

# MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	INTRASTROMAL CORNEAL RING SEGMENTS (ICRS) FOR KERATOCONUS
Policy Number	9.01.13
Category	Technology Assessment
Effective Date	09/15/05
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Product Disclaimer	<ul style="list-style-type: none"> <li>• If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</li> <li>• If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</li> <li>• If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</li> </ul>

## POLICY STATEMENT

- I. Based upon our criteria and assessment of peer-reviewed literature, insertion of intrastromal corneal ring segments (ICRS) (e.g., INTACS) as a treatment for keratoconus is considered **medically appropriate** when ALL of the following criteria are met:
  - A. The patient can no longer achieve adequate vision correction with either glasses or contact lenses and corneal transplantation is the only remaining option to improve visual function;
  - B. The patient age is 21 years or older;
  - C. The patient has a clear central cornea; and
  - D. The patient's corneal thickness is at least 450 microns.
- II. Based upon our criteria and assessment of peer-reviewed literature, insertion of ICRS (e.g., INTACS) as a treatment alternative in patients with keratoconus who continue with adequate vision correction with glasses or contact lenses has not been medically proven to be effective and therefore, is considered **investigational**.

*Refer to Corporate Medical Policy # 9.01.01 regarding Phototherapeutic Keratoplasty.*

*Refer to Corporate Medical Policy # 9.01.08 regarding Refractive Procedures.*

*Refer to Corporate Medical Policy # 9.01.15 regarding Keratoprosthesis.*

*Refer to Corporate Medical Policy #9.01.17 regarding Gas Permeable Scleral Contact Lens.*

*Refer to Corporate Medical Policy # 11.01.03 regarding Experimental or Investigational Services.*

## POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

## DESCRIPTION

Keratoconus is a non-inflammatory progressive eye disease that affects the cornea. The cornea is the clear front surface of the eye that is responsible for two thirds of the focusing power in the eye. With keratoconus, the cornea, which is normally spherical, becomes progressively cone-shaped, distorting vision. The central cornea protrudes forward and corneal thinning can occur. Keratoconus often appears in the late teens or early twenties and can occur in one or both eyes. Nearsightedness and astigmatism may be accompanied by glare and light-sensitivity. Treatment consists of

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spectacles initially to correct the refractive error and rigid gas permeable contact lens once spectacle-corrected acuity becomes inadequate. When contact lenses no longer provide adequate vision correction, or contact lens wear becomes intolerable, surgical intervention is usually required. ICRS have been proposed as an alternative to surgical intervention (e.g., phototherapeutic keratoplasty or corneal transplant).

ICRS are two clear plastic arc-shaped removable implants, which are inserted through a small surgical incision on the perimeter of the cornea stroma. ICRS are designed to reshape the anterior surface to reduce or eliminate myopia and astigmatism, by raising the peripheral cornea and indirectly flattening the central cornea. The amount of correction is related to the thickness of the implant segments. ICRS can be removed and replaced. The procedure is usually performed in the ambulatory setting under local anesthesia.

### RATIONALE

INTACS™ ICRS received FDA approval for the treatment of refractive errors in 1999. In July 2004, INTACS™ also received FDA Humanitarian Device approval for the treatment of 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. According to the FDA, the specific subset of keratoconic patients proposed to be treated with INTACS prescription inserts are those who: 1) 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; 2) who are 21 years of age or older; 3) who have clear central corneas; 4) who have a corneal thickness of 450 microns or greater at the proposed incision site; and 5) who have corneal transplantation as the only remaining option to improve their functional vision.

Boxer Wachler, et al. (2003) reported on a retrospective study of 74 eyes of 50 persons who received INTACS implantation. The investigators found that the mean improvement in uncorrected visual acuity in persons with keratoconus who received INTACS was four lines of uncorrected visual acuity and two lines of best-corrected visual acuity. The investigators also reported decreases in irregular astigmatism. In a prospective study involving 10 patients with keratoconus, Colin, et al. (2000) reported a 70% improvement in uncorrected visual acuity and a 50% improvement in best-corrected visual acuity.

Well-designed studies remain necessary to determine the role ICRS play in delay or elimination of the need for a corneal transplant. Currently there are no studies that have provided data concerning the efficacy of ICRS on delaying the progression of keratoconus, nor are there any studies that demonstrate that ICRS reduces or delays the incidence of the eventual need for a corneal transplant.

### CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
- CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

#### CPT Codes

Code	Description
65785	Implantation of intrastromal corneal ring segments

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#### HCPCS Codes

Code	Description
No specific codes	

#### ICD10 Codes

Code	Description
H18.601-H18.629	Keratoconus (code range)

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\*Key Article

### **KEY WORDS**

Keratoconus, ICRS, INTACS

### **CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based on our review, the insertion of intrastromal corneal ring segments is not specifically addressed in National or Regional Medicare coverage determinations or policies.