

# MEDICAL POLICY



<b>SUBJECT: INTRASTROMAL CORNEAL RING SEGMENTS (ICRS) FOR KERATOCONUS</b>	<b>EFFECTIVE DATE: 09/15/05</b> <b>REVISED DATE: 07/20/06, 06/21/07, 06/19/08</b> <b>ARCHIVED DATE: 05/28/09</b> <b>EDITED DATE: 05/27/10, 05/19/11, 05/24/12, 05/23/13, 05/22/14, 05/28/15, 05/25/16, 05/18/17, 05/17/18</b>
<b>POLICY NUMBER: 9.01.13</b> <b>CATEGORY: Technology Assessment</b>	<b>PAGE: 1 OF: 4</b>
<ul style="list-style-type: none"><li>• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i></li><li>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i></li><li>• <i>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.</i></li></ul>	

## POLICY STATEMENT:

- I. Based upon our criteria and assessment of peer-reviewed literature, insertion of intrastromal corneal ring segments (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 intrastromal corneal ring segments (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 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. Intrastromal corneal ring segments have been proposed as an alternative to surgical intervention (e.g., phototherapeutic keratoplasty or corneal transplant).

Intrastromal corneal ring segments (ICRS) are 2 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

<p><b>SUBJECT: INTRASTROMAL CORNEAL RING SEGMENTS ICRS FOR KERATOCONUS</b></p> <p><b>POLICY NUMBER: 9.01.13</b></p> <p><b>CATEGORY: Technology Assessment</b></p>	<p><b>EFFECTIVE DATE: 09/15/05</b></p> <p><b>REVISED DATE: 07/20/06, 06/21/07, 06/19/08</b></p> <p><b>ARCHIVED DATE: 05/28/09</b></p> <p><b>EDITED DATE: 05/27/10, 05/19/11, 05/24/12, 05/23/13 05/22/14, 05/28/15, 05/25/16, 05/18/17 05/17/18</b></p> <p><b>PAGE: 2 OF: 4</b></p>
---	---

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 percent improvement in uncorrected visual acuity and a 50 percent 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:**      Number                      Description

*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:**              65785                      Implantation of intrastromal corneal ring segments  
*Copyright© 2018 American Medical Association, Chicago, IL*

**HCPCS:**      No specific codes

**ICD10:**      H18.601-H18.629      Keratoconus (code range)

**REFERENCES:**

Alio JL, et al. One or 2 Intacs segments for the correction of keratoconus. J Cataract Refract Surg 2005 May;31(5):943-53.

Alio JL, et al. Intracorneal ring segments for keratoconus correction: long-term follow-up. J Cataract Refract Surg 2006 Jun;32(6):978-85.

Alio JL, et al. Analysis of results related to good and bad outcomes of Intacs implantation for keratoconus correction. J Cataract Refract Surg 2006 May;32(5):756-61.

BlueCross BlueShield Association. Implantation of Intrastromal Corneal Ring Segments. Medical Policy Reference Manual Policy #9.03.14. 2018 March 8.

<p><b>SUBJECT: INTRASTROMAL CORNEAL RING SEGMENTS ICRS FOR KERATOCONUS</b></p> <p><b>POLICY NUMBER: 9.01.13</b></p> <p><b>CATEGORY: Technology Assessment</b></p>	<p><b>EFFECTIVE DATE: 09/15/05</b></p> <p><b>REVISED DATE: 07/20/06, 06/21/07, 06/19/08</b></p> <p><b>ARCHIVED DATE: 05/28/09</b></p> <p><b>EDITED DATE: 05/27/10, 05/19/11, 05/24/12, 05/23/13 05/22/14, 05/28/15, 05/25/16, 05/18/17 05/17/18</b></p> <p><b>PAGE: 3 OF: 4</b></p>
---	---

\*Boxer Wachler BS, et al. Intacs for keratoconus. Ophthalmol 2003 May;110(5):1031-40.

Carrasquillo KG, et al. Intacs for keratoconus and post-LASIK ectasia: mechanical versus femtosecond laser-assisted channel creation. Cornea 2007 Sep;26(8):956-62.

\*Chan SM, et al. Reversibility and exchangeability of intrastromal corneal ring segments. J Cataract Refract Surg 2002 Apr;28(4):676-81.

\*Colin J, et al. Correcting keratoconus with intracorneal rings. J Cataract Refract Surg 2000 Aug;26(8):1117-22.

\*Colin J, et al. INTACS inserts for treating keratoconus: one-year results. Ophthalmol 2001 Aug;108(8):1409-14.

Colin J. Intacs prescription inserts to treat keratoconus: European data. American Society of Cataract and Refractive Surgery (ASCRS). American Society of Ophthalmic Administrators (ASOA) 2004 Symposium and Congress; May 1-5, 2004; San Diego, California. Abstract 148.

Colin J, et al. Intacs for the correction of keratoconus: two- year follow-up. J Cataract Refract Surg 2007 Jan;33(1):69-74.

Colin J. European Clinical evaluation: use of Intacs for the treatment of keratoconus. J Cataract Refract Surg 2006 May;32(5):747-55.

Coskunseven E, et al. One-year results of intrastromal corneal ring segment implantation (KeraRing) using femtosecond laser in patients with keratoconus. Am J Ophthalmol 2008 May;145(5):775-9.

El Dib RP, et al. A systematic review of Ferrara's ring in the treatment of keratoconus. J Refract Surg 2008 Nov;24(9):865-6.

Ertan A, et al. Intacs insertion with the femtosecond laser for the management of keratoconus: one-year results. J Cataract Refract Surg 2006 Dec;32(12):2039-42.

Ertan A, et al. Intrastromal ring segment insertion using a femtosecond laser to correct pellucid marginal corneal degeneration. J Cataract Refract Surg 2006 Oct;32(10):1710-6.

Ertan A, et al. Comparison of outcomes of 3 channel sizes for intrastromal ring segment implantation with femtosecond laser in eyes with keratoconus. J Cataract Refract Surg 2007 Apr;33(4):648-53.

Ertan A, et al. Intacs implantation using femtosecond laser for management of keratoconus: Comparison of 306 cases in different stages. J Cataract Refract Surg 2008 Sep;34(9):1521-6.

Hellstedt T, et al. Treating keratoconus with intacs corneal ring segments. J Refract Surg 2005 May-Jun;21(3):236-46.

\*Hofling-Lima AL, et al. Corneal infections after implantation of intracorneal ring segments. Cornea 2004 Aug;23(6):547-9.

Jackson MA. Clinical management of keratoconus: intacs or not? American Society of Cataract and Refractive Surgery (ASCRS). American Society of Ophthalmic Administrators (ASOA) 2004 Symposium and Congress; May 1-5, 2004; San Diego, California. Abstract 147.

Kanellopoulos AJ, et al. Modified intracorneal ring segment implantations (INTACS) for the management of moderate to advanced keratoconus: efficacy and complications. Cornea 2006 Jan;25(1):29-33.

Kymionis GD, et al. Long-term follow-up of Intacs in keratoconus. Am J Ophthalmol 2007 Feb;143(2):236-44.

Kymionis GD, et al. Long-term follow-up of Intacs for post-LASIK corneal ectasia. Ophthalmol 2006 Nov;113(11):1909-17.

Levinger S, et al. Keratoconus managed with intacs: one-year results. Arch Ophthalmol 2005 Oct;123(10):1308-14.

<p><b>SUBJECT: INTRASTROMAL CORNEAL RING SEGMENTS ICRS FOR KERATOCONUS</b></p> <p><b>POLICY NUMBER: 9.01.13</b></p> <p><b>CATEGORY: Technology Assessment</b></p>	<p><b>EFFECTIVE DATE: 09/15/05</b></p> <p><b>REVISED DATE: 07/20/06, 06/21/07, 06/19/08</b></p> <p><b>ARCHIVED DATE: 05/28/09</b></p> <p><b>EDITED DATE: 05/27/10, 05/19/11, 05/24/12, 05/23/13, 05/22/14, 05/28/15, 05/25/16, 05/18/17, 05/17/18</b></p> <p><b>PAGE: 4 OF: 4</b></p>
---	---

Mularoni A, et al. Conservative treatment of early and moderate pellucid marginal degeneration: a new refractive approach with intracorneal rings. Ophthalmol 2005 Apr;112(4):660-6.

National Institute for Health and Clinical Excellence. Interventional procedure guidance. Corneal implants for keratoconus. [<http://www.nice.org.uk/guidance/index.jsp?action=download&o=35865>] accessed 4/5/18.

Pokroy R, et al. Intacs adjustment surgery for keratoconus. J Cataract Refract Surg 2006 Jun;32(6):986-92.

\*Rabinowitz YS. Intacs for keratoconus: 1-year follow-up of 20 eyes. American Society of Cataract and Refractive Surgery (ASCRS). American Society of Ophthalmic Administrators (ASOA) 2004 Symposium and Congress; May 1-5, 2004; San Diego, California. Abstract 284.

\*Rabinowitz YS. Intacs with IntraLase for keratoconus: six month results on 20 eyes. Annual meeting of the American Academy of Ophthalmology, Subspecialty day; Refractive Surgery; Oct 14, 2005: Chicago IL.

Rodriguez LA, et al. Penetrating keratoplasty versus intrastromal corneal ring segments to correct bilateral corneal ectasia: preliminary study. J Cataract Refract Surg 2007 Mar;33(3):488-96.

Samimi S, et al. Histopathological findings after intracorneal ring segment implantation in keratoconic human corneas. J Cataract Refract Surg 2007 Feb;33(2):247-53.

Shabayek MH, et al. Intrastromal corneal ring segment implantation by femtosecond laser for keratoconus correction. Ophthalmology 2007 Sep;114(9):1643-52.

Sharma M, et al. Comparison of single-segment and double-segment Intacs for keratoconus and post-LASIK ectasia. Am J Ophthalmol 2006 May;141(5):891-5.

Shetty R, et al. Intacs in advanced keratoconus. Cornea 2008 Oct;27(9):1022-9.

\*Signos CS, et al. Management of keratoconus with Intacs. Am J Ophthalmol 2003 Jan;135(1):64-70.

\*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..