

9.03.14 Implantation of Intrastromal Corneal Ring Segments			
Original Policy Date:	December 18, 2009	Effective Date:	May 1, 2021
Section:	7.0 Surgery	Page:	Page 1 of 13

Policy Statement

Implantation of intrastromal corneal ring segments (ICRS) may be considered **medically necessary** when **all** of the following criteria are met:

- I. Used for treatment of keratoconus
- II. The patient is 21 years of age or older
- III. Progressive deterioration in vision, and documentation of **all** of the following:
 - A. Adequate functional vision can no longer be achieved with corrective lenses (contact lenses or spectacles)
 - B. Corneal transplantation is the only other alternative to improve functional vision
 - C. Clear central cornea with a corneal thickness of 450 microns or greater at the proposed incision site

Implantation of intrastromal corneal ring segments (ICRS) is considered **not medically necessary** as a treatment of myopia.

Implantation of intrastromal corneal ring segments (ICRS) is considered **investigational** for all other conditions.

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

The following category I CPT code is for this procedure:

- **65785:** Implantation of intrastromal corneal ring segments

Description

Intrastromal corneal ring segments (ICRS) are composed of micro thin 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.

Related Policies

- Corneal Collagen Cross-Linking
- Endothelial Keratoplasty
- Keratoprosthesis

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these

instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Intacs®, an intraström corneal ring, was approved by the U.S. Food and Drug Administration (FDA) for 2 indications. In 1999, Intacs® (KeraVision, now Addition Technology) was approved by the FDA through the premarket approval process 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 additional approval by the FDA through the humanitarian device exemption 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 manufacturers to provide data confirming the efficacy of a device but rather data supporting its “probable” benefit. The humanitarian device exemption process is available for devices treating conditions that affect fewer than 4000 Americans per year.

ICRS devices available outside of the United States include:

- Intacs SK
- Ferrara intraström corneal ring segments
- KeraRing intraström corneal ring segments
- MyoRing intracorneal continuous ring.

FDA product code: LQE.

Rationale

Background

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 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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be

adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Keratoconus

Clinical Context and Test Purpose

The purpose of intrastromal corneal ring segments is to provide a treatment option that is an alternative to or an improvement on penetrating keratoplasty, in patients with keratoconus. The question addressed in this evidence review is: Does intrastromal corneal ring segments improve the net health outcome in patients with keratoconus.

The following PICO was used to select literature to inform this review.

Patients

The relevant population of interest is individuals with keratoconus.

Interventions

The intervention of interest is intrastromal corneal ring segments.

Comparators

The comparator of interest is penetrating keratoplasty.

Outcomes

The beneficial outcomes of interest are change in disease status, functional outcomes, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

According to a Cochrane review by Zadnik et al (2019), there are no published RCTs of intrastromal corneal ring segments for treating keratoconus.¹ The published data on Intacs for keratoconus consists of single-institution case series, many of which used the device commercially available in the United States.^{2,3,4,5,6,7,8,9,10,11,12,13,14,15} Sample sizes ranged from 19 to 105 eyes. Findings from a systematic review of case series by Izquierdo et al (2019) (N=1325 eyes) indicated that intrastromal corneal ring implantation improved uncorrected distance visual acuity (0.23 ± 0.28 , Logarithm of the Minimum Angle of Resolution) and corrected distance visual acuity (0.06 ± 0.21 , Logarithm of the Minimum Angle of Resolution) at 12 months.¹⁶ Additionally, these case series have indicated that a substantial proportion of patients with keratoconus treated with this device have improved vision at 1 to 2 years of follow-up. Most studies have reported improvements (in uncorrected or corrected visual acuity) in at least 75% to 80% of patients in whom changes in 2 to 3 lines of corrected or uncorrected visual acuity were considered a success.^{3,4,5,7,11} Approximately 10% of patients required a second procedure because of an unsatisfactory initial result.^{5,6}

One of the larger studies was published by Colin and Malet (2007).¹² They reported on 2-year follow-up from a prospective, single-center European study in 100 eyes with keratoconus (82 consecutive patients) and Intacs implantation. Patients had been referred for a penetrating keratoplasty procedure due to contact lens intolerance for correction of myopia and irregular astigmatism. Intacs inserts were removed from 4 (4%) eyes due to poor visual outcome or

extrusion, and 14 eyes were lost to follow-up. Of the 82 remaining eyes (68 patients), both corrected and uncorrected visual acuity remained relatively stable between 1 and 2 years of follow-up.

