INTRASTROMAL CORNEAL RING SEGMENTS FOR KERATOCONUS (INTACS®)

Policy Number: 2016M00101A     Effective Date: April 01, 2016

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
**POLICY DESCRIPTION:**

INTACS® Inserts are two curved, clear plastic segments that are implanted in the perimeter of the cornea to reduce nearsightedness (myopia). INTACS® Inserts are intended for 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. Keratoconus is a visual disorder that occurs when the normally round and dome-shaped cornea progressively thins, causing a cone-like bulge to develop. This results in significant distorted visual impairment. The inserts may restore functional vision for patients with keratoconus and postpone the need for a corneal transplant.

**COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:**

Intrastromal corneal rings segments for keratoconus (INTACS®) are considered medically necessary for adults 21 years of age or older, when used under the FDA Humanitarian Device Exemption for the treatment of keratoconus, when all of the following criteria are met:

1. No longer able to achieve vision of at least 20/40 or better correction with eyeglasses or contact lenses, and
2. Demonstrates an inability to perform activities of daily living (ADLs), and
3. Procedure will reduce or eliminate myopia and/or astigmatism, and
4. Procedure will restore functional vision, and
5. Procedure will defer the need for corneal transplant procedure, and
6. Patient must have clear central corneas, and
7. Patient must have a corneal thickness of 450 microns or greater at the proposed incision site.

Intrastromal corneal ring segments are considered INVESTIGATIONAL and NOT MEDICALLY NECESSARY in the following scenarios, due to the lack of published peer-reviewed medical literature in addition to minimal ongoing trials:

1. Patients with more than 1 diopter of astigmatism
2. Patients with hyperopia
3. Ectasia after laser-assisted in situ keratomileusis (LASIK) or after photorefractive keratectomy (PRK)
4. All other indications not listed above

**Clinical Considerations:**

Treatment for keratoconus consists of spectacles for astigmatism and myopia initially, and rigid gas permeable (RGP) contact lenses once spectacle-corrected acuity becomes inadequate. When contact lenses no longer provide adequate acuity, become uncomfortable or painful, or the steepness of the cornea is such that lenses cannot be maintained in position, then surgical treatment with a corneal transplant is indicated. The objective of treating keratoconus with intrastromal corneal rings (INTACS®) is to delay or eliminate the need for a corneal graft. Implantation of INTACS® would typically be prescribed by an ophthalmologist and performed by an ophthalmologic surgeon.
Contraindications:
Intrastromal corneal rings (INTACS®) for keratoconus are contraindicated and not medically necessary in any of the following:

1. Patients who have abnormally thin corneas or who have corneal thickness of 449 microns or less at the proposed incision site
2. Patients with collagen vascular, autoimmune or immunodeficiency diseases
3. Pregnant or nursing women
4. The presence of ocular conditions, such as recurrent corneal erosion syndrome or corneal dystrophy, since that may predispose the patient to future complications
5. Patients who are taking one or more of the following medications: isotretinoin (Accutane®), amiodarone (Cordarone®), or sumatriptan (Imitrex®).

INTACS® implantation is not recommended for patients who have systemic diseases that can affect wound healing or for patients who have had ocular Herpes simplex or Herpes Zoster infections.

Possible Complications: Complications associated with implantation of INTACS® are usually mild or readily managed and included the following on a per-eye basis:

- Segment breakage (2%)
- Segment overlap (3%)
- Segment decentration (4%)
- Segment extrusion (1% to 6%)
- Late neovascularization of the stromal channel (6%)
- Lamellar deposits in the stromal channel (12%)
- Mild superficial neovascularization (12%)
- Segment explantation (15%)
- Segment migration (27%)
- Microbial keratitis (1%)

BACKGROUND:
Keratoconus is a noninflammatory corneal disorder that affects approximately 0.05% of the general population, with onset typically occurring in the teen and young adult years. Due to progressive corneal steepening and thinning, patients who have keratoconus develop progressive myopia and astigmatism. Keratoconus is bilateral in > 90% of cases, although the disease develops asymmetrically, with diagnosis of disease in the second eye lagging approximately 5 years behind diagnosis in the first. The disease process is typically active for approximately 5 to 10 years and then may become stable for many years. During the active stage, change may be rapid.

Although the cause of keratoconus is not known, in the earlier stages, it can usually be corrected with eyeglasses or rigid contact lenses; however, contact lenses may cause scarring of the cornea in these patients. For patients who have more severe disease or who cannot tolerate contact lenses, surgery may be indicated. The most common surgery for keratoconus is a corneal transplantation procedure such as...
penetrating keratoplasty. Approximately 15% to 20% of patients who develop keratoconus eventually require corneal transplantation (Rabinowitz et al., 1998; Colin et al., 2001; Colin and Velou, 2003; NKCF, 2012).

