09-V0000-02

Original Effective Date: 02/15/06

Reviewed: 09/26/24

Revised: 10/15/24

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

Summary and Analysis of Evidence: An UpToDate review, "Keratoconus" (Wayman, 2024) 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." 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."

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

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18. 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 09/26/24.

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.