09-V0000-02

Original Effective Date: 02/15/06

Reviewed: 09/25/25

Revised: 10/15/25

Subject: Implantation of Intrastromal Corneal Ring Segments

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	<u>Definitions</u>	Related Guidelines
<u>Other</u>	References	<u>Update</u>			

DESCRIPTION:

Keratoconus is a progressive bilateral dystrophy characterized by paracentral steepening and stromal thinning that impairs visual acuity.

Intrastromal corneal ring segments (ICRS) consist of micro-thin, soft plastic inserts of variable thickness that are placed .in the periphery of the cornea. They are inserted through an incision made in the cornea, into which channels have been created by rotating a lamellar dissector or by using a femtosecond laser. One or 2 segments are implanted in each channel, and various implants with a range of thicknesses are available for different degrees of correction. They affect refraction in the eye by physically changing the shape of the cornea (flattening the front of the eye), thereby correcting the irregular corneal shape and restoring a degree of functional vision. If required, the implants can be removed or replaced at a later date.

<u>INTACS</u>® are an intrastromal corneal ring approved by the U.S. Food and Drug Administration (FDA) in 1999.

Corneal allogenic intrastromal ring segments (CAIRS) has been described as a novel, biocompatible alternative to synthetic intracorneal ring segments (ICRS) for treatment of keratoconus and corneal ectasia. CAIRS entails implanting ring segments crafted from donor corneal stromal tissue into stromal channels within the patient's cornea. CAIRS was developed as a natural alternative to synthetic intrastromal ring segments to improve corneal stability and decrease astigmatism while reducing the risks associated with synthetic implants.

Summary and Analysis of Evidence: An UpToDate review, "Keratoconus" (Wayman, 2025) states "(k)eratoconus is a noninflammatory disorder of the cornea with genetic and environmental risk factors.

It is characterized by progressive thinning and cone-shaped protrusion of the cornea leading to visual impairment. Patients may present with blurry vision or a sudden decrease in visual acuity. Corrective lenses may be difficult to fit and require frequent changes due to progressive myopia and irregular astigmatism. Visual impairment can be managed initially with corrective lenses ..." "Intrastromal corneal ring segments ... were approved by the US Food and Drug Administration (FDA) in 2004 for patients with keratoconus who cannot achieve functional vision with contact lenses, who are 21 years old or older, who have clear central corneas with corneal thickness of 450 microns or more, and only have corneal transplant as an option to obtain functional vision. This technique has also been studied in combination with collagen cross-linking. These thin, semicircular plastic inserts are implanted into the mid-corneal layers to flatten the cornea. The goal is to improve the patient's visual acuity by reducing the amount of astigmatism. Several authors have reported flattening of the cornea and significant improvement of refractive errors. However, this treatment is contraindicated in patients with collagen vascular, autoimmune, or immunodeficiency disease; those who are pregnant or breastfeeding; have recurrent corneal erosion syndrome or a corneal dystrophy; or who are taking isotretinoin or amiodarone."

Hayat et al (2025) conducted a literature review was conducted using a total of 117 peer-reviewed manuscripts, including review articles, randomized controlled trials, case series, reports, and publication reference lists. The authors stated "(s)tudies indicate slight corneal stiffening post-ICRS implantation, with no significant changes in intraocular pressure. Topographic changes post-ICRS show significant corneal flattening and reduction in astigmatism. Complications include epithelial defects, segment migration, and keratitis, but long-term follow-up reveals low rates of serious adverse events. ICRS provide<s> an effective option for enhancing vision in select keratoconus patients, ultimately lowering the chances of requiring a corneal transplant. They are of particular use in those intolerant to contact lenses and without central corneal scarring. Combining ICRS with other procedures like CXL may enhance outcomes, though careful patient selection is crucial."

