KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Procedures for Keratoconus

- Collagen Cross-Linking for the Treatment of Keratoconus
- Intrastromal Corneal Ring Segments (INTACS)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Intrastromal Corneal Ring Segments (INTACS Inserts)***," "***Collagen Cross-Linking for the Treatment of Keratoconus,"*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria
Collagen Cross-Linking for the Treatment of Keratoconus	A. To qualify for photochemical cross-linkage using riboflavin and Ultraviolet A light **ALL** of the following must be met: 1. Has a diagnosis of keratoconus 2. Patient is not older than 50 years old 3. Treatment is limited to a once in a lifetime **Notes:** Kaiser Permanente considers epithelium-off photochemical collagen cross-linkage using riboflavin and ultraviolet medically necessary for keratoconus. For any other diagnosis, such as keratectasia, collagen cross-linking is considered experimental and investigational, as the effectiveness has not been established. Epithelium-on (transepithelial) collagen cross-linkage and performance of photochemical collagen cross-linkage in combination with other procedures (CXL-plus) (e.g., intrastromal corneal ring segments, PRK or phakic intra-ocular lens implantation) is considered experimental and investigational.
Intrastromal Corneal Ring Segments	1. Implantation of intrastromal corneal ring segments may be considered medically necessary for the treatment of keratoconus when **ALL of the following** criteria are met: • Functional vision cannot be achieved with contact

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	lenses or spectacles • Age 21 years or older • Clear central cornea • Corneal transplantation is the only other remaining option to improve functional vision 2. Implantation of intrastromal corneal ring segments is considered not medically necessary for the treatment of myopia. 3. Implantation of intrastromal corneal ring segments is considered investigational for all other conditions including, but not limited to, pellucid marginal degeneration.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Keratoconus is a progressive noninflammatory corneal disorder characterized by corneal thinning and protrusion of the central cornea. Signs and symptoms of keratoconus vary and depend on disease severity. In the early stages of keratoconus, individuals may be asymptomatic; however, as the disease progresses, there is considerable distortion of vision in the form of myopia and irregular astigmatism. For patients with mild to moderate keratoconus, vision may be corrected with spectacles or contact lenses. However, as the disorder progresses, or when the patients can no longer tolerate contact lenses, they are referred for corneal transplant (penetrating keratoplasty). The outcomes of this surgery are generally favorable; however, the surgery is not without complications. Complications of penetrating keratoplasty include graft rejection, intraocular damage, postoperative astigmatism, recurrence of keratoconus, and side effects from the long-term use of topical corticosteroids (Ambekar 2011, Ertan 2007, Romero-Jimémez 2010).

Intrastromal corneal ring segments (Intacs®) inserts are an alternative treatment strategy for patients with mild to moderate keratoconus who are no longer able to achieve adequate vision using contact lenses or glasses and for whom corneal transplant is the only remaining option. Intacs® inserts are small rings of synthetic material that are implanted in the deep corneal stroma with the aim of generating modifications of corneal curvature in an attempt to improve visual acuity, contact lens tolerance, and prevent or delay corneal transplant. The procedure is performed outside the corneal visual axis and the inserts may be removed or replaced if the desired outcome is not achieved. Intacs® inserts should not be used in patients who can achieve functional vision on a daily basis using contact lenses, are younger than 21 years of age, do not have clear corneas, or have corneal thickness less than 450 microns at the proposed incision site. Complications associated with Intacs® inserts include patient dissatisfaction with visual quality, discomfort, and ring segment extrusion or migration (Ambekar 2011, Bromley 2010, Ertan 2007, Romero-Jimémez 2010).

Corneal collagen crosslinking aims to slow the progression of keratoconus by increasing covalent bonds in the cornea. During the corneal crosslinking treatment, riboflavin drops saturate the cornea, which is then activated by ultraviolet light. In laboratory and clinical studies this procedure has been shown to strengthen the cornea. CXL is not a cure for keratoconus. The goal of this treatment is to stop the progression of keratoconus and prevent further deterioration in vision. The procedure consists of applying riboflavin every 3-5 minutes for 25-30 minutes and irradiating the cornea with UVA light after removal of the corneal epithelium. Then bandage lens is applied, and assessment of re-epithelialization is performed about one week after the treatment. The intervention lasts one hour to 90 minutes. Although no approval statement was found on the Food and Drug Administration website, Avedro, the manufacturer of Photrexa® Viscous, Photrexa® and KXL® System indicated that in 2016, the US Food and Drug Administration approved corneal collagen cross-linking using riboflavin and UV for progressive keratoconus (Avedro 2016). Collagen crosslinking is believed to flatten the cornea and improve vision.

