

09-V0000-02

Original Effective Date: 02/15/06

Reviewed: 06/23/22

Revised: 07/15/22

## 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](#)

[Definitions](#)

[Related Guidelines](#)

[Other](#)

[References](#)

[Update](#)

### 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.

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

### 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.

### **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.

### **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:

1. 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.0000000000000500. PMID: 33196572.
5. 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.
6. Kubaloglu, Anl MD; 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*
7. 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.
8. 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.
9. 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.
10. 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.
11. National Institute of Health and Care Excellence (NICE). Interventional procedures guidance [IPG227]: Corneal implants for keratoconus (April 2007). NICE; London UK.
12. 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)
13. 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.
14. Siganos CS, et al. Management of Keratoconus with Intacs. *Am J of Ophthalmol.* Jan 2003; 135:1.

15. 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.
16. UpToDate. Keratoconus. 2022. Accessed at uptodate.com.
17. 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 06/23/22.

**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.