

Corporate Medical Policy

Implantation of Intrastromal Corneal Ring Segments

File Name: implantation_of_intrastromal_corneal_ring_segments
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Last Review: 6/2018

Description of Procedure or Service

Intrastromal corneal ring segments (ICRS) consist of micro-thin 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, pellucid marginal degeneration, and for refractive surgery to correct mild myopia and astigmatism following penetrating keratoplasty.

Intrastromal corneal ring segments are flexible, crescent-shaped rings of polymethylmethacrylate that are placed in the periphery of the cornea. An incision is made in the cornea and channels are created in it by rotating a lamellar dissector or by using a femtosecond laser. One or two corneal implant segments are introduced to each channel, and various implants with a range of implant 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. If required, the implants can be removed at a later date.

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 often consists of hard contact lenses. A penetrating keratoplasty (i.e., corneal grafting) is the next line of treatment in those patients who develop intolerance to contact lenses. While visual acuity is typically improved with a 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 LASIK, but in general results of these techniques have been poor. In deep anterior lamellar keratoplasty, pathological 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 represents an additive technique in which the implants are intended to reinforce the cornea, prevent further deterioration, and potentially obviate the need for a penetrating keratoplasty.

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Rigid gas permeable contact lenses may be used to treat pellucid marginal degeneration. Intracorneal ring segment implantation (ICRS), crescentic lamellar keratoplasty, penetrating keratoplasty, and corneal wedge excision have also been proposed.

ICRS correct myopia by flattening the center of the cornea and represent an alternative to laser in situ keratomileusis (LASIK) and other refractive surgeries. The proposed advantages of the intrastromal corneal rings are 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 are reversible. However, mild myopia is effectively treated with either spectacles or contact lenses. Therefore, this application of Intacs is not addressed in this evidence review.

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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

INTACS® represents an intrastromal corneal ring that has received approval by the U.S. Food and Drug Administration (FDA) for 2 indications:

In 1999, INTACS® 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 FDA approval 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;

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- Who have corneal transplantation as the only remaining option to improve their functional vision.”

Note: The humanitarian device exemption (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.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Related Policies:

Keratoprosthesis
Endothelial Keratoplasty
Corneal Collagen Cross-Linking

Policy

BCBSNC will provide coverage for implantation of intrastromal corneal ring segments as a treatment of keratoconus when determined to be medically necessary because the medical criteria and guidelines shown below are met.

BCBSNC will not provide coverage for implantation of intrastromal corneal ring segments to correct refractive errors including myopia. Implantation of corneal ring segments to treat refractive errors is refractive surgery which is considered a benefit exclusion. BCBSNC does not cover services that are excluded.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Most BCBSNC certificates do not provide benefits for refractive eye surgery. Side effects and complications of non-covered services are also benefit exclusions.

When Implantation of Intrastromal Corneal Ring Segments 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 **all** of the following criteria:

- The patient has experienced a progressive deterioration in their vision, such that they can no longer achieve adequate functional vision with best correction of 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 Implantation of Intrastromal Corneal Ring Segments is not covered

Refractive eye surgery is specifically excluded under most benefit plans.

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Implantation of intrastromal corneal ring segments as a treatment of myopia is considered refractive eye surgery and therefore a benefit exclusion. In the rare instance of a BCBSNC certificate that does provide benefits for refractive surgery, the use of intrastromal corneal ring segments as a treatment for myopia would be considered not medically necessary. (Myopia can be corrected with more conservative measures such as glasses or contact lenses.)

For patients with myopia, astigmatism, or keratoconus, implantation of intrastromal corneal ring segments to enable the patient to successfully wear soft or hard contact lenses is considered refractive eye surgery and therefore is a benefit exclusion.

Implantation of intrastromal corneal ring segments following LASIK, PRK (photorefractive keratectomy) or other refractive surgical procedures is considered not covered. A small percentage of patients may have problems after these procedures (i.e., the procedure may not fully correct the refractive error, the procedure can result in a condition known as ectasia (a forward bulging of the cornea), or the initial full correction may regress to only a partial correction). Treatment of side effects or complications as a result of a non-covered procedure (refractive eye surgery) is a benefit exclusion under most benefit plans.

