MEDICAL POLICY

POLICY TITLE	**IMPLANTATION OF INTRASTROMAL CORNEAL RING SEGMENT (FORMERLY CORNEAL SURGERY, IMPLANTATION OF INTRASTROMAL CORNEAL RING SEGMENT AND CORNEAL TOPOGRAPHY/ PHOTOKERATOSCOPY)**
POLICY NUMBER	**MP 1.044**

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**RETIRED 9/1/2026**

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 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.

Intrastromal corneal ring implant (i.e., Intac Prescription Inserts) is considered **investigational** as a treatment of myopia. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure

Intrastromal corneal ring segments are considered **investigational** for all other conditions, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-References:

MP 2.028 Eye Care
MP 6.031 Gas Permeable Scleral Contact Lens and Therapeutic Soft Contact Lens
MP 5.062 Computer Assisted Corneal Topography
MP 9.011 Corneal Surgery

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PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO – Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

DESCRIPTION/BACKGROUND

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Implantation of Intrastromal Corneal Ring Segments

Intrastromal corneal ring segments are composed of micro-thin, 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. 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 functional vision. If required, the implants can be removed or replaced.

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 (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 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.

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 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.

RATIONALE

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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 1 to 2 years of follow-up. More limited data are available on long-term efficacy. ICRS is associated with a number of adverse events and explantation. Although, a single case series of 572 eyes have suggested that risk of explantation may be modest (6.1%). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 evaluated 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 6 months after surgery. Moreover, explantation occurred in about 20% of eyes due to visual deterioration. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 9 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 that the technology results in an improvement in the net health outcome.

DEFINITIONS

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CORNEA is the transparent anterior portion of the sclera (the fibrous outer layer of the eyeball), about one sixth of its surface: the first part of the eye that refracts light.

DISCLAIMER

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Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as required by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These polices are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes								
65785								

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Implantation of Intrastromal Corneal Ring Segments

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POLICY HISTORY TOP

MP 1.044	**02/17/2020 Consensus Review.** Policy statement unchanged. References reviewed.
	09/02/2020 Administrative Update. ICD10 codes added, H18.501, H18.502, H18.503, H18.509, H18.511, H18.512, H18.513, H18.519, H18.521, H18.522, H18.523, H18.529, H18.531, H18.532, H18.533, H18.529, H18.541, H18.542, H18.543, H18.549, H18.551, H18.552, H19.553, H18.559, H18.591, H18.592, H18.593, H18.599
	04/16/2021 Consensus Review. No change to policy statement. References reviewed and updated. No coding changes.
	06/10/2022 Consensus Review. Policy statements unchanged. FEP language revised. References updated.
	05/02/2023 Consensus Review. No change to policy statement. Background, Rationale and References updated. Removed outdated ICD10 codes H18.50, H18.51, H18.52, H18.53, H18.54, H18.55, H18.59.
	05/15/2024 Consensus Review. No change to policy statement. Background, references updated. Added ICD10 codes H18.711- H18.719, and S05.00XA-S05.02XS to list of covered diagnoses.

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POLICY NUMBER	**MP 1.044**

	04/24/2025 Major Review. Policy now only speaks to intrastromal corneal ring segments. Corneal surgery and corresponding codes moved to MP 9.011, and computer assisted corneal topography and code move to MP 5.062.
	08/13/2025 Administrative Update. Removed Benefit Variations Section and updated Disclaimer.
	05/07/2026 Retirement Review.