09-V0000-02

Original Effective Date: 02/15/06

Reviewed: 12/08/23

Revised: 01/01/24

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	<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.

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
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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: 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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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 12/08/23.

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.