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

Policy Guidelines

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.

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Note: Please refer to separate policies: Investigational (Experimental) Services and Medical Necessity.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 65785

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 4/1/05.

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 3/7/06

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 12/12/06.

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 1/10/08.

U.S. Food and Drug Administration. Humanitarian Use Devices. Retrieved on 11/1/07 from <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm>

U.S. Food and Drug Administration. New Humanitarian Device Approval. INTACS® Prescription Inserts for Keratoconus - H040002. Retrieved on 11/1/07 from <http://www.fda.gov/cdrh/mda/docs/h040002.html>

U.S. Food and Drug Administration. Approval Order - H040002 - INTACS® Prescription Inserts for Keratoconus (0.25mm, 0.30mm and 0.35mm); July 26, 2004. Retrieved on 11/1/07 from <http://www.fda.gov/cdrh/pdf4/h040002a.pdf>

U.S. Food and Drug Administration. Summary of Safety and Probable Benefit. Retrieved on 6/10/08 from <http://www.fda.gov/cdrh/pdf4/h040002b.pdf>

Specialty Matched Consultant Advisory Panel review - 4/6/09.

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 9/10/09.

Senior Medical Director review - 10/2009.

U.S. Food and Drug Administration. PMA - Premarket Approval. 1999; Available online at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=14092> . Last accessed August, 2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 9/16/2010.
Specialty Matched Consultant Advisory Panel review -6/2011.

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 9/13/12.

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Specialty Matched Consultant Advisory Panel Review- 10/2012.

Specialty Matched Consultant Advisory Panel Review- 6/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 9/12/13

Specialty Matched Consultant Advisory Panel review- 6/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 9/11/14

Specialty Matched Consultant Advisory Panel review- 6/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 9/10/15

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 3/10/16

Specialty Matched Consultant Advisory Panel review- 6/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 3/9/17

Specialty Matched Consultant Advisory Panel review- 6/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 3/8/18

Specialty Matched Consultant Advisory Panel review- 6/2018

Policy Implementation/Update Information

8/25/08 New policy issued. Verbiage indicating that the implantation of intrastromal corneal ring segments is considered investigational has been removed from Corporate Medical Policy entitled "Refractive Surgery", policy number SUR6590. The implantation of intrastromal corneal ring segments remains investigational. (pmo)

4/27/09 No changes to criteria. Reference source added. (pmo)

11/23/0 Description section and Policy Guidelines updated. Policy statement revised. When Covered criteria added. Reference sources added. (pmo)

6/22/10 Policy Number(s) removed (amw)

7/19/11 Specialty Matched Consultant Advisory Panel review 6/29/2011. References added. No change in policy statement. (lpr)

11/13/12 Specialty Matched Consultant Advisory Panel review 10/17/2012. Reference added. Description section updated. No change to policy statement. (lpr)

7/16/13 Specialty Matched consultant advisory panel review 6/19/2013. No change to policy statement. (lpr)

10/29/13 Reference updated. No change to policy statement. (lpr)

7/15/14 Specialty matched consultant advisory panel review meeting 6/24/2014. No change to policy statement. (lpr)

10/28/14 Reference added. No change to policy statement. (lpr)

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- 7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. No changes to policy statements. (lpr)
- 10/30/15 Reference added. Updated Description and Policy Guidelines sections. No change to policy statement. (lpr)
- 12/30/15 Added CPT code 65785 and deleted CPT code 0099T in Billing/Coding section for effective date 1/1/2016. (lpr)
- 4/29/16 Reference added. No change to policy statement. (lpr)
- 7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. No change to policy statement. (lpr)
- 4/28/17 Updated Policy Guidelines section. Reference added. No change to policy statement. (lpr)
- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/28/2017. No change to policy statement. (lpr)
- 8/10/18 Updated Description section. Specialty Matched Consultant Advisory Panel review 6/2018. Reference added. No change to policy statement. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.