Studies with 5 years of follow-up include Bedi et al (2012).¹³ They evaluated the risk of keratoconus progression in a study of 105 consecutive eyes (85 patients) that had undergone Intacs implantation. At the 1-year follow-up, 1 eye had extrusion and 12 (11.4%) had undergone removal of Intacs because of unsatisfactory results; these eyes were managed by penetrating or deep lamellar keratoplasty. Of the 105 eyes, 80% retained the Intacs implant and showed no keratoconus progression over 5 years of follow-up. In addition, Vega-Estrada et al (2013) reported that, in a series of 51 eyes, the improvement in vision obtained at 6 months after Intacs implantation was maintained out to 5 years postoperatively.² However, the analysis only included cases without significant changes in corneal topography over the 12 months prior to surgery. Kymionis et al (2007) reported on 5-year follow-up on 28 patients (36 eyes) who had initially participated in a clinical trial evaluating the safety and efficacy of Intacs implantation in patients with keratoconus.¹⁴ In 5 patients (7 eyes), the Intacs segments were removed due to patient dissatisfaction. Five-year follow-up was reported for 17 (59%) eyes. Refractive stability was obtained at the 6-month follow-up and remained stable throughout the 5-year follow-up. Alternatively, Kang et al (2019) reported mixed visual acuity findings at the 5-year follow-up for 30 eyes. While improvements in corrected distance visual acuity were maintained at 5 years, compared to preoperative values, uncorrected distance visual acuity and spherical and spherical equivalent worsened at 5 years.¹⁷

For adverse events, a larger retrospective study by Nguyen et al (2019)¹⁸ evaluated a consecutive series of 572 eyes with femtosecond laser-created Intacs intracorneal ring implantation for keratoconus or corneal ectasia to assess the incidence of explantation and its determinants. Overall, the intracorneal ring segments (Intacs) were explanted in 35 eyes (6.1%) of 31 patients. Explantation was due to medical complications in 15 eyes (2.6%), most frequently being keratitis with signs of inflammation (n=11, 31%). A total of 20 (3.8%) explantations were due to optical/refractive considerations. Use of adjunctive corneal crosslinking did not affect explantation risk.

Section Summary: Keratoconus

For individuals who have keratoconus who receive intrastromal corneal ring segments, the evidence includes 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 has generally reported that a substantial proportion of patients with keratoconus treated with this device have improved vision at 1 to 2 years of follow-up. A single case series of 572 eyes have suggested that risk of explantation may be modest (6.1%). However, long-term data are more limited. Therefore, the evidence is insufficient to determine the effects of the technology on health outcomes.

Pellucid Marginal Degeneration

Clinical Context and Test Purpose

The purpose of intrastromal corneal ring segments is to provide a treatment option that is an alternative to or an improvement on penetrating keratoplasty, in patients with pellucid marginal degeneration.

The question addressed in this evidence review is: Does intrastromal corneal ring segments improve the net health outcome in patients with pellucid marginal degeneration.

The following PICO was used to select literature to inform this review.

Patients

The relevant population of interest is individuals with pellucid marginal degeneration.

Interventions

The intervention of interest is intrastromal corneal ring segments.

Comparators

The comparator of interest is penetrating keratoplasty.

Outcomes

The beneficial outcomes of interest are change in disease status, functional outcomes, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Pinero et al (2009) published a European multicenter retrospective analysis of 21 consecutive eyes in 15 patients who had been implanted with intrastromal corneal ring segments (3 Intacs, 18 KeraRings) for pellucid marginal degeneration. All subjects had experienced reduced best spectacle-corrected visual acuity and/or contact lens intolerance or dissatisfaction prior to implantation.¹⁹ At 6 months after surgery, uncorrected visual acuity had not changed; 17% of eyes lost lines of best-corrected visual acuity, and 44% of eyes gained 2 or more lines of best spectacle-corrected visual acuity. Ring explantation was performed in 4 (19%) eyes due to visual deterioration during the follow-up. Mean keratometry decreased 1.76 diopters (D), from 44.95 to 43.19 D at 6 months postoperatively ($p < 0.01$).

