

Corporate Medical Policy

Implantation of Intraström Corneal Ring Segments

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Description of Procedure or Service

Intraström corneal ring segments (ICRS) consist of micro-thin soft plastic inserts of variable thickness that are placed in the periphery of the cornea. Intraström corneal ring segments have been investigated as a means of improving vision in diseases such as keratoconus and for refractive surgery to correct mild myopia.

Intraström 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.

In myopia, the intraström inserts 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 intraström 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.

Keratoconus is a progressive bilateral dystrophy that is characterized by paracentral steepening and stromal thinning that impairs visual acuity. 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. Implantation of intraström 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. This technique has primarily been investigated in patients in whom the cornea has remained transparent and who are intolerant of contact lenses.

INTACS® represent an intraström 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:

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“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; AND
- 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.*

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;

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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 Intraström Corneal Ring Segments is covered

Implantation of intraström 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 is no longer able to achieve vision of at least 20/40 or better with best correction of contact lenses or spectacles; AND
- The patient demonstrates an inability to perform daily activities such as driving, reading, watching TV, computer work; AND
- The procedure will reduce or eliminate myopia and/or astigmatism; AND
- The procedure will restore functional vision; 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 Intraström Corneal Ring Segments is not covered

Refractive eye surgery is specifically excluded under most benefit plans.

Implantation of intraström 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 intraström 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 intraström corneal ring segments to enable the patient to successfully wear soft or hard contact lenses is considered refractive eye surgery and therefore a benefit exclusion.

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

Policy Guidelines

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Myopia

The FDA approval for the INTACS® device was based on results of a multi-institutional study involving 361 subjects with mild myopia. Subsequently, the 2-year results of this study were published in the peer-reviewed literature. These data suggested that the intrastromal rings predictably and effectively reduced or eliminated mild myopia (-1.00 to -3.00 diopter) and that the refractive effect was stable over time. However, mild myopia is effectively treated with either spectacles or contact lenses. Therefore, this application of intrastromal corneal implants is considered not medically necessary. In addition, as noted in the Benefits Applications section, many Plan benefits or contracts contain a specific exclusion for refractive eye surgery.

Keratoconus

As indicated previously, INTACS® received FDA approval through the humanitarian device exemption (HDE) process for the treatment of myopia and astigmatism in patients with keratoconus who are no longer able to achieve adequate vision using contact lenses or glasses and for whom corneal transplant is the only remaining option. This regulatory category (HDE) was established in 1996 and only applies to devices intended to benefit less than 4,000 patients. The approval process is similar to that of a premarket approval application (PMA), but is exempt from the effectiveness requirements of the PMA. Thus the application is not required to provide results of scientifically valid clinical investigations, but must contain sufficient information for the FDA to determine that the device does not pose unreasonable or significant risk of illness or injury. A humanitarian use device may only be used in facilities that have an Institutional Review Board (IRB) to supervise clinical testing of the device.

A single prospective study with 2-year follow-up reports stable visual acuity in the 68 patients (82 eyes) out of 68 patients available for follow-up. 4% had INTACS® removed due to poor visual outcome or extrusion. In the 82 eyes in whom follow-up was complete, there was a decrease in central corneal thickness from 478 microns preoperatively to 421 microns at 2 years.

A retrospective study that included 8 patients (8 eyes) who had penetrating keratoplasty (PKP) after removal of INTACS® revealed keratocyte apoptosis. The INTACS® had been removed because of poor refractive outcome or insert extrusion. The authors note further study is needed to determine whether INTACS® accelerate corneal thinning and keratoconus progression.

Another study 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 keratoconic patients. In 5 patients (7 eyes) the INTACS® were removed due to patient dissatisfaction. An additional 8 patients (12 eyes) were unable to attend follow up appointments. Five year follow-up was reported for the remaining 17 eyes (59%). Refractive stability was obtained at the 6-month follow-up (spherical equivalent error at baseline -5.54 to -2.68 at 6 months) and remained stable throughout the 5-year follow-up (-3.02). With the exception of one eye that had a decrease of 3 lines, the best corrected visual acuity was maintained to the pre-INTACS® level. Keratometric values showed a mean reduction of 1.57 diopters (49.59 to 48.02 diopters).

While published data regarding intrastromal corneal implants for keratoconus reflect ongoing evaluation, the data does not adequately address long-term outcomes in sufficient numbers of patients, or evaluate whether or not the use of the inserts will significantly delay or prevent the need for a corneal transplant.

Clinical input strongly supports the use of intrastromal corneal ring segments in a select group of patients with advanced keratoconus whose only other option for restoration of visual function is the more invasive penetrating keratoplasty. Although questions remain regarding the impact of this procedure on long-term health outcomes, the risk of adverse events is decreased in comparison with the existing alternative (corneal transplant), and there is a potential (as yet unproven) to delay the need for the more invasive procedure. Therefore, use of intrastromal corneal ring segments may be

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considered medically necessary in patients who meet the FDA-HDE criteria for use of this device.

Note: Please refer to separate policy Investigational (Experimental) Services and policy 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: 0099T

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.

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Specialty Matched Consultant Advisory Panel review -6/2011.

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)

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.