



# Louisiana

## Implantation of Intrastromal Corneal Ring Segments

**Policy #** 00164

**Original Effective Date:** 05/23/2005

**Current Effective Date:** 06/20/2018

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### **When Services May Be Eligible for Coverage**

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider implantation of intrastromal corneal ring segments (ICRS) as a treatment of keratoconus to be **eligible for coverage**.

### Patient Selection Criteria

Coverage eligibility for implantation of intrastromal corneal ring segments (ICRS) as a treatment of keratoconus will be considered when all of the following criteria are met:

- Patients 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; and
- Patients are 21 years of age or older; and
- Patients have clear central corneas; and
- Patients have a corneal thickness of 450 microns or greater at the proposed incision site; and
- Patients who have corneal transplantation as the only other remaining option to improve their functional vision.

### **When Services Are Considered Investigational**

*Note: Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers implantation of intrastromal corneal ring segments (ICRS) when criteria are not met to be **investigational**.\*

Based on review of available data, the Company considers implantation of intrastromal corneal ring segments (ICRS) for all other conditions to be **investigational**.\*

*Note: The correction of refractive errors of the eye is considered an exclusion in most member contracts.*

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### **Background/Overview**

#### **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

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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.

### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration (FDA)**

INTACS<sup>®†</sup> represents an intrastromal corneal ring that has received approval by the U.S. 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: HDE 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 ICRS
- Keraring ICRS

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- MyoRing intracorneal continuous ring (ICCR)

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination.

### **Rationale/Source**

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. 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 was considered a success. Approximately 10% of patients required a second procedure because of an unsatisfactory initial result.

One of the larger studies was published in 2007 by Colin and Malet. They reported 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.

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Studies with 5 years of follow-up include Bedi et al (2012). 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. However, the analysis only included cases without significant changes in corneal topography over the 12 months prior to surgery. Kymionis et al (2007) reported 5-year follow-up on 28 patients (36 eyes) who had initially participated in a clinical trial for safety and efficacy of Intacs implantation in patients with keratoconus. 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**

In 2009, Pinero et al published a European multicenter retrospective analysis of 21 consecutive eyes in 15 patients who had been implanted with 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. 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 (BSCVA). Ring explantation was performed in 4 (19%) eyes due to visual deterioration during the follow-up. Mean keratometry decreased 1.76 D, from 44.95 to 43.19 diopters (D) at 6 months postoperatively ( $p < 0.01$ ).

A 2010 publication from Europe retrospectively analyzed ICRS implantation (210° arc length 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. 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.

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### **Section Summary: Pellucid Marginal Degeneration**

Only a few case series 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.

### **ASTIGMATISM AFTER PENETRATING KERATOPLASTY**

Two cases (2009, 2012) were identified in which ICRS were implanted to correct residual astigmatism after penetrating keratoplasty. In 1 of the studies, conducted in Spain, 9 patients received ICRS (KeraRings) for high astigmatism (>4 D) after the procedure. 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, ICRS should not be used because the segments would be proximate to the graft-host junction. In another study, by Coscarelli et al (2012) in Brazil, chart records of 54 patients (59 eyes) who had ICRS with the Ferrara ring were retrospectively reviewed. 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. They were conducted outside of the United States and used devices not cleared by the FDA.

### **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. 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. Histopathologic examination of 8 eyes that underwent penetrating keratoplasty after removal of Intacs implants revealed keratocyte apoptosis.

### **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

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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 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 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.

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### **Policy History**

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- |            |   |
|------------|---|
| 04/05/2005 | Medical Director review   |
| 04/27/2005 | Medical Policy Committee review   |
| 05/23/2005 | Managed Care Advisory Council approval  |
| 02/01/2006 | Medical Director review   |
| 02/15/2006 | Medical Policy Committee review. Coverage changed from investigational to eligible with criteria.   |
| 02/23/2006 | Quality Care Advisory Council approval  |
| 07/07/2006 | Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.  |
| 04/04/2007 | Medical Director review   |
| 04/18/2007 | Medical Policy Committee approval   |
| 06/13/2007 | Medical Director review   |
| 06/20/2007 | Medical Policy Committee approval. When services are considered not medically necessary section was deleted. Myopia was deleted from the statement "BCBS considers ICRS as a treatment of any other condition except keratoconus and myopia to be investigational". |
| 06/13/2007 | Medical Director review   |
| 06/20/2007 | Medical Policy Committee approval   |
| 07/02/2008 | Medical Director review   |
| 07/16/2008 | Medical Policy Committee approval. No change to coverage eligibility.   |

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06/04/2009 Medical Director review  
 06/17/2009 Medical Policy Committee approval. No change to coverage eligibility.  
 06/03/2010 Medical Policy Committee review  
 06/16/2010 Medical Policy Implementation Committee approval. Title changed to "Implantation of Intrastromal Corneal Ring Segments."  
 06/02/2011 Medical Policy Committee review  
 06/15/2011 Medical Policy Implementation Committee approval. No change to coverage.  
 06/14/2012 Medical Policy Committee review  
 06/20/2012 Medical Policy Implementation Committee approval. No change to coverage.  
 06/06/2013 Medical Policy Committee review  
 06/25/2013 Medical Policy Implementation Committee approval. No change to coverage.  
 06/05/2014 Medical Policy Committee review  
 06/18/2014 Medical Policy Implementation Committee approval. No change to coverage.  
 06/04/2015 Medical Policy Committee review  
 06/17/2015 Medical Policy Implementation Committee approval. No change to coverage.  
 06/02/2016 Medical Policy Committee review  
 06/20/2016 Medical Policy Implementation Committee approval. No change to coverage.  
 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes  
 06/01/2017 Medical Policy Committee review  
 06/21/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
 06/07/2018 Medical Policy Committee review  
 06/20/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
 Next Scheduled Review Date: 06/2019

### Coding

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT)<sup>®</sup>‡, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	65785
HCPCS	C1780
ICD-10 Diagnosis	H18.601-H18.629

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

\*\*Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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 that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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