**Preauthorization is not required.**

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>• With keratoconus</td>
<td>• Intrastromal corneal ring segments</td>
<td>• Penetrating keratoplasty</td>
<td>• Change in disease status</td>
</tr>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>• Functional outcomes</td>
</tr>
<tr>
<td>• With pellucid</td>
<td>• Intrastromal corneal ring segments</td>
<td>• Penetrating keratoplasty</td>
<td>• Treatment-related morbidity</td>
</tr>
<tr>
<td>marginal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>degeneration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>• With astigmatism</td>
<td>• Intrastromal corneal ring segments</td>
<td>• Contact lenses or correction with</td>
<td>• Change in disease status</td>
</tr>
<tr>
<td>after penetrating</td>
<td></td>
<td>correction with spectacles</td>
<td>• Functional outcomes</td>
</tr>
<tr>
<td>keratoplasty</td>
<td></td>
<td></td>
<td>• Treatment-related morbidity</td>
</tr>
</tbody>
</table>

**Description**

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 have been investigated as a means of improving vision in diseases such as keratoconus and pellucid marginal degeneration, and for astigmatism following penetrating keratoplasty (PK).

**Summary of Evidence**

For individuals who have keratoconus who receive ICRS, the evidence includes primarily single-institution case series. Relevant outcomes are change in disease status, functional outcomes, and treatment-related morbidity. A number of single-center case series with sample sizes ranging from 19 to 105 eyes have been published. These series have generally reported that a substantial proportion of patients with keratoconus treated with this device have improved vision at one to two years of follow-up. More limited data are available on long-term efficacy. ICRS is associated with a number of adverse events and explantation. The net health outcome is uncertain. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have pellucid marginal degeneration who receive ICRS, the evidence includes a few case series. Relevant outcomes are change in disease status, functional outcomes, and treatment-related morbidity. A small number of case series with fewer than 25 eyes per study have been published on ICRS in patients with pellucid marginal degeneration. Most reports have assessed devices not available in the United States. In one study, which included some patients implanted with Intacs, there was no improvement in uncorrected visual acuity six months after surgery. Moreover, explantation occurred in about 20% of eyes due to visual deterioration. 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. Relevant outcomes are change in disease status, functional outcomes, and treatment-related morbidity. Two case series, with nine and 54 patients, were identified; both used devices not available in the United States. ICRS was associated with adverse events such as extrusion and Descemet membrane detachment. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Policy**

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 vision, such that he or she 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.

Implantation of intrastromal corneal ring segments is considered **not medically necessary** as a treatment of myopia.

Implantation of intrastromal corneal ring segments is considered **investigational** for all other conditions.

**Background**

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 two 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. 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 PK.

Keratoconus is a progressive bilateral dystrophy characterized by paracentral steepening and stromal thinning that impairs visual acuity. Initial treatment often consists of hard contact lenses. A PK (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 PK, 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 ICRS represents an additive technique, in which the implants are intended to reinforce the cornea, prevent further deterioration, and potentially obviate the need for PK.

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. Rigid gas permeable contact lenses may be used to treat pellucid marginal degeneration. ICRS, crescentic lamellar keratoplasty, PK, 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.

Regulatory Status

Intacs®, an intrastromal corneal ring, was approved by the U.S. Food and Drug Administration (FDA) for two 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 the FDA through the humanitarian device exemption (HDE) 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.”
Note: The HDE does not require manufacturers to provide data confirming the efficacy of a device but rather data supporting its “probable” benefit. The HDE process is available for devices treating conditions that affect fewer than 4000 Americans per year.

Intrastromal corneal ring devices available outside of the United States include:

- Intacs SK
- Ferrara intrastromal corneal ring segments
- KeraRing intrastromal corneal ring segments
- MyoRing intracorneal continuous ring

FDA product code: LQE.

Related Protocols

Endothelial Keratoplasty
Keratoprosthesis

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.