

Medical Coverage Policy | Implantation of Intraströmral Corneal Ring Segments



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OVERVIEW

Intraströmral corneal ring segments (ICRS) are composed of microthin soft plastic inserts of variable thickness that are placed in the periphery of the cornea. Intraströmral corneal ring segments have been investigated as a means of improving vision in diseases such as keratoconus and pellucid marginal degeneration, and for refractive surgery to correct mild myopia and astigmatism following penetrating keratoplasty (PK).

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products

Implantation of intraströmral corneal ring segments may be considered **medically necessary** for the treatment of keratoconus in patients 21 years of age or older who meet the following criteria:

- The patient has experienced a progressive deterioration in their vision, such that they can no longer achieve adequate functional vision with 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.

PRIOR AUTHORIZATION

BlueCHiP for Medicare and Commercial Products

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial products and is obtained via the online tool for participating providers for the treatment of keratoconus. See the Related Policies section.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Implantation of intraströmral corneal ring segments may be considered **medically necessary** for the treatment of keratoconus when the medical criteria above have been met.

Implantation of intraströmral corneal ring segments is **not covered** and is a contract exclusion as a treatment of myopia.

Implantation of intraströmral corneal ring segments is considered **not medically necessary** for all other conditions due to insufficient peer-reviewed scientific literature proving the efficacy of the procedure.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable surgery benefits/coverage and limitations of benefits/coverage when services are not medically necessary.

BACKGROUND

Intraströmral corneal ring segments 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 corneal implant segments are implanted in 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 and restoring a degree of functional vision. If required, the implants can be removed or replaced at a later date. ICRS have been investigated as a means of improving vision in diseases such as keratoconus and pellucid marginal degeneration, and for refractive surgery to correct mild myopia and astigmatism after penetrating keratoplasty.

Keratoconus

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) was traditionally considered the next line of treatment in patients who developed intolerance to contact lenses. While visual acuity is typically improved with 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 laser in situ keratomileusis (LASIK), but in general, results of these techniques have been poor. In deep anterior lamellar keratoplasty, pathologic 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.

Pellucid Marginal Degeneration

Pellucid marginal degeneration is a noninflammatory progressive degenerative disease, typically characterized by bilateral peripheral thinning (ectasia) of the inferior cornea. Deterioration of visual function results from the irregular astigmatism induced by asymmetric distortion of the cornea, and visual acuity typically cannot be restored by using spherocylindrical lenses. Rigid gas permeable contact lenses may be used to treat pellucid marginal degeneration. Intracorneal ring segment implantation, crescentic lamellar keratoplasty, penetrating keratoplasty, and corneal wedge excision have also been proposed.

Myopia

In myopia, intrastromal inserts correct myopia by flattening the center of the cornea and represent an alternative to 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 may be removed or replaced. However, mild myopia is effectively treated with either spectacles or contact lenses.

The evidence for ICRS in individuals who have keratoconus, pellucid marginal degeneration, and astigmatism following PK includes primarily single-institution case series. For eyes with keratoconus there are number of prospective series that have shown improvement in visual function from baseline to posttreatment, although data on net health outcome in the long-term are limited.

Although questions remain about the impact if ICRS on long-term health outcomes, the risk of adverse events is decreased compared with the existing alternative (corneal transplant), and there is a potential (as yet unproven) to delay the need for the more invasive procedure. Therefore, the use of intrastromal corneal ring segments may be considered medically necessary in patients who meet the U.S. Food and Drug Administration (FDA) humanitarian device exemption criteria for use of this device.

For pellucid marginal degeneration and astigmatism following PK, there are very limited data at this time. The evidence is insufficient to determine the effects of the technology on health outcomes.

There is insufficient evidence to evaluate health outcomes in patients with conditions other than keratoconus. Therefore, intrastromal corneal ring segments in this population are considered not medically necessary.

CODING

BlueCHiP for Medicare and Commercial Products

The following CPT code is considered medically necessary when the medical criteria above are met:

65785 Implantation of intrastromal corneal ring segments

RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, December 2017

Provider Update, September 2016

Provider Update, January 2016

Provider Update, July 2010

REFERENCES

1. Vega-Estrada A, Alio JL, Brenner LF, et al. Outcomes of intrastromal corneal ring segments for treatment of keratoconus: Five-year follow-up analysis. *J Cataract Refract Surg.* Aug 2013;39(8):1234-1240. PMID 23747207
2. Alio JL, Shabayek MH, Belda JI, et al. Analysis of results related to good and bad outcomes of Intacs implantation for keratoconus correction. *J Cataract Refract Surg.* May 2006;32(5):756-761. PMID 16765791
3. Boxer Wachler BS, Christie JP, Chandra NS, et al. Intacs for keratoconus. *Ophthalmology.* May 2003;110(5):1031-1040. PMID 12750109
4. Colin J. European clinical evaluation: use of Intacs for the treatment of keratoconus. *J Cataract Refract Surg.* May 2006;32(5):747-755. PMID 16765790
5. Levinger S, Pokroy R. Keratoconus managed with intacs: one-year results. *Arch Ophthalmol.* Oct 2005;123(10):1308-1314. PMID 16219721
6. Siganos CS, Kymionis GD, Kartakis N, et al. Management of keratoconus with Intacs. *Am J Ophthalmol.* Jan 2003;135(1):64-70. PMID 12504699
7. Ziaei M, Barsam A, Shamie N, et al. Reshaping procedures for the surgical management of corneal ectasia. *J Cataract Refract Surg.* Apr 2015;41(4):842-872. PMID 25840308
8. Beniz LA, Queiroz GH, Queiroz CF, et al. Intrastromal corneal ring segments delay corneal grafting in patients with keratoconus. *Arq Bras Oftalmol.* Feb 2016;79(1):30-32. PMID 26840163
9. Heikal MA, Abdelshafy M, Soliman TT, et al. Refractive and visual outcomes after Keraring intrastromal corneal ring segment implantation for keratoconus assisted by femtosecond laser at 6 months follow-up. *Clin Ophthalmol.* 2017;11:81-86. PMID 28096650
10. Miraftab M, Hashemi H, Hafezi F, et al. Mid-Term Results of a Single Intrastromal Corneal Ring Segment for Mild to Moderate Progressive Keratoconus. *Cornea.* Dec 14 2016. PMID 27984365
11. Colin J, Malet FJ. Intacs for the correction of keratoconus: two-year follow-up. *J Cataract Refract Surg.* Jan 2007;33(1):69-74. PMID 17189796
12. Bedi R, Touboul D, Pinsard L, et al. Refractive and topographic stability of Intacs in eyes with progressive keratoconus: five-year follow-up. *J Refract Surg.* Jun 2012;28(6):392-396. PMID 22589292
13. Kymionis GD, Siganos CS, Tsiklis NS, et al. Long-term follow-up of Intacs in keratoconus. *Am J Ophthalmol.* Feb 2007;143(2):236-244. PMID 17184717
14. Fernandez-Vega Cueto L, Lisa C, Poo-Lopez A, et al. Intrastromal Corneal Ring Segment Implantation in 409 Paracentral Keratoconic Eyes. *Cornea.* Nov 2016;35(11):1421-1426. PMID 27490048
15. Pinero DP, Alio JL, Morbelli H, et al. Refractive and corneal aberrometric changes after intracorneal ring implantation in corneas with pellucid marginal degeneration. *Ophthalmology.* Sep 2009;116(9):1656-1664. PMID 19643482

16. Kubaloglu A, Sari ES, Cinar Y, et al. A single 210-degree arc length intrastromal corneal ring implantation for the management of pellucid marginal corneal degeneration. *Am J Ophthalmol.* Aug 2010;150(2):185-192 e181. PMID 20570241
17. Arriola-Villalobos P, Diaz-Valle D, Guell JL, et al. Intrastromal corneal ring segment implantation for high astigmatism after penetrating keratoplasty. *J Cataract Refract Surg.* Nov 2009;35(11):1878-1884. PMID 19878819
18. Coscarelli S, Ferrara G, Alfonso JF, et al. Intrastromal corneal ring segment implantation to correct astigmatism after penetrating keratoplasty. *J Cataract Refract Surg.* Jun 2012;38(6):1006-1013. PMID 22624900
19. Ferrer C, Alio JL, Montanes AU, et al. Causes of intrastromal corneal ring segment explantation: clinicopathologic correlation analysis. *J Cataract Refract Surg.* Jun 2010;36(6):970-977. PMID 20494769
20. Kanellopoulos AJ, Pe LH, Perry HD, et al. Modified intracorneal ring segment implantations (INTACS) for the management of moderate to advanced keratoconus: efficacy and complications. *Cornea.* Jan 2006;25(1):29-33. PMID 16331037
21. Samimi S, Leger F, Touboul D, et al. Histopathological findings after intracorneal ring segment implantation in keratoconic human corneas. *J Cataract Refract Surg.* Feb 2007;33(2):247-253. PMID 17276265
22. National Institute for Health and Care Excellence (NICE). Guidance on corneal implants for keratoconus [IPG227]. 2007; <http://www.nice.org.uk/nicemedia/pdf/IPG227guidance.pdf>. Accessed February 15, 2017.

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