Another treatment that avoids the maintenance associated with visual aids such as contact lenses and that also avoids the potential complications associated with penetrating keratoplasty is chemical cross-linking to strengthen the cornea. For this procedure, a solution of riboflavin (vitamin B2) is applied to the eye, which is then exposed to ultraviolet light. The riboflavin is believed to absorb energy from the ultraviolet light and transfer it to oxygen, which reacts with tyrosine side chains in collagen molecules, causing formation of tyrosine dimers that cross-link the collagen molecules. The safety and efficacy of this procedure are currently being evaluated by the Food and Drug Administration (FDA); the procedure is designed to slow or stop further progression of keratoconus rather than correct existing damage (Kato et al., 1994; Raiskup-Wolf et al., 2008; Wittig-Silva et al., 2008; Grewal et al., 2009; NKCF, 2012).

The implantation of INTACS® intrastromal corneal ring segments is a surgical procedure that has received FDA approval for the correction of keratoconus. The objective of treating keratoconus with intrastromal corneal rings is to delay or eliminate the need for a corneal graft. INTACS® are designed to reshape the anterior surface of the cornea for the reduction or elimination of mild myopia by flattening the front of the eye.

Treatment with INTACS® involves minimally invasive surgery to implant one or two thin, clear, semicircular-shaped, plastic segments into the cornea of an affected eye through a single corneal incision. To create the intracorneal tunnels needed for insert implantation, a specially designed dissector is used that relies on vacuum pressure to remain in a centered position on the cornea. The implanted inserts do not directly alter the passage of light through the pupil. Instead, the inserts correct vision indirectly by stretching and flattening the cornea. The amount of correction achieved is directly related to the thickness of the segments; the thicker Intacs are used for higher amounts of correction. If they are removed, the eyes return to preoperative refractive status within 3 months. The procedure is performed in an ambulatory setting under local anesthesia.

REGULATORY STATUS:

1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):

INTACS® (Addition Technology Inc.): Intrastromal corneal ring system is regulated by the FDA as a Class III device that is subject to the most extensive regulations enforced by the FDA via the premarket approval (PMA) process.

INTACS® prescription inserts received a PMA from the FDA on April 9, 1999, for patients with myopia of –1.0 to –3.0 diopters who are ≥ 21 years of age with an astigmatic component of no more than +1.0 diopter and with stable refraction as shown by a change of no more than 0.5 diopter in the preceding year (CDRH, 2012a). On July 26, 2004, the FDA issued a humanitarian device exemption (HDE) approving INTACS® implantation for keratoconus when the following criteria are met (CDRH, 2006):

- ≥ 21 years of age
- Progressive deterioration of vision
- Inadequate vision correction with eyeglasses or contacts
- Clear central cornea
- Corneal thickness ≥ 0.45 mm at the proposed incision site
- Corneal transplantation as the only option other than INTACS® to improve vision

Implantation of INTACS® inserts requires a specially designed keratome that has clockwise and counterclockwise dissectors and that uses pressure from a vacuum pump to remain centered on the cornea. Electrically powered keratomes are regulated by the FDA as Class II devices and 76 of these devices, including the KeraVision Vacuum Ring System (KeraVision Inc.), have been approved via the FDA 510(k) process (CDRH, 2012b).

The KeraVision Vacuum Ring System received 510(k) approval from the FDA on April 28, 1999. The summary accompanying that decision states that this device is intended for fixation of eye position during ophthalmic surgery when a lamellar corneal dissection is required (CDRH, 2012b).

See the following Web site for more information:


The FDA issued the following precautions in conjunction with its 1999 approval order for INTACS® inserts: See the following Web site for more information:


Patients treated with the 0.35-mm insert may have worse outcomes than those treated with 0.25- or 0.30-mm inserts.

- Overcorrection is more likely for patients with -1.0 diopter myopia.
- INTACS® inserts may have long-term effects on endothelial cell density but this has not been determined.
- INTACS® implantation causes a temporary decrease in corneal sensation for some patients, although this effect does not seem to be clinically significant.
- Patients are predisposed to low-light visual symptoms if they have dilated pupil diameters 7.0 mm.
- Patients may experience some loss of contrast sensitivity in low-light conditions.
- The efficacy and safety of other procedures to modify refraction have not been established for patients who have undergone INTACS® implantation and removal.

In addition to the precautions listed above, INTACS® implantation is contraindicated under the following circumstances: use of Accutane® (isotretinoin), Cordarone® (amiodarone) or Imitrex® (sumatriptan), recurrent corneal erosion syndrome, corneal dystrophy, or other ocular disorders that might cause complications in the future; and known autoimmune, immunodeficiency, or collagen vascular disease. INTACS® implantation is not recommended for patients who have systemic diseases that can affect wound healing or for patients who have had ocular Herpes simplex or Herpes Zoster infections. See the following Web site for more information:


**Humanitarian Device Exemption (HDE):**
The Safe Medical Devices Act (SMDA) of 1990 provided for a humanitarian device exemption to encourage the discovery and use of devices that benefit fewer than 4,000 individuals in the U.S. This provision allows FDA to grant an exemption from the effectiveness requirements of sections 514 (Special Controls) and 515 (Premarket Approval) of the FD&C Act after finding that:

- The device is designed to treat or diagnose a disease or condition that affects fewer than 4,000 individuals per year in the U.S.;
- The device is not available otherwise, and there is no comparable device available to treat or diagnose the disease or condition; and
- The device will not expose patients to unreasonable or significant risk, and the benefits to health from the use outweigh the risks.