Medical Technology Assessment Committee (MTAC)

Collagen Cross-Linking for the treatment of Keratoconus
09/19/2016: MTAC REVIEW

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Evidence Conclusion: The body of evidence is of low quality and there is insufficient evidence to determine whether CXL is effective and safe in stopping the progression of keratoconus as compared to the use of alternative treatments.

Articles:

The literature revealed a number of articles; the following articles were selected for critical appraisal:
Safety and Effectiveness of the UV-X System for Corneal Collagen Cross-Linking in Eyes with Progressive Keratoconus (NCT00647699)
https://clinicaltrials.gov/ct2/show/results/NCT00647699?term=corneal+collagen+crosslinking&rank=19&sect=X016 See Evidence Table 1 (not peer reviewed). Corneal collagen crosslinking for progressive keratoconus in Saudi Arabia: One-year controlled clinical trial analysis (Khattak, Nakhli et al. 2015) See Evidence Table 2.

The use of Collagen Cross-Linking for the treatment of Keratoconus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

INTACS Inserts in the Treatment of Keratoconus

10/03/2005: MTAC REVIEW

Evidence Conclusion: The studies reviewed, as well as others revealed by the literature search, were all case series comparing the postoperative results to the preoperative values among the same groups of patients. Case series have potential selection and observation biases as well as other threats to internal validity. The results of these series may indicate some improvement in visual acuity after the implantation of Intacs in patients with keratoconus with a clear central cornea and intolerability to contact lenses. However, the technology was not compared to penetrating keratoplasty or other alternative therapies, and the follow-up duration was insufficient to determine the stability of the observed outcomes and the long-term harms that could be associated with Intacs inserts. Moreover, these studies do not provide evidence to determine if this technology would prevent the progression of keratoconus and eliminate the need for penetrating keratoplasty (PK). In conclusion, larger studies with longer follow up and that compare the outcomes of the technology with those achieved with PK are needed to determine the efficacy and long-term stability, benefits, and harms of the technology.

Articles: The search revealed 18 articles. There were no meta-analyses or randomized controlled trials. All published studies identified were prospective or retrospective case series and had no control groups. Two prospective series on the use of Intacs for the management of keratoconus were selected for critical appraisal. Selection was based on the sample size, duration of follow-up, and quality of study. *Evidence tables were created for the following studies:* Hellstedt T, Makela J, Uusitalo R, et al. Treating keratoconus with Intacs corneal ring segments. *J Refract Surg.* 2005; 21:236-246. See Evidence Table. Siganos CS, Kymionis GD, Kartakis N, et al. Management of keratoconus with Intacs. *AM J Opthalmol* 2003; 135:64-70. See Evidence Table.

The use of INTACS Inserts in the treatment of keratoconus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/19/2011: MTAC REVIEW

INTACS Inserts in the Treatment of Keratoconus

Evidence Conclusion: There is insufficient evidence to determine the safety and efficacy of Intacs® inserts for the treatment of keratoconus.

Articles: The literature search did not reveal any meta-analyses or randomized controlled trials. The published studies identified were prospective or retrospective case series. The largest prospective case series with the longest duration of follow-up was selected for review.
The following study was critically appraised: Colin J and Malet F. Intacs for the correction of keratoconus: two-year follow-up. *J Cataract Refract Surg. 2007;* 33:69-74. See Evidence Table.

The use of INTACS Inserts in the treatment of keratoconus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Collagen Cross-Linking for the Treatment of Keratoconus

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (Report medication separately)

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Intrastromal Corneal Ring Segments

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
65785	Implantation of intrastromal corneal ring segments

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Dates Reviewed	Date Last Revised
10/03/2005	Reinstated criteria on 01/03/2012 MDCRPC, 12/04/2012 MDCRPC ,10/01/2013 MPC, 08/05/2014 MPC, 06/02/2015 MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 10/02/2018MPC, 10/01/2019MPC, 10/06/2020MPC, 10/05/2021MPC , 10/04/2022MPC , 10/03/2023MPC, 08/06/2024MPC	08/21/2024

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
09/18/2015	Revised LCD L35008
12/05/2017	Adopted INTACS Kaiser Permanente Policy for Medicare
08/21/2024	Merged INTACS & Collagen Crosslinking criteria; Renamed policy to *Procedures for Keratoconus*

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