BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Implantation of Intrastromal Corneal Ring Segments (ICRS®, INTACS®)

Policy #: 080
Latest Review Date: November 2022
Category: Surgical

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for date of service on or after March 24, 2020:

Blue Advantage will treat **implantation of intrastromal corneal ring segments** as a **covered benefit** for the treatment of keratoconus in patients 21 years of age or older who meet ALL the following criteria:

- The patient has experienced a progressive deterioration in their vision, such that they can no longer achieve adequate functional vision with contact lenses or spectacles; AND
- Corneal transplantation is the only alternative to improve their functional vision; AND
- The patient has a clear central cornea with a corneal thickness of 450 microns or greater at the proposed incision site.

Blue Advantage will treat **implantation of intrastromal corneal ring segments** as a **non-covered benefit** as a treatment of myopia.

Blue Advantage will treat **implantation of intrastromal corneal ring segments** as a **non-covered benefit** and as investigational for all other conditions.

Effective for dates of service February 26, 2018 through March 23, 2020, refer to LCD L36954.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Intrastromal corneal ring segments (ICRS) are composed of microthin soft plastic inserts of variable thickness that are placed in the periphery of the cornea. 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 (PK).

Vision Disorders

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

Pellucid marginal degeneration is a noninflammatory 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.

Treatment
Initial treatment for keratoconus often consists of hard contact lenses. A penetrating keratoplasty (i.e., corneal grafting) was traditionally considered the next line of treatment in patients who developed intolerance to contact lenses. While visual acuity is typically improved with penetrating keratoplasty, perioperative complications are an associated risk; long-term topical steroid use is required; and endothelial cell loss occurs over time, which is a particular concern in younger patients. As an alternative, a variety of keratorefractive procedures have been attempted, broadly divided into subtractive and additive techniques. Subtractive techniques include photorefractive keratectomy or laser in situ keratomileusis (LASIK), although, generally, results of these techniques have been poor. In deep anterior lamellar keratoplasty, pathologic corneal stromal tissue is selectively removed to the level of the Descemet membrane, followed by transplantation of a donor graft. Implantation of intrastromal corneal ring segments (ICRS) represents an additive technique, in which the implants are intended to reinforce the cornea, prevent further deterioration, and potentially obviate the need for penetrating keratoplasty.

Rigid gas permeable contact lenses may be used to treat pellucid marginal degeneration. ICRS, crescentic lamellar keratoplasty, penetrating keratoplasty, and corneal wedge excision have also been proposed as treatments.

ICRS correct myopia by flattening the center of the cornea and represent an alternative to LASIK and other refractive surgeries. A proposed advantage of ICRS is that their insertion does not affect the central cornea and, thus, their effect is not related to the healing process in the cornea. No corneal tissue is removed, and the implants may be removed or replaced. However, mild myopia is effectively treated with spectacles or contact lenses.

Intrastromal Corneal Ring Segments
ICRS are composed of microthin 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 two segments are implanted in each channel, and various implants with a range of thicknesses are available for different degrees of correction. These implants 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.

KEY POINTS:
The most recent literature review was updated through November 9, 2022.

Summary of Evidence
Clinical input obtained in 2009 strongly supported the use of intrastromal corneal ring segments in a select group of patients with advanced keratoconus whose only other option for restoration of functional vision was the more invasive penetrating keratoplasty. Some clinicians may opt to delay a more invasive procedure, although the success rate of this strategy is as yet unproven. Therefore, use of intrastromal corneal ring segments may be considered medically necessary in

patients with keratoconus who meet the criteria defined in this policy based on the FDA the humanitarian device exemption (HDE).

For individuals who have keratoconus who receive ICRS, the evidence includes primarily single-institution case series. Relevant outcomes are change in disease status, functional outcomes, and treatment-related morbidity. A number of single center case series with sample sizes ranging from 19 to 105 eyes have been published. The series generally report that a substantial proportion of patients with keratoconus treated with this device have improved vision at one to two years of follow-up. More limited data are available on long-term efficacy. ICRS is associated with a number of adverse events and explantation. Although, a single case series of 572 eyes have suggested that risk of explantation may be modest (6.1%). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have pellucid marginal degeneration who receive ICRS, the evidence includes a few case series. Relevant outcomes are change in disease status, functional outcomes, and treatment-related morbidity. A small number of case series with fewer than 25 eyes per study have been published on ICRS in patients with pellucid marginal degeneration. Most of the reports were on devices not available in the United States. In one study that included some patients who were implanted with INTACS, there was not improvement in uncorrected visual acuity six months after surgery. Moreover, explantation occurred in about 20% of eyes due to visual deterioration. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have astigmatism after penetrating keratoplasty who receive intrastromal corneal ring segments, the evidence includes a few case series. Relevant outcomes are change in disease status, functional outcomes, and treatment-related morbidity. Two case series, with nine and 54 patients, were identified; both used devices not available in the United States. Intrastromal corneal ring segments was associated with adverse events such as extrusion and Descemet membrane detachment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

The National Institute for Health and Care Excellence issued guidance in 2007 on corneal implants for keratoconus. The guidance, based on nine case series, a nonrandomized controlled trial, and specialists' opinions, concluded that "[c]urrent evidence on the safety and efficacy of corneal implants for keratoconus appears adequate to support the use of this procedure…."

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:

Intrastromal corneal ring segments, INCRS, INTACS, intracorneal rings, keratoconus, KeraVision Intacs, INTACS SK , Ferrara intrastromal corneal ring segment (ICRS), Keraring intrastromal corneal ring segments (ICRS), MyoRing intracorneal continuous ring (ICCR), CAIRS, Corneal Allogenic Intrastromal Ring Segments procedure

APPROVED BY GOVERNING BODIES:

Intacs® represents an intrastromal corneal ring that has received approval by the U.S. Food and Drug Administration (FDA) for two indications. In 1999, INTACS inserts 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) in patients:

- Who are 21 years of age or older;
- With documented stability of refraction as demonstrated by a change of less than or equal to 0.50 diopter 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 approval by the FDA 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 patients 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 patients proposed to be treated with INTACS® prescription inserts are those patients:

- 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 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 fewer than 4,000 Americans per year.

Intrastromal corneal ring devices available outside of the U.S. include:

- Intacs SK
- Ferrara intrastromal corneal ring segment (ICRS)
- Keraring intrastromal corneal ring segments (ICRS)
- MyoRing intracorneal continuous ring (ICCR)

FDA product code: LQE.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

65785	Implantation of intrastromal corneal ring segments

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POLICY HISTORY:

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Medical Policy Group, July 2005
Available for comment August 18-October 3, 2005
Medical Policy Group, December 2006
Available for comment January 11-February 24, 2007
Medical Policy Group, February 2008
Medical Policy Group, September 2009
Available for comment October 2-November 16, 2009
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Medical Policy Group, March 2016
Medical Policy Group, March 2017
Medical Policy Group, February 2018
Medical Policy Group, April 2020: Reinstated policy effective March 24, 2020.
Medical Policy Group, March 2021
Medical Policy Group, December 2021: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, November 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