Devices granted an exemption may only be used at facilities that have an established institutional review committee, and the humanitarian use must be approved by the committee before use can begin.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):

No National Coverage Determination (NCD) or Local Coverage Determination (LCD) for intrastromal corneal ring segments (ICRS) procedure for keratoconus was identified on the CMS website (CMS, 2016).

Category III CPT® Codes, January 2016 Revisions (L33392): CPT® III code 0099T (implantation of intrastromal corneal ring segments) was deleted from Group 1, effective for services rendered on or after 1/1/2016, and replaced with Category 1 CPT code 65785.


Medicare may make payment for a Category B IDE device and routine care items and services furnished in an FDA-approved Category B IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria are met.

Payment for Items and Services in Category B IDE Studies:

The 2015 national Medicare rate for ambulatory surgery centers (ASCs) for code 0099T is $960. The 2015 national Medicare rate for a hospital outpatient department (HOPD) is $1,752. Local rates vary. The ICRS is an inherent part of the surgical procedure, 0099T. Payment for the prosthetic device is typically included in the facility fee for the ASC or HOPD. Some facilities negotiate contracts with payers that include carve out payments for prosthetic devices – these are the exception.

For Medicare payment purposes, the patient’s medical record should contain documentation that the use of the HUD is medically necessary and that no alternative exists.

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):

Minnesota DHS does not have a policy statement regarding Intrastromal corneal ring system for treatment of keratoconus in its Provider Manual or other specific provider references.

CLINICAL EVIDENCE:

1. EXTERNAL SOURCES/ GROUPS POLICY:

American Academy of Optometry (AAOPT): In a position paper addressing treatments for keratoconus,
the American Academy of Optometry (AAOPT) states that treatment with INTACS® is not a common procedure and its long-term success is not known. In addition, this position paper warns that patients still require contact lenses for vision correction after INTACS® implantation and fitting contact lenses is more difficult after the procedure (AAOPT, 2008). The AAO states that long-term efficacy of this procedure for ectasia remains to be determined (AAO, 2012).

The AAO’s Preferred Practice Pattern for Refractive Errors and Refractive Surgery states that intrastromal corneal ring segments are now rarely utilized to correct myopia (AAO, 2012).

**American Academy of Ophthalmology (AAO):** The American Academy of Ophthalmology (AAO) has performed a technology assessment and concluded that INTACS® inserts are reasonably safe and effective for the treatment of low myopia (−1.0 to −3.0 diopters) when patients have stable manifest refraction and < 1 diopter of astigmatism. However, the AAO assessment cautions that further research is needed to determine the long-term effectiveness of this procedure as well as its safety, effectiveness, and cost compared with other treatments such as laser-assisted in situ keratomileusis (LASIK) and photorefractive keratectomy. This technology assessment was reviewed by the AAO in 2009 but was not expanded to address INTACS® inserts for keratoconus (Rapuano et al., 2001; AAO, 2009).

**Ontario Ministry of Health (OMH):** A technology assessment addressing intrastromal corneal ring implants was prepared by the OMH and states that “Despite the limited evidence base for corneal implants, which consists solely of longitudinal follow-up studies, they appear to be a valuable clinical tool for improving vision in patients with corneal thinning” (MAS, 2009, p. 12). Particular benefits noted by the OMH were low risk, high technical success rate, adjustability and ready removal of implants, and implantation on an outpatient basis. The OMH assessment also states that further information concerning vision quality, functional vision, patient satisfaction, durability of treatment effects, and influence on underlying disease processes are needed to more accurately evaluate the impact of this technology (MAS, 2009).

**The National Institute for Health and Care Excellence (NICE):** NICE issued guidance on the use of corneal implants for keratoconus. The NICE guidance states that current evidence on the safety and efficacy of corneal implants for keratoconus appears adequate to support the use of this procedure (NICE, Corneal implants for keratoconus, 2007).

2. **EXPERT OPINION:** No expert opinion was sought for this policy.

**SUMMARY:**

A moderately large body of evidence of low quality suggests that implantation of INTACS® segments is reasonably safe and provides some improvements in visual outcomes for patients who have keratoconus. These studies also suggest that the efficacy of INTACS® inserts is essentially the same as the efficacy of similar ocular implants such as Keraring and Ferrara inserts and that variations of the Intacs procedure, such as implantation of segments of unequal lengths, do not have a significant influence on visual outcomes; however, the available studies did not compare INTACS® implantation with corneal transplantation, the usual treatment for keratoconus that cannot be managed adequately with eyeglasses or rigid contact lenses.
APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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REFERENCES:


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<td>New policy 2016M00101A reviewed and approved by Medical Policy Committee (MPC).</td>
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<tr>
<td>2/25/2016</td>
<td>Approved by the Quality Improvement Advisory and Credentialing Committee (QIACC).</td>
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