Torquetti et al (2009) reported on the report the long-term follow-up of Ferrara intrastromal corneal ring segment (ICRS) implantation for the management of keratoconus. This study comprised patients with keratoconus who completed at least 5 years of follow-up. One or 2 ICRS were inserted in the cornea, embracing the keratoconus area. Statistical analysis included preoperative and postoperative uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), and keratometry (K) values. Thirty-five eyes of 28 patients were evaluated. The mean UDVA improved from 0.15 preoperatively to 0.31 postoperatively and the mean CDVA, from 0.41 to 0.62, respectively; the increases were statistically significant. Corneal topography showed corneal flattening in all eyes. The mean minimum K value decreased from 48.99 D preoperatively to 44.45 D postoperatively and the mean maximum K value, from 54.07 D to 48.09 D, respectively; the decreases were statistically significant. The authors concluded that "(f)ive years after ICRS implantation, the UDVA and CDVA were improved in eyes with keratoconus. There was significant postoperative corneal flattening that remained stable over the follow-up period."

Colin and Malet (2007) evaluated the long-term safety and efficacy of Intacs segments (Addition Technology, Inc.) for the treatment of keratoconus in terms of intraoperative and postoperative complications, visual outcome, restoration of contact lens tolerance, and inhibition of disease progression. This prospective, 2-year follow-up study comprised 100 keratoconic eyes with clear central corneas and contact lens intolerance. The best spectacle-corrected visual acuity (BSCVA), uncorrected visual acuity (UCVA), refractive error, keratometry, pachymetry, and slit lamp examination were

assessed preoperatively and 1 and 2 years after Intacs implantation. At 2 years, the UCVA and BSCVA improved in 80.5% and 68.3% of eyes, respectively. The authors concluded that "Intacs implantation was a safe and efficacious treatment for keratoconus. Significant and sustained improvements in objective visual outcomes were achieved in most cases, with restoration of contact lens tolerance."

Levy et al (2025) evaluated the clinical outcomes of CAIRS through literature review. Inclusion criteria were studies with a minimum of 20 eyes and six months of follow up. The primary outcome measure was uncorrected distance visual acuity (UDVA). The secondary outcomes were a change in corrected distance visual acuity (CDVA), spherical equivalent (SE), mean keratometry (K-mean), maximum keratometry (K-max), K1, K2, and pachymetry. The primary outcome UDVA improved from 0.83 ± 0.15 to 0.40 ± 0.08 logMAR, while CDVA improved from 0.52 ± 0.22 to 0.19 ± 0.09 logMAR. K-max decreased from 57.8 ± 1.09 D to 53.57 ± 2.66 D, and K-mean reduced from 49.27 ± 0.28 D to 45.30 ± 1.46 D. An average of 84.92% ± 11.4% of eyes had an improvement in UDVA. No major complications or significant visual acuity deterioration were reported. The authors concluded that "CAIRS serves as an alternative to synthetic ICRSs and even corneal transplantation in some cases. They represent a safe, effective, and biocompatible promising advancement in corneal ectasia management to improve visual acuity and corneal topography with minimal complications." Acknowledged limitations of their literature review included restricted availability of data, data heterogeneity, lack of standardization and consistency in procedures, and variations in tissue preparation, thickness. Authors noted "(w)hile the short-tomedium-term results are promising, there are limited long-term data regarding the durability of outcomes, potential complications, and tissue integration. Larger studies are needed for more standardized and high-quality data."

Friedrich et al (2025) conducted a systematic literature review and meta-analysis on the effect of CAIRS. Eyes with keratoconus were included. Exclusion criteria were preimplanted ring segments, ectatic diseases other than keratoconus, as well as no reported pre- or postoperative outcome parameters. Fourteen clinical studies with a total of 442 eyes were included in the meta-analysis. The mean improvement in corrected distance visual acuity (CDVA) was 0.37 logMAR (95% CI: 0.28, 0.46; 14 studies; n = 442 eyes). Uncorrected distance visual acuity (UDVA) improved by 0.43 logMAR (95% CI: 0.34, 0.55; 11 studies; n = 427 eyes). Spherical equivalent (SE) improved by 4.59 D (95% CI: 3.35, 5.84; 12 studies; n = 430 eyes). Maximum keratometry (Kmax) was reduced by -4.49 D (95% CI: -6.05, -2.92; 13 studies; n = 439 eyes) and total higher order aberrations (HOAs) decreased by -0.33 μm (95% CI: -0.62, -0.03; 6 studies; n = 171 eyes). One severe adverse event (0.2%) reported was an acute rejection, which necessitated explantation. The authors concluded "(t)his meta-analysis demonstrates that CAIRS transplantation is an effective procedure that can significantly improve UDVA, CDVA, and topographic outcomes in keratoconus eyes with low complication rates." Meta-analysis authors acknowledged several potential limitations, including a novel procedure with a limited number of studies available; no randomization or comparison to other treatment procedures (e.g. DALK, CXL, etc.); and the possibility of patient overlap because some studies were conducted by the same research group under different conditions. However, no publication bias was found.