A 2010 publication from Europe retrospectively analyzed intrastromal corneal ring segments implantation (KeraRing) in 16 consecutive eyes of 10 patients with pellucid marginal degeneration who had reduced best spectacle-corrected visual acuity and dissatisfaction with spectacle and contact lens-corrected vision.²⁰ At 12 months after implantation, uncorrected visual acuity improved from 1.69 to 0.83 (Logarithm of the Minimum Angle of Resolution). At the 36-month follow-up, patients ($n=11$ eyes) had gained a mean of 2.4 lines uncorrected visual acuity and 3.3 lines of best spectacle-corrected visual acuity. There was a statistically significant reduction in manifest spherical refraction from -2.43 to -0.72 D. For the patients ($n=11$ eyes) who completed 36-month follow-up, there was no significant change in outcome measures between 12 and 36 months. No intraoperative or postoperative complications were noted aside from white deposits around the segments in 1 patient.

Section Summary: Pellucid Marginal Degeneration

For individuals who have pellucid marginal degeneration who receive intrastromal corneal ring segments, the evidence includes only a few case series, most of which have assessed devices not available in the United States. Relevant outcomes are change in disease status, functional outcomes, and treatment-related morbidity. In 1 study, which included some patients implanted with Intacs, there was no improvement in uncorrected visual acuity 6 months after surgery. Moreover, explantation occurred in about 20% of eyes due to visual deterioration. Therefore, the evidence is insufficient to determine the effects of the technology on health outcomes.

Astigmatism After Penetrating Keratoplasty**Clinical Context and Test Purpose**

The purpose of intrastromal corneal ring segments is to provide a treatment option that is an alternative to or an improvement on penetrating keratoplasty, in patients with astigmatism after penetrating keratoplasty.

The question addressed in this evidence review is: Does intrastromal corneal ring segments improve the net health outcome in patients with astigmatism after penetrating keratoplasty. The following PICO was used to select literature to inform this review.

Patients

The relevant population of interest is individuals with astigmatism after penetrating keratoplasty.

Interventions

The intervention of interest is intrastromal corneal ring segments.

Comparators

The comparator of interest is penetrating keratoplasty.

Outcomes

The beneficial outcomes of interest are change in disease status, functional outcomes, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Two case series (2009, 2012) were identified in which intrastromal corneal ring segments were implanted to correct residual astigmatism after penetrating keratoplasty.^{21,22} In 1, conducted in Spain, 9 patients received intrastromal corneal ring segments (KeraRings) for high astigmatism (>4 D) after the procedure.²¹ Mean keratometry decreased 4.17 D (from 46.28 to 42.11 D). Of the 9 patients, 1 reported night halos and 2 had the implant removed due to compulsive eye rubbing and vascularization in the stromal tunnel. The authors noted that, in patients with a corneal transplant with a diameter of 7.5 mm or smaller, intrastromal corneal ring segments should not be used because the segments would be proximate to the graft-host junction. In another study, Coscarelli et al (2012) in Brazil retrospectively reviewed chart records of 54 patients (59 eyes) who had intrastromal corneal ring segments with the Ferrara ring.²² Mean corrected distance visual acuity improved from 0.45 Logarithm of the Minimum Angle of Resolution preoperatively to 0.30 Logarithm of the Minimum Angle of Resolution postoperatively. Mean corneal topographic astigmatism decreased from 3.37 D preoperatively to 1.69 D postoperatively.

Section Summary: Astigmatism After Penetrating Keratoplasty

For individuals who have astigmatism after penetrating keratoplasty who receive intrastromal corneal ring segments, the evidence includes 2 case series. Relevant outcomes are change in disease status, functional outcomes, and treatment-related morbidity. The case series (n=9 and 54, respectively) were identified assessing intrastromal corneal ring segments in patients with astigmatism after penetrating keratoplasty. Neither provides evidence relevant to this review because both were conducted outside of the United States and used devices not cleared by the U.S. Food and Drug Administration. Therefore, the evidence is insufficient to determine the effects of the technology on health outcomes.

Adverse Events

Literature searches have identified case reports of adverse events following implantation of intrastromal corneal ring segments, including persistent pain, extrusion, traumatic shattering, bacterial keratitis, fungal keratitis, corneal edema, deep corneal vascularization, Descemet

membrane detachment, and alterations of extracellular matrix components and proteinases. In a 2010 multicenter series of 251 intrastromal corneal ring segments implantations, 58 eyes of 47 patients had the devices explanted.²³ The main cause was extrusion (48%), followed by poor refractive outcomes (38%), keratitis (7%), and corneal melting and perforation (7%). The time from implantation to explantation ranged from 0.1 to 82 months.

