inc.) for treating keratoconus. https://www.ecri.org. Published November 30, 2018.

16. Hayes, Inc. Medical Technology Directory. Comparative effectiveness of corneal cross-linking for treatment of keratoconus. https://evidence.hayesinc.com. Published February 15, 2018. Updated January 13, 2022.

17. Hayes, Inc. Medical Technology Directory. Conventional corneal collagen cross-linking for treatment of LASIK-related ectasia. https://evidence.hayesinc.com. Published December 27, 2018. Updated March 24, 2023.

18. Hayes, Inc. Medical Technology Directory. Intacs for the treatment of keratoconus. https://evidence.hayesinc.com. Published March 7, 2018. Updated February 17, 2022.

19. Hayes, Inc. Search & Summary (ARCHIVED). Concurrent corneal cross-linking and Intacs implantation for treatment of keratoconus. https://evidence.hayesinc.com. Published April 25, 2019.

20. MCG Health. Corneal cross linking. https://humana.access.mcg.com/index.

21. UpToDate, Inc. Keratoconus. https://www.uptodate.com. Updated May 31, 2024.

22. US Food & Drug Administration (FDA). Approval package: Photrexa viscous 0.146%, Photrexa, 0.146% with the KXL system. https://www.fda.gov. Published July 15, 2016.

23. US Food & Drug Administration (FDA). Full prescribing information: Photrexa viscous and Photrexa. https://www.fda.gov. Published July 2016. Updated October 2022.

24. US Food & Drug Administration (FDA). Intacs professional use information manual for correction of myopia and astigmatism. https://www.fda.gov. Published July 20, 2004.

25. US Food & Drug Administration (FDA). New drug approval letter: Photrexa viscous and Photrexa. https://www.fda.gov. Published April 15, 2016.

26. US Food & Drug Administration (FDA). Proprietary name: KXL system; mosaic system. https://www.fda.gov. Accessed July 8, 2016.

27. US Food & Drug Administration (FDA). Summary of safety and probable benefit: INTACS prescription inserts for keratoconus. https://www.fda.gov. Published July 26, 2004.

## Change Summary

07/25/2024 Annual Review, No Coverage Change.