POSITION STATEMENT:

Implantation of intrastromal corneal ring segments for the treatment of keratoconus **meets the definition of medical necessary** when **ALL** of the following criteria are met:

- 21 years of age or older
- There is progressive deterioration in vision, such that adequate functional vision with contact lenses or spectacles can no longer be achieved
- Corneal transplantation is the only alternative to improve functional vision
- There is a clear central cornea with a corneal thickness of 450 microns or greater at the proposed incision site

Implantation of intrastromal corneal ring segments **does not meet the definition of medical necessity** as a treatment of myopia.

Implantation of intrastromal corneal ring segments is considered **experimental or investigational** for all other conditions, as there is insufficient published clinical evidence to support safety and effectiveness.

Corneal allogenic intrastromal ring segments (CAIRS) is considered **experimental or investigational**, as there is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on safety and net health outcomes.

BILLING/CODING INFORMATION:

CPT Coding

65785	Implantation of intrastromal corneal ring segments

ICD-10 Diagnosis Codes That Support Medical Necessity:

H18.601 – H18.629	Keratoconus
-------------------	-------------

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Astigmatism: an imperfection in the curvature of the cornea or lens of the eye, causing blurred or distorted vision.

Cornea: the clear, round dome covering the iris and pupil of the eye.

Myopia: near-sightedness; a refractive error which causes close objects to look clear but distant objects to appear blurred.

RELATED GUIDELINES:

Endothelial Keratoplasty and Corneal Collagen Cross-Linking, 02-65000-15

Prosthetic Eyes and Lens Implants, 09-V0000-01

OTHER:

None applicable

REFERENCES:

- Abdellah MM, Ammar HG. Femtosecond Laser Implantation of a 355-Degree Intrastromal Corneal Ring Segment in Keratoconus: A Three-Year Follow-Up. J Ophthalmol. 2019; 2019:6783181. Published 2019 Oct 9. doi:10.1155/2019/6783181.
- 2. Blue Cross Blue Shield Association Evidence Positioning System®. 9.03.14 Implantation of Intrastromal Corneal Ring Segments (Archived 04/21).
- 3. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) Noncovered Services (L33777) (Retired 07/01/20).
- 4. Costa JV, Monteiro T, et al. Five-year long-term outcomes of intrastromal corneal ring segment implantation using the manual technique for keratoconus management. J Cataract Refract Surg. 2021 Jun 1;47(6):713-721. doi: 10.1097/j.jcrs.000000000000000. PMID: 33196572.
- 5. Friedrich M, Auffarth GU, Soiberman U, Augustin VA, Khoramnia R, Son HS. Visual and Topographic Outcomes After Corneal Allogeneic Intrastromal Ring Segments for Keratoconus: A Systematic Review and Meta-Analysis. Am J Ophthalmol. 2025 Aug; 276:81-91. doi: 10.1016/j.ajo.2025.03.028. Epub 2025 Mar 27.
- Hayat UK, Shiwani HA, Memon D, Walkden A. Intracorneal Ring Segments in Keratoconus: A Narrative Literature Review. Clin Ophthalmol. 2025 Jul 11; 19:2249-2257. doi: 10.2147/OPTH.S520174.
- 7. Janani L, et al. MyoRing Implantation in Keratoconic Patients: 3 years Follow-up Data. J Ophthalmic Vis Res. 2016 Jan-Mar;11(1):26-31. doi: 10.4103/2008-322X.180713.
- 8. Kubaloglu, Anl MDı; Sari, Esin Sogutlu MD; Cinar, Yasin MD; Koytak, Arif MD; Kurnaz, Ekrem MD; Özertürk, Yusuf MD. Intrastromal Corneal Ring Segment Implantation for the Treatment of Keratoconus. Cornea: January 2011 Volume 30 Issue 1 pp 11-17
- 9. Levy I, Mukhija R, Nanavaty MA. Corneal Allogenic Intrastromal Ring Segments: A Literature Review. J Clin Med. 2025 Feb 18;14(4):1340. doi: 10.3390/jcm14041340.
- 10. Maguen E, Rabinowitz YS, Regev L, et al. Alterations of Extracellular Matrix Components and Proteinases in Human Corneal Buttons with Intacs for Post-Laser In Situ Keratomileusis Keratectasia and Keratoconus. Cornea 2009 June; 27(5):565-573.

