**Medical Coverage Policy |** Implantation of Intrastromal Corneal Ring Segments

**EFFECTIVE DATE:** 01|01|2016
**POLICY LAST UPDATED:** 11|03|2015

## OVERVIEW

Intrastromal corneal ring segments consist of microthin soft plastic inserts of variable thickness that are placed in the periphery of the cornea. Intrastromal 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 intrastromal 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 µm 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 intrastromal corneal ring segments may be considered **medically necessary** for the treatment of keratoconus when the medical criteria above have been met.

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

Implantation of intrastromal 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

Intrastromal corneal ring segments consist of microthin soft plastic inserts of variable thickness 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 2 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. Intrastromal 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.

**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 are reversible. However, mild myopia is effectively treated with either spectacles or contact lenses.

The evidence on intrastromal corneal ring segments in patients 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. 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. Myopia can be addressed by contact lenses or spectacles, therefore, intrastromal corneal ring segments are considered not medically necessary for this indication.

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**

## RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures

## PUBLISHED

Provider Update, January 2016
Provider Update, July 2010

## REFERENCES


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