



Kansas City

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# Implantation of Intrastromal Corneal Ring Segments (INTACS)

**Policy Number:** 9.03.14

**Last Review:** 11/2018

**Origination:** 12/2005

**Next Review:** 11/2019

## Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for implantation of intrastromal corneal ring segments (INTACS) when it is determined to be medically necessary because the criteria shown below are met.

## When Policy Topic is covered

Implantation of intrastromal corneal ring segments may be considered **medically necessary** for the treatment of keratoconus in patients 21 years of age or older who meet 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.

## When Policy Topic is not covered

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

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

## Description of Procedure or Service

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>▪ With keratoconus</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>▪ Intrastromal corneal ring segments</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>▪ Penetrating keratoplasty</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>▪ Change in disease status</li> <li>▪ Functional outcomes</li> <li>▪ Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>▪ With pellucid</li> </ul>	Interventions of interest are:	Comparators of interest are:	Relevant outcomes include: <ul style="list-style-type: none"> <li>▪ Change in disease status</li> </ul>

marginal degeneration	<ul style="list-style-type: none"> <li>Intrastromal corneal ring segments</li> </ul>	<ul style="list-style-type: none"> <li>Penetrating keratoplasty</li> </ul>	<ul style="list-style-type: none"> <li>Functional outcomes</li> <li>Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>With astigmatism after penetrating keratoplasty</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Intrastromal corneal ring segments</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Contact lenses or correction with spectacles</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Change in disease status</li> <li>Functional outcomes</li> <li>Treatment-related morbidity</li> </ul>

Intrastromal corneal ring segments are composed of microthin soft plastic inserts of variable thickness that are placed in the periphery of the cornea. Intrastromal corneal ring segments have been investigated as a means of improving vision in diseases such as keratoconus and pellucid marginal degeneration, and for refractive surgery to correct mild myopia and astigmatism following penetrating keratoplasty (PK).

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. 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. ICRS is associated with a number of adverse events and explantation. The net health outcome is uncertain. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input strongly supported the use of ICRS in a select group of patients with advanced keratoconus whose only other option for restoration of functional vision was the more invasive PK. Some clinicians may opt to delay a more invasive procedure, although the success rate of this strategy is as yet unproven. Therefore, use of ICRS may be considered medically necessary in patients with keratoconus who meet the U.S. Food and Drug Administration humanitarian device exemption criteria for use of this device.

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 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 PK who receive ICRS, 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. ICRS 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.

## **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 (ie, 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.

## **Regulatory Status**

Intacs®, an intrastromal 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 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 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.

## **Rationale**

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This evidence review was created in April 2005 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through January 8, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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 is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials 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**

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. [1-14](#) Sample sizes ranged from 19 to 105 eyes. 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.<sup>2-4,6,10</sup> Approximately 10% of patients required a second procedure because of an unsatisfactory initial result.<sup>4,5</sup>

One of the larger studies was published by Colin and Malet (2007).<sup>11</sup> 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).<sup>12</sup> 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.<sup>1</sup> 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.<sup>13</sup> 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.

### **Section Summary: Keratoconus**

A number of single-center case series with sample sizes ranging from 19 to 105 eyes have been published. The 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. However, data are available on treatment efficacy and adverse events in the long-term is more limited.

### **Pellucid Marginal Degeneration**

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 (ICRS [3 Intacs, 18 KeraRings]) for pellucid marginal degeneration. All subjects had experienced reduced best spectacle-corrected visual acuity (BSCVA) and/or contact lens intolerance or dissatisfaction prior to implantation.<sup>15</sup> 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 BSCVA. 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 ICRS implantation (KeraRing) in 16 consecutive eyes of 10 patients with pellucid marginal degeneration who had reduced BSCVA and dissatisfaction with spectacle and contact lens-corrected vision.<sup>16</sup> At 12 months after implantation, uncorrected visual acuity improved from 1.69 to 0.83 logMAR. 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 BSCVA. 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**

Only a few case series have evaluated ICRS in patients with pellucid marginal degeneration. Most 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.

### **Astigmatism After Penetrating Keratoplasty**

Two cases (2009, 2012) were identified in which ICRS were implanted to correct residual astigmatism after penetrating keratoplasty.<sup>17,18</sup> In one, conducted in Spain, 9 patients received ICRS (KeraRings) for high astigmatism ( $>4$  D) after the procedure.<sup>17</sup> Mean keratometry decreased 4.17 D (from 46.28 to 42.11 D). Of the 9 patients, one reported night halos and two 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, ICRS 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 ICRS with the Ferrara ring.<sup>18</sup> Mean corrected distance visual acuity improved from 0.45 LogMAR preoperatively to 0.30 LogMAR postoperatively. Mean corneal topographic astigmatism decreased from 3.37 D preoperatively to 1.69 D postoperatively.

### **Section Summary: Astigmatism After Penetrating Keratoplasty**

Two case series ( $n=9$  and 54, respectively) were identified assessing ICRS 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 Food and Drug Administration.

### **Adverse Events**

Literature searches have identified case reports of adverse events following implantation of ICRS, 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 ICRS implantations, 58 eyes of 47 patients had the devices explanted.<sup>19</sup> The main cause was extrusion (48%), followed by poor refractive outcome (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.<sup>20</sup> Histopathologic examination of 8 eyes that underwent penetrating keratoplasty after removal of Intacs implants revealed keratocyte apoptosis.<sup>21</sup>

### **Summary of Evidence**

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. 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. ICRS is associated with a number of adverse events and explantation. 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 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 evaluated ICRS 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 ICRS, 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. ICRS 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, input was received through 1 physician specialty society and 3 academic medical centers while this policy was under review 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

The National Institute for Health and Care Excellence issued guidance in 2007 on corneal implants for keratoconus.<sup>22</sup> 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
<b>Ongoing</b>			
<b>NCT02138669</b>	Intacs for Keratoconus	25	Dec 2020
<b>NCT02512432</b>	INTACS (Intraström Corneal Ring Segments) for Corneal Ectasia	1000	Jun 2025

NCT: national clinical trial.

## References

- Vega-Estrada A, Alio JL, Brenner LF, et al. Outcomes of intrastromal corneal ring segments for treatment of keratoconus: Five-year follow-up analysis. J Cataract Refract Surg. Aug 2013;39(8):1234-1240. PMID 23747207

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## **Billing Coding/Physician Documentation Information**

- 0099T** Implantation of intrastromal corneal ring segments (Deleted code 1/1/2016)
- 65785** Implantation of intrastromal corneal ring segments (New code 1/1/2016)
- 66999** Unlisted procedure, anterior segment of eye

ICD-10 Codes

- H18.601-** Keratoconus code range
- H18.629**

## **Additional Policy Key Words**

N/A

## **Policy Implementation/Update Information**

- 12/1/05 New policy. Added to Surgery section.
- 6/1/06 No policy statement changes.
- 12/1/06 No policy statement changes.
- 6/1/07 No policy statement changes.
- 12/1/07 No policy statement changes.
- 6/1/08 No policy statement changes.
- 12/1/08 No policy statement changes.
- 6/1/09 No policy statement changes.
- 9/10/09 Policy statement revised; may be medically necessary in specified conditions.
- 11/1/10 No policy statement changes.
- 11/1/11 No policy statement changes.
- 11/1/12 No policy statement changes.
- 11/1/13 No policy statement changes.
- 11/1/14 No policy statement changes.
- 11/1/15 No policy statement changes.
- 11/1/16 No policy statement changes.
- 11/1/17 No policy statement changes.
- 11/1/18 No policy statement changes.

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State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.