- 11. Maharramov PM, Aghayeva FA. Evaluation of the effectiveness of combined staged surgical treatment in patients with keratoconus. PLoS One. 2022 Mar 7;17(3): e0264030. doi: 10.1371/journal.pone.0264030.
- 12. Moscovici BK, Rodrigues PF, et al. Evaluation of keratoconus progression and visual improvement after intrastromal corneal ring segments implantation: A retrospective study. Eur J Ophthalmol. 2021 Nov;31(6):3483-3489. doi: 10.1177/11206721211000646. Epub 2021 Mar 15.
- 13. Mounir A, Farouk MM, Abdellah MM, Mohamed Mostafa E. Extrusion of Femtosecond Laser-Implanted Intrastromal Corneal Ring Segments in Keratoconic Eyes: Prevalence, Risk Factors, and Clinical Outcomes. J Ophthalmol. 2020; 2020:8704219. Published 2020 Mar 28.
- 14. National Institute of Health and Care Excellence (NICE). Interventional procedures guidance [IPG227]: Corneal implants for keratoconus (April 2007). NICE; London UK.
- 15. Rapuano CJ, Sugar A, Koch DD, Agapitos PJ, Culbertson WW, de Luise VP, Huang D, A Varley GA. Intrastromal corneal ring segments for low. myopia: a report by the American academy of ophthalmology. Ophthalmology: Volume 108, Issue 10, Pages 1922-1928, October 2001 (maintained 2009)
- 16. Shetty, R, Kannan N, et al. Safety and efficacy of Intacs in Indian eyes with keratoconus: An initial report. Indian J Ophthalmol: 2009; 57:115-119.
- 17. Siganos CS, et al. Management of Keratoconus with Intacs. Am J of Ophthalmol. Jan 2003; 135:1.
- 18. Tan, BU, Purcell TL, Torres LF, Schanzlin DJ. New Surgical Approaches to the Management of Keratoconus and Post-Lasik. Trans Am Ophthalmol Soc. Vol 104; 2006: 212-220.
- 19. Torquetti L, Berbel RF, Ferrara P. Long-term follow-up of intrastromal corneal ring segments in keratoconus. J Cataract Refract Surg. 2009 Oct;35(10):1768-73. doi: 10.1016/j.jcrs.2009.05.036.
- 20. UpToDate. Keratoconus. 2025. Accessed at uptodate.com.
- 21. U.S. Food and Drug Administration (FDA); Consumer Information INTACS® Prescription Inserts for Keratoconus H040002.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/25/25.

GUIDELINE UPDATE INFORMATION:

02/15/06	New Medical Coverage Guideline.
02/15/07	Scheduled review; no change in coverage statement.
06/15/07	Reformatted Medical Coverage Guideline.
02/15/08	Scheduled review; no change in position statement; references updated.
02/15/09	Scheduled review; no change in position statement; references updated.
02/15/10	Scheduled review with literature search; position statement change; coverage criteria
	added; references updated.
12/15/11	Scheduled review; position statement unchanged; references updated; related ICD-9
	and ICD-10 diagnosis codes added: formatting changes.

11/01/15	Revision: ICD-9 Codes deleted.
01/01/16	Annual CPT/HCPCS coding update. Added code 65785. Deleted code 0099T. Revised
	Program Exceptions section.
02/15/19	Scheduled review. Revised description and definitions. Position statement maintained.
	Updated references.
10/15/20	Scheduled review. Maintained position statement and updated references.
07/15/22	Scheduled review. Maintained position statement and updated references.
01/01/24	Position statements maintained.
10/15/24	Scheduled review. Revised description, maintained position statement and updated
	references.
10/15/25	Scheduled review. Revised description, added coverage statement for CAIRS, and
	updated references.