

09-V0000-02

Original Effective Date: 02/15/06

Reviewed: 01/24/19

Revised: 02/15/19

Subject: Implantation of Intrastromal Corneal Ring Segments

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DESCRIPTION:

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. They have been investigated as a means of improving vision in diseases such as keratoconus and pellucid marginal degeneration, and for astigmatism following penetrating keratoplasty.

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

Pellucid marginal degeneration is a non-inflammatory progressive degenerative disease, typically characterized by bilateral peripheral thinning (ectasia) of the inferior cornea. Deterioration of functional vision results from the irregular astigmatism induced by asymmetric distortion of the cornea, and visual acuity typically cannot be restored by using spherocylindrical lenses.

INTACS®, an intrastromal corneal ring, was approved by the U.S. Food and Drug Administration (FDA) for two indications. In 1999, INTACS® were approved through a premarket approval process (PMA) for the following labeled indication:

The KeraVision Intacs are intended for the reduction or elimination of mild myopia (-1.00 to -3.00 diopters spherical equivalent at the spectacle plane) for the following:

- Those who are 21 years of age or older, **AND**
- With documented stability of refraction as demonstrated by a change of less than or equal to 0.50d for at least 12 months prior to the preoperative examination, **AND**
- Where the astigmatic component is +1.00 diopter or less

In 2004, INTACS® received an additional FDA approval through the Humanitarian Device Exemption (HDE) process for the following indication:

This device is indicated for the reduction or elimination of myopia and astigmatism in individuals with keratoconus, who are no longer able to achieve adequate vision with their contact lenses or spectacles, so that their functional vision may be restored and the need for a corneal transplant procedure may potentially be deferred. The specific set of keratoconic individuals proposed to be treated with INTACS® prescription inserts are those:

- Who have experienced a progressive deterioration in their vision, such that they can no longer achieve adequate functional vision on a daily basis with their contact lenses or spectacles
- Who are 21 years of age or older
- Who have clear central corneas
- Who have a corneal thickness of 450 microns or greater at the proposed incision site, **AND**
- Who have corneal transplantation as the only remaining option to improve their functional vision

NOTE: The humanitarian device exemption (HDE) does not require the manufacturer to provide data confirming the efficacy of the device, but rather data supporting its “probable” benefit. The HDE process is available for devices treating conditions that affect less than 4,000 Americans per year.

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 he/she can no longer achieve adequate functional vision with contact lenses or spectacles
- 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

BILLING/CODING INFORMATION:

CPT Coding

65785	Implantation of intrastromal corneal ring segments
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ICD-10 Diagnosis Codes That Support Medical Necessity:

H18.601 – H18.629	Keratoconus
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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: The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Noncovered Services (L33777), located at fcso.com.

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:

[Keratoplasty, 02-65000-15](#)

[Prosthetic Eyes and Lens Implants, 09-V0000-01](#)

OTHER:

None applicable.

REFERENCES:

1. American Medical Association CPT coding (current edition).
2. Blue Cross Blue Shield Association Medical Reference Manual. Policy 9.03.14, Implantation of Intrastromal Corneal Ring Segments (March 2018).
3. ClinicalTrials.gov. Intacs for keratoconus. NCT 00347230.
4. First Coast Service Options (FCSO). Local Coverage Determination (LCD): Noncovered Services (L33777). Revised 10/25/18.
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. National Institute of Health and Care Excellence (NICE). Interventional procedures guidance [IPG227]: Corneal implants for keratoconus (April 2007). NICE; London UK.
9. 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)
10. 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.
11. Siganos CS, et al. Management of Keratoconus with Intacs. Am J of Ophthalmol. Jan 2003;135:1.
12. 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.
13. U.S. Food and Drug Administration (FDA); Consumer Information – INTACS® Prescription Inserts for Keratoconus – H040002, (accessed at FDA website 04/05).

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 01/24/19.

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.