In another study (2006), 6 of 20 eyes had “significant” problems at 3 to 6 months postoperatively related to corneal thinning and subsequent ring exposure, and a dense corneal infiltrate developed in 1 patient at 7 months.²⁴ Histopathologic examination of 8 eyes that underwent penetrating keratoplasty after removal of Intacs implants revealed keratocyte apoptosis.²⁵

Summary of Evidence

For individuals who have keratoconus who receive intrastromal corneal ring segments, 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. These series have generally reported that a substantial proportion of patients with keratoconus treated with this device have improved vision at 1 to 2 years of follow-up. More limited data are available on long-term efficacy. Intrastromal corneal ring segments 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 net health outcome is uncertain. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pellucid marginal degeneration 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. A small number of case series with fewer than 25 eyes per study have evaluated intrastromal corneal ring segments in patients with pellucid marginal degeneration. Most reports have assessed devices not available in the United States. In 1 study, which included some patients implanted with Intacs, there was no improvement in uncorrected visual acuity 6 months after surgery. Moreover, explantation occurred in about 20% of eyes due to visual deterioration. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 9 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 the effects of the technology on health outcomes.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests from Blue Cross Blue Shield Association, input was received through 1 physician specialty society and 3 academic medical centers in 2009. Input considered implantation of intrastromal corneal ring segments to be medically necessary for select patients with keratoconus when the only other option for improving visual acuity is corneal transplantation. Input agreed that implantation of intrastromal corneal ring segments is not medically necessary for treatment of myopia.

Practice Guidelines and Position Statements

In 2007, the National Institute for Health and Care Excellence (NICE) issued guidance on corneal implants for keratoconus.²⁶ The guidance, based on 9 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.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02138669	Intacs for Keratoconus	25	Dec 2021
NCT02512432	INTACS (Intrastromal Corneal Ring Segments) for Corneal Ectasia	1000	Jun 2025

NCT: national clinical trial.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
 - Corneal description (e.g., thickness, clarity)
 - Previous treatment(s) and response(s) including duration
 - Reason for procedure
- Progress notes with eye exam records for the past year

Post Service (in addition to the above, please include the following):

- Operative report

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	65785	Implantation of intrastromal corneal ring segments
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
12/18/2009	New Policy Adoption
03/29/2013	Policy revision without position change
06/30/2015	Coding Update
01/01/2016	Coding update
02/01/2016	Policy revision without position change
05/01/2016	Policy revision without position change
05/01/2017	Policy revision without position change
05/01/2018	Policy revision without position change
05/01/2019	Policy revision without position change
05/01/2020	Annual review. No change to policy statement. Literature review updated.
06/01/2020	Administrative update. Policy statement, guidelines and literature updated.
05/01/2021	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p>Implantation of Intrastromal Corneal Ring Segments 9.03.14</p> <p>Policy Statement: Implantation of intrastromal corneal ring segments (ICRS) may be considered medically necessary when all of the following criteria are met:</p> <ul style="list-style-type: none"> • Used for treatment of keratoconus • The patient is 21 years of age or older <ul style="list-style-type: none"> • Progressive deterioration in vision, and documentation of all of the following: <ul style="list-style-type: none"> ○ Adequate functional vision can no longer be achieved with corrective lenses (contact lenses or spectacles) ○ Corneal transplantation is the only other alternative to improve functional vision ○ Clear central cornea with a corneal thickness of 450 microns or greater at the proposed incision site <p>Implantation of intrastromal corneal ring segments (ICRS) is considered not medically necessary as a treatment of myopia.</p> <p>Implantation of intrastromal corneal ring segments (ICRS) is considered investigational for all other conditions.</p>	<p>Implantation of Intrastromal Corneal Ring Segments 9.03.14</p> <p>Policy Statement: Implantation of intrastromal corneal ring segments (ICRS) may be considered medically necessary when all of the following criteria are met:</p> <ol style="list-style-type: none"> I. Used for treatment of keratoconus II. The patient is 21 years of age or older III. Progressive deterioration in vision, and documentation of all of the following: <ol style="list-style-type: none"> A. Adequate functional vision can no longer be achieved with corrective lenses (contact lenses or spectacles) B. Corneal transplantation is the only other alternative to improve functional vision C. Clear central cornea with a corneal thickness of 450 microns or greater at the proposed incision site <p>Implantation of intrastromal corneal ring segments (ICRS) is considered not medically necessary as a treatment of myopia.</p> <p>Implantation of intrastromal corneal ring segments (ICRS) is considered investigational for all other conditions.</p>