Medical Coverage Policy | Implantation of Intrastromal Corneal Ring Segments

EFFECTIVE DATE: 01|01|2016
POLICY LAST REVIEWED: 02|07|2024

OVERVIEW

Intrastromal corneal ring segments (ICRS) are composed 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 astigmatism following penetrating keratoplasty.

MEDICAL CRITERIA

Medicare Advantage Plans 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 microns or greater at the proposed incision site.

PRIOR AUTHORIZATION

Medicare Advantage Plans and Commercial Products

Prior authorization is required for Medicare Advantage Plans 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

Medicare Advantage Plans 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.

Medicare Advantage Plans

Implantation of intrastromal corneal ring segments is not covered for all other conditions as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Implantation of intrastromal corneal ring segments is considered not medically necessary for all other conditions as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

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

BACKGROUND

Vision Disorders

Keratoconus is a progressive bilateral dystrophy characterized by paracentral steepening and stromal thinning that impairs visual acuity.

Pellucid marginal degeneration is a noninflammatory progressive degenerative disease, typically characterized by bilateral peripheral thinning (ectasia) of the inferior cornea. Deterioration of functional vision results from the irregular astigmatism induced by asymmetric distortion of the cornea, and visual acuity typically cannot be restored by using spherocylindrical lenses.

Treatment

Initial treatment for keratoconus often consists of hard contact lenses. A penetrating keratoplasty (ie, 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 penetrating 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), although, generally, 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 (ICRS) represents an additive technique, in which the implants are intended to reinforce the cornea, prevent further deterioration, and potentially obviate the need for penetrating keratoplasty.

Rigid gas permeable contact lenses may be used to treat pellucid marginal degeneration. ICRS, crescentic lamellar keratoplasty, penetrating keratoplasty, and corneal wedge excision have also been proposed as treatments.

ICRS correct myopia by flattening the center of the cornea and represent an alternative to LASIK and other refractive surgeries. A proposed advantage of ICRS is 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 spectacles or contact lenses.

Intrastromal Corneal Ring Segments

ICRS 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 segments are implanted in each channel, and various implants with a range of 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.

Intacs®, an intrastromal corneal ring, was approved by the U.S. Food and Drug Administration (FDA) for 2 indications. In 1999, Intacs® (KeraVision, now Addition Technology) was approved by FDA through the premarket approval process for the following labeled indication:

"The KeraVision Intacs are intended for the reduction or elimination of mild myopia (-1.00 to -3.00 diopters spherical equivalent at the spectacle plane) in patients:

- Who are 21 years of age or older;
- With documented stability of refraction as demonstrated by a change of less than or equal to 0.50 diopter for at least 12 months prior to the preoperative examination; and
- Where the astigmatic component is +1.00 diopter or less."

In 2004, Intacs® received additional approval by FDA through the humanitarian device exemption process for the following indication:
"This device is indicated for the reduction or elimination of myopia and astigmatism in patients with keratoconus, who are no longer able to achieve adequate vision with their contact lenses or spectacles, so that their functional vision may be restored and the need for a corneal transplant procedure may potentially be deferred. The specific set of keratoconic patients proposed to be treated with Intacs prescription inserts are those patients:

- Who 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;
- Who are 21 years of age or older;
- Who have clear central corneas;
- Who have a corneal thickness of 450 microns or greater at the proposed incision site; AND
- Who have corneal transplantation as the only remaining option to improve their functional vision."

For individuals who have pellucid marginal degeneration who receive ICRS, most case series report have assessed devices not available in the United States. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have astigmatism after penetrating keratoplasty who receive ICRS, the evidence includes a few case series. Two case series used devices not available in the United States. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

Medicare Advantage Plans 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, April 2024
Provider Update, April 2023
Provider Update May 2022
Provider Update, September 2021
Provider Update, June 2020

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