# Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/25**
**(See policy history boxes for previous effective dates)**

# Title: Refractive Keratoplasties, Phototherapeutic Keratectomy and Implantation of Intrastromal Corneal Ring Segments

## Description/Background

Refractive keratoplasty is a broad term that includes all surgical procedures on the cornea to improve vision by changing the refractive index of the corneal surface. Refractory errors include myopia, hypermyopia/hyperopia, presbyopia and astigmatism. Refractive keratoplasties used to correct refractory errors include a number of different surgeries:

- ***Automated Lamellar Keratoplasty (ALK)*** can correct hyperopia. For the treatment of moderate farsightedness, the cornea is opened across the top to form a type of "cap," using an automated instrument. When the "cap" is positioned back into its original location on top of the eye, microscopic scar tissue is formed, causing the "cap" to bulge out, thus correcting the overly flattened cornea that is associated with hyperopia. Almost like Velcro, the cornea and "cap" adhere to each other, eliminating the need for sutures. Normally, one eye is treated at a time, with about 3 to 4 weeks allowed between each eye surgery. To ease any discomfort, the eye is anesthetized with special drops, and the patient is given a mild sedative to remain relaxed and aware throughout the procedure.

- ***Clean Lens Extraction (CLE) Phacoemulsification*** of the lens with intraocular lens implantation (also called clear lens (CLE) extraction) has been proposed as an alternative to corneal refractive surgery in patients with moderate to severe hyperopia or high myopia (nearsightedness). The surgeon first makes a small incision at the edge of the cornea and then creates an opening in the membrane that surrounds the cataractous lens. This thin membrane is called the capsule. A small ultrasonic probe is inserted through the opening in the cornea and capsule. The probe's vibrating tip breaks up or "emulsifies" the cloudy lens into tiny fragments that are suctioned out of the capsule by an attachment on the probe tip. After the lens is completely removed, the probe is withdrawn, leaving only the clear (now empty) bag-like capsule, which will act as support for the intraocular lens (IOL).

- ***Hexagonal Keratotomy*** is a form of refractive corneal surgery used to treat naturally occurring hyperopia (far-sightedness) and presbyopia (loss of accommodation in the eyes in advancing age) following radial keratotomy. A hexagonal pattern of intersecting incisions in the cornea is used in performing this procedure.

- ***Intrastromal corneal ring segments*** (brand name ***Intacs®***) consist of micro-thin methylmethacrylate inserts of variable thickness that are placed circumferentially into two-thirds depth of the peripheral corneal stroma. They have been investigated as a refractive surgery to correct mild myopia and as a treatment of keratoconus. In myopia, the intrastromal inserts correct myopia by flattening the center of the cornea and represent an alternative to laser in situ keratomileusis (LASIK) and other refractive surgeries. Keratoconus causes the cornea to become cone shaped and thinner, disrupting the visual function. Intacs® can reshape the curvature of the cornea from within, enhancing the natural shape of the eye. As no tissue is removed, natural optics are enhanced which adds to the structural integrity of the cornea.

  For patients with keratoconus whose vision is no longer correctable with glasses and who cannot tolerate contact lenses because of the distortion of the corneal shape, corneal transplant is the usual standard of care. The use of Intacs® in such patients has become a viable option to delay or avoid corneal transplant.

- ***Laser-assisted sub-epithelial keratomileusis (LASEK)*** is the detachment of the epithelium with the use of an alcohol solution that softens the epithelium and allows it to be rolled back into a flap. The flap of epithelium is then repositioned over the cornea following excimer ablations. LASEK is a recent modification of PRK that attempts to preserve the epithelium.

- ***Laser-Assisted in Situ keratomileusis (LASIK)*** is a procedure that permanently changes the shape of the cornea. A knife, called a microkeratome, is used to cut a flap in the cornea. A hinge is left at one end of this flap. The flap is folded back revealing the stroma, the middle section of the cornea. Pulses from a computer-controlled laser vaporize a portion of the stroma and the flap is replaced.

- ***Minimally Invasive radial keratotomy (mini-RK)*** is intended to be used in cases of myopia to alter the cornea's shape and consequently the refraction by reducing the millimeters of cornea that are incised.

- ***Photorefractive Keratectomy (PRK)*** uses a computerized laser to correct myopia. The excimer laser is well suited for cornea reshaping, because the removal of just tiny amounts of tissue can produce the results needed to correct nearsightedness. The excimer laser produces a beam of ultraviolet light in pulses that last only a few billionths of a second. Each pulse removes a microscopic amount of tissue by evaporating it, producing very little heat and usually leaving underlying tissue almost untouched. Overall, the surgery takes approximately 10–20 minutes; however, the use of the laser beam lasts only 15–40 seconds.

- ***Phototherapeutic Keratectomy (PTK)*** uses the excimer laser to treat visual impairment or irritative symptoms relating to diseases of the anterior cornea by sequentially ablating uniformly thin layers of corneal tissue. Phototherapeutic keratectomy must be distinguished

from photorefractive keratectomy, which involves the use of the excimer laser to correct refractive errors of the eye. (i.e., myopia, astigmatism, hyperopia and presbyopia).

- ***Radial Keratotomy (RK)*** *is a surg*ical correction for myopia (nearsightedness). Using a high-powered microscope, the physician places microincisions (usually eight or fewer) on the surface of the cornea in a pattern much like the spokes of a wheel. The incisions are very precise in terms of depth, length and arrangement. The microincisions allow the central cornea to flatten, thus reducing the convexity of the cornea, which produces an improvement in vision.

**All of the above procedures can be used alone or in combination to produce optimal results.** Other procedures that are used to correct vision include:

- ***Epikeratophakia*** (epikeratoplasty, lamellar keratoplasty) involves suturing a pre-lathed donor cornea onto the surface of the recipient's cornea. This surgery has been proposed as a means of correcting adult and pediatric aphakia (aphakia is the absence of the lens of the eye), keratoconus (a conical protrusion of the cornea) and myopia. As a treatment of myopia, this technique has been largely abandoned because of its lack of predictability and poor results.

- ***Keratomileusis*** involves removing, freezing and lathing the patient's cornea, followed by its replacement onto the corneal bed. This surgery has been proposed for myopia and aphakic hyperopia.

- ***Keratophakia*** involves removing the patient's cornea followed by placement of a lathed donor cornea beneath the recipient's cornea, which is then reattached. This surgery has been proposed for aphakic hyperopia.

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## Regulatory Status

In 2004, Intacs® received 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: HDE does not require the manufacturer to provide data confirming the efficacy of the device but rather data supporting its "probable" benefit. The HDE process is available for devices treating conditions that affect fewer than 4,000 Americans per year.

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## Medical Policy Statement

Epikeratophakia (donor cornea is transplanted onto the anterior surface of the recipient's cornea) for the treatment of aphakia (absence of the eye lens) is an established procedure. It may be a useful therapeutic option when indicated.

Refractive procedures mentioned in this policy may be considered cosmetic and not medically necessary when used to correct myopia (nearsightedness), hyperopia (farsightedness), astigmatism (imperfection in the curvature of the cornea), or presbyopia (gradual loss of ability to focus on nearby objects, acquired with age). Individual contract language will apply.

Implantation of intrastromal corneal ring segments (Intacs®) is established for the treatment of keratoconus (cornea thins and begins to bulge into a cone-like shape). It may be a useful therapeutic option when indicated.

Implantation of intrastromal corneal ring segments (Intacs®) for the treatment of myopia (nearsightedness) is not medically necessary.

Keratophakia (placement of a donor cornea under the recipient's cornea) is experimental/investigational. It has not been scientifically demonstrated to be as safe and effective as conventional treatment.

Phototherapeutic keratectomy for treatment of recurrent corneal erosions is an established procedure. It may be a therapeutic useful option when indicated.

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## Inclusionary and Exclusionary Guidelines

**Inclusions:**

- Epikeratophakia (donor cornea is transplanted onto the anterior surface of the recipient's cornea) for the treatment of aphakia (absence of the eye lens)
- Implantation of intrastromal corneal ring segments (Intacs®) for the treatment of keratoconus (cornea thins and bulges like a cone) is appropriate when ALL of the following criteria are met:
  - The patient has experienced a deterioration in their vision
  - Corneal transplantation is the only alternative to improve their functional vision;
  - The patient has a clear central cornea with a corneal thickness of 450 microns or greater at the proposed incision site
- Phototherapeutic keratectomy is an established surgical modality for treatment of recurrent corneal erosions when non-operative methods have failed.

**Exclusions:**

- Refractive keratoplasty procedures for indications not listed above, including those that are cosmetic in nature
- Implantation of intrastromal corneal ring segments (Intacs®) for the treatment of myopia (nearsightedness) and all other conditions not listed above.
- Keratophakia (placement of a donor cornea under the recipient's cornea)
- Phototherapeutic keratectomy for indications not listed above, including those that are cosmetic in nature

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## CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

### *Established codes:*

| | | | | |
|---|---|---|---|---|
| 65710 | 65767* | 65785** | L8699** | S0812 |

* Established for the diagnosis of aphakia (absence of the eye lens)
**Established for the diagnosis of keratoconus only

### *Other codes (investigational, not medically necessary, etc.):*

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|---|---|---|---|---|---|
| 65760 | 65765 | 65770 | 65771 | 65772 | 65775 |
| 66999** | S0800 | S0810 | | | |

*** This code is to be used when billing for the following procedures:*

- Minimally invasive radial keratotomy or mini-RK
- Hexagonal keratotomy

*Note: The code(s) listed above may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.*

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## Rationale

Refractive keratoplasty describes various procedures that modify the shape of the eye. When the shape of the eye, corneal discrepancies or aging of the lens interferes with bending light correctly (refractive error), blurred images are a result. Myopia (nearsightedness), hyperopia (farsightedness), presbyopia (loss of near vision with age) and astigmatism are the primary types of refractive errors. Corrective lenses (eyeglasses or contact lenses) provided the safest avenue for vision correction as they are not associated with medical complications when used as directed.

Refractive surgery aims to change the shape of the cornea permanently. Motives for seeking out refractive keratoplasty generally revolve around cosmetic issues and the desire to reduce dependency on eyeglasses or contact lenses. Refractive keratoplasty carries risk and therefore is promoted after conservative (eyeglasses and contact lenses) or medical therapy have failed. Certain cases of repair following surgically induced- or traumatic injury, aphakia, or keratoconus may be the exception.

**Intrastromal Corneal Ring Segments**
According to a Cochrane review by Zadnik et al (2019), there are no published RCTs of intrastromal corneal ring segments for treating keratoconus. The published data on Intacs for keratoconus consists of single-institution case series, many of which used the device commercially available in the United States. Sample sizes ranged from 19 to 105 eyes. Findings from a systematic review of case series by Izquierdo et al (2019) (N=1325 eyes) indicated that intrastromal corneal ring implantation improved uncorrected distance visual acuity (0.23 ± 0.28, Logarithm of the Minimum Angle of Resolution) and corrected distance visual acuity (0.06 ± 0.21, Logarithm of the Minimum Angle of Resolution) at 12 months. Additionally, these case series have indicated that a substantial proportion of patients with keratoconus treated with this device have improved vision at one to two years of follow-up. Most studies have reported improvements (in uncorrected or corrected visual acuity) in at least 75% to 80% of patients in whom changes in two to three lines of corrected or uncorrected visual acuity were considered a success. Approximately 10% of patients required a second procedure because of an unsatisfactory initial result.

One of the larger studies was published by Colin and Malet (2007). They reported on two-year follow-up from a prospective, single-center European study in 100 eyes with keratoconus (82 consecutive patients) and Intacs implantation. Patients had been referred for a penetrating keratoplasty procedure due to contact lens intolerance for correction of myopia and irregular astigmatism. Intacs inserts were removed from four (4%) eyes due to poor visual outcome or extrusion, and 14 eyes were lost to follow-up. Of the 82 remaining eyes (68 patients), both corrected and uncorrected visual acuity remained relatively stable between one and two years of follow-up.

Studies with five years of follow-up include Bedi et al (2012). They evaluated the risk of keratoconus progression in a study of 105 consecutive eyes (85 patients) that had undergone Intacs implantation. At the one-year follow-up, 1 eye had extrusion and 12 (11.4%) had undergone removal of Intacs because of unsatisfactory results; these eyes were managed by penetrating or deep lamellar keratoplasty. Of the 105 eyes, 80% retained the Intacs implant and showed no keratoconus progression over five years of follow-up. In addition, Vega-Estrada et al (2013) reported that, in a series of 51 eyes, the improvement in vision obtained at six months after Intacs implantation was maintained out to five years postoperatively. However, the analysis only included cases without significant changes in corneal topography over the 12 months prior to surgery. Kymionis et al (2007) reported on five-year follow-up on 28 patients (36 eyes) who had initially participated in a clinical trial evaluating the safety and efficacy of Intacs implantation in patients with keratoconus. In five patients (seven eyes), the Intacs segments were removed due to patient dissatisfaction. Five-year follow-up was reported for 17 (59%) eyes. Refractive stability was obtained at the six-month follow-up and remained stable throughout the five-year follow-up.

**Summary:**
A number of single-center case series with sample sizes ranging from 19 to 105 eyes have been published. The 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. However, data are available on treatment efficacy and adverse events in the long-term is more limited.

Approval by the FDA for the Intacs® device was based on the results of a multi-institutional study involving 361 subjects with mild myopia. Subsequently, the two-year results of this study were published in the peer-reviewed literature. These data suggested that the intrastromal rings predictably and effectively reduced or eliminated mild myopia (-1.00 to -3.00 diopter) and that the refractive effect was stable over time. However, mild myopia is effectively treated with either spectacles or contact lenses. Therefore, this application of Intacs is considered not medically necessary.

**Recurrent Corneal Erosion Syndrome**
Recurrent corneal erosion syndrome is a common clinical disorder involving the corneal epithelium and epithelial basement membrane. The disorder is characterized by the repeated breakdown of epithelium, causing moderate to severe eye pain, photophobia, lacrimation, and corneal scarring leading to visual changes. Patients are often debilitated by the resulting pain and visual deficits and are frustrated by the lack of response to treatment. The usual causes are trauma, epithelial basement membrane dystrophy, and a combination of trauma and epithelial basement membrane dystrophy.

Trauma includes mechanical trauma to the corneal surface, the subsequent inflammation from which can cause disruption in the extracellular adhesion in the corneal epithelium.
Patients with epithelial basement membrane dystrophy, a congenital condition, have an anterior epithelium that does not adhere well to the basement membrane due to morphological changes in the epithelial cells or basement membrane matrix, which creates a loose epithelial layer prone to shifting and tearing when damaged.

Treatment includes medical methods of eye lubrication (artificial tears with a lubricating ointment), antibiotic/pain medications, bandage, soft contact lenses and combination of the above modalities. Patients often require repeated visits to their ophthalmologists. There are many treatment options for recurrent corneal erosion syndrome, each of which has varying degrees of efficacy. Due to the apparent risks, surgery should be reserved for patients who have failed aggressive medical therapