Corneal implants

Clinical Policy ID: CCP.1257

Recent review date: 10/2021

Next review date: 2/2023

Policy contains: Corneal ectasia; corneal inlay; intrastromal corneal ring segments; keratoconus.

This policy is a Sandhills Center Clinical Coverage Policy adopted from AmeriHealth Caritas of North Carolina. These clinical policies are used to assist with making coverage determinations. Sandhills Center's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Sandhills Center when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Sandhills Center clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Sandhills Center's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Sandhills Center will update its clinical policies as necessary. Sandhills Center clinical policies are not guarantees of payment.

Coverage policy

Intacs® intrastromal corneal ring segments (Addition Technology, Lombard, Illinois) are clinically proven and, therefore, medically necessary for treatment of keratoconus when **all** of the following criteria are met (American Academy of Ophthalmology, 2017, 2019; National Institute for Health and Care Excellence, 2007; U.S. Food and Drug Administration, 1999a):

- No longer able to achieve adequate functional vision on a daily basis with either contact lenses or eyeglasses.
- Age 21 years or older.
- Clear central corneas.
- Corneal thickness of 450 µ or greater at the proposed incision site.
- Corneal transplantation is the only remaining option to improve functional vision.

Limitations

All other uses of Intacs are not medically necessary because the effectiveness for indications other than keratoconus has not been established.

Absolute contraindications to Intacs implants include but are not limited to (U.S. Food and Drug Administration, 1999a):

- Individuals who have abnormally thin corneas or who have corneal thickness of 449 µ or less at the proposed incision site.

- Individuals with collagen, vascular, autoimmune, or immunodeficiency diseases.
- Women who are pregnant or nursing.
- The presence of ocular conditions, such as recurrent corneal erosion syndrome or corneal dystrophy, which may predispose the individual to future complications.
- Individuals who are taking one or more of the following medications: isotretinoin (Accutane) and amiodarone (Cordarone).

The use of corneal implants for treatment of presbyopia is not medically necessary.

Alternative covered services

- Eyeglasses.
- Contact lenses.
- Contemporary keratoplasty and keratectomy procedures (e.g., penetrating [full thickness] keratoplasty, Lamellar [partial thickness] keratoplasty, endothelial keratoplasty).

Background

The cornea is the clear, dome-shaped outermost layer of the eye and a key refractive element of the eye (National Eye Institute, 2019a). It is a highly organized tissue arranged in three basic layers with two thinner membranes between them. The stroma is the thickest, strongest layer of the cornea. For optimal vision, all layers of the cornea must be of normal shape and curvature and free of any cloudy or opaque areas.

Corneal ectasia is an abnormal thinning of the cornea. It can result in permanent eye damage and varying degrees of functional disability (National Eye Institute, 2019b). Causes include primary disease conditions (e.g., keratoconus and pellucid marginal corneal degeneration) or surgically induced thinning and protrusion (e.g., after laser-assisted in situ keratomileusis [LASIK] refractive surgery). Keratoconus is a rare condition with an early age of onset (median age of 25 years) and is the most common corneal thinning disorder.

The rationale for treatment depends on disease severity and the amount of vision loss (National Eye Institute, 2019). When eyeglasses and/or contact lenses can no longer correct vision or be tolerated, surgical options (e.g., keratectomy and keratoplasty) may be considered. Corneal transplant may be indicated as a final option. Despite high graft survival rates of up to 20 years, transplant surgery requires a lengthy recovery time. In addition, corneal transplant is donor-limited and associated with potential complications from long-term steroid use following surgery, the risk of developing secondary conditions (e.g., cataracts and glaucoma) needing intervention, and residual refractive errors and astigmatism.

Corneal implants

Corneal implants (also called corneal inlays or intracorneal implants) have emerged as a treatment option for corneal ectasia. Corneal implants are small segments of rings or full rings of synthetic material implanted in the corneal stroma to normalize corneal surface topography, improve contact lens tolerability, and restore visual acuity to delay or defer the need for corneal transplant. Implant placement is a minimally invasive procedure usually performed by either corneal specialists or refractive surgeons in the outpatient setting with topical anesthesia. The implants are adjustable and reversible and do not limit the performance of subsequent surgical approaches or interfere with corneal transplant. Typically one is implanted in the nondominant eye.

The U.S. Food and Drug Administration (1999a, 2015, 2016a, 2018, 2019) has approved three premarket approval applications (product code LQE) for corneal implants for commercial use in the United States. They are:

- Intacs corneal implants/prescription inserts — Intrastromal corneal ring segments indicated for the reduction or elimination of mild myopia (-2.00 to -3.00 diopters (d) spherical equivalent at the spectacle plane) in patients: who are age 21 years or older; with documented stability of refraction as demonstrated by a change of ≤0.50 d for at least 12 months prior to the preoperative examination; and where the astigmatic components are +1.00 d or less. Intacs was approved through a Humanitarian Device Exemption in 2004 for use in patients with keratoconus whose corneas are not scarred, when spectacles and contact lenses no longer provide adequate visual correction.
- KAMRA® inlay (AcuFocus™, Inc., Irvine, California) — A dark, ring-shaped device indicated for intrastromal corneal implantation to improve near vision by extending the depth of focus in the nondominant eye of phakic, presbyopic patients between the ages of 45 and 60 years who have cycloplegic refractive spherical equivalent of +0.50 d to -0.75 d with ≤ 0.75 d of refractive cylinder, who do not require glasses or contact lenses for clear distance vision, and who require near correction of +1.00 d to +2.50 d of reading add.
- Raindrop® Near Vision Inlay (REVISION OPTICS, Inc., Forest, California) — A biocompatible hydrogel corneal inlay indicated for intrastromal implantation to improve near vision in the nondominant eye of phakic, presbyopic patients, 41 to 65 years of age, who have manifest refractive spherical equivalent of +1.00 d to -0.50 d with ≤ 0.75 d of refractive cylinder, who do not require correction for clear distance vision, but who do require near correction of +1.50 d to +2.50 d of reading add. In October 2018, Raindrop was withdrawn from the market due to an increased risk of corneal haze with device use.

Findings

For this policy, we identified two systematic reviews (Fischer, 2015; Health Quality Ontario, 2009); two individual studies (Dexl, 2015; Whitman, 2016) not included in the systematic reviews; and three evidence-based guidelines (American Academy of Ophthalmology, 2013a, 2013b; National Institute for Health and Care Excellence, 2007). In addition, we added three Summary of Safety and Effectiveness data reports that provided the basis for U.S. Food and Drug Administration pre-market approval and product labeling instructions for the three corneal implant devices (U.S. Food and Drug Administration, 1999b, 2014, 2016b).

The evidence consists of uncontrolled longitudinal cohort studies and small case series. Direct comparisons to other treatment alternatives or to no treatment are lacking. Overall, the evidence suggests corneal implants offer clinically significant improvements in corneal topography, refraction, and visual acuity. The major safety concerns include corneal perforation, infection, corneal infiltrates, corneal neovascularization, ring migration and extrusion, and corneal thinning. Reported complications were generally minor, reversible, and attributable to early surgeon experience. Treatment may result in an over- or under-correction of refraction and may induce astigmatism or asymmetry of the cornea. Other reasons for treatment failure or patient dissatisfaction include foreign body sensation and unsatisfactory visual quality with symptoms such as double vision, fluctuating vision, poor night vision, or visual side effects related to ring edge or induced or unresolved astigmatism.

There is sufficient evidence and clinical experience to support intrastromal corneal ring segments (Intacs) as treatment for progressing keratoconus, and available guidelines concur. The National Institute for Health and Care Excellence (2007) recommended intrastromal corneal ring segments for treatment of progressive keratoconus and pellucid marginal degeneration. The American Academy of Ophthalmology (2013a) recommended intrastromal corneal ring segments implantation as a surgical option to improve contact lens tolerance and best-corrected visual acuity for patients with keratoconus, a clear cornea, and contact lens intolerance. Contraindications to intrastromal corneal ring segments implantation include central corneal scarring and a corneal thickness of less than 400 µ at the incision site.

Progression of keratoconus is an indication for corneal transplant. While no study has compared the outcomes of Intacs to corneal transplant in this population, Intacs is advantageous for its ability to be removed or exchanged to improve vision without limiting subsequent interventions, particularly corneal transplant. Both eyes can be treated at once, and the treatment is adjustable and reversible. In the presence of limited corneal donors, Intacs may be considered an alternative to defer or defray corneal transplant.

For other indications, early studies reported on the safety and effectiveness of intrastromal corneal ring segments for myopia in normal eyes, but LASIK has emerged as the preferred approach (American Academy of Ophthalmology, 2013b). Intrastromal corneal ring segments are now rarely used to correct myopia (American Academy of Ophthalmology, 2013a, 2013b).

The evidence supporting intrastromal corneal ring segments for off-label indications such as rescue treatment for post-LASIK corneal ectasia, refractive errors following corneal transplant or combined with other surgeries, is far more limited, and long-term outcomes are lacking. Furthermore, the narrow range of approved correction specified by the U.S. Food and Drug Administration and inability to correct astigmatism limit the application of intrastromal corneal ring segments after refractive surgery (American Academy of Ophthalmology, 2013a, 2013b).

For surgical management of presbyopia, there is strong evidence to support keratorefractive surgery for monovision or intraocular lens implantation as the preferred surgical options (American Academy of Ophthalmology, 2013b). Limited experience with the KAMRA intrastromal ring and Raindrop hydrogel inlay suggests these implants may grow in popularity for persons with presbyopia who desire spectacle-free living. KAMRA and Raindrop implants are not approved for any other indication.

The evidence is insufficient to conclude that emerging alternative treatment strategies, such as collagen cross-linking aimed at strengthening the underlying corneal tissue, might prove more effective or increase the effectiveness of the implants, particularly in advances stages of corneal thinning.

In 2017, we found one updated practice recommendation (American Academy of Ophthalmology, 2013a, updated 2016), but there were no changes to their conclusions. No policy changes are warranted at this time.

In 2018, we updated two updated guidelines by the American Academy of Ophthalmology (2017a, 2017b) and one retrospective case series with long-term follow up in 14 pediatric patients who underwent implantation with Intacs for keratoconus (Abreu, 2018). The results suggest Intacs may be an inadequate treatment in pediatric populations, as keratoconus is more aggressive in pediatric cases than in adults with corresponding higher rates of treatment failure, and regulatory criteria have not changed. Raindrop was withdrawn from the market due to an increased risk of corneal haze with device use (U.S. Food and Drug Administration, 2019). No policy changes are warranted. The policy ID was changed from CP# 10.03.06 to CCP.1257.

In 2019, we updated an American Academy of Ophthalmology Preferred Practice Pattern on Cornea/External Disease (2018) and added one systematic review of intrastromal corneal ring implantation in adults with keratoconus (Izquierdo, 2019) and one narrative review of the management of keratoconus in children (Mukhtar, 2018). The new information confirms previous findings and warrants no policy changes.

In 2020, we updated one professional guidance from the American Academy of Ophthalmology (2019) on corneal/external disease and added one systematic review (Bautista-Llamas, 2019) of 39 low-quality studies examining complications and explantation rates after intracorneal ring segment implantation. The new results confirm previous findings and warrant no policy changes.

In 2021, we added a retrospective case series of 659 patients (932 total eyes) who underwent Intacs implantation for keratoconus between September 1997 and November 2017 (Warrak, 2020). The mean total follow up time was three years. Intacs implantation showed long-term improvement and stability in visual and topographic outcomes. In patients under 35 years of age, keratoconus progressed in 2.66% of eyes. No policy changes are warranted.

References

On July 21, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “keratoconus,” “myopia,” “presbyopia,” “nearsighted,” “astigmatism,” “corneal ring,” “corneal inlay,” “Intacs,” “KAMRA,” and “keravision.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-

analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

8/2016: initial review date and clinical policy effective date: 10/2016

8/2017: Policy references updated.

10/2018: Policy references updated. Policy ID changed.

10/2019: Policy references updated.

10/2020: Policy references updated.

10/2021: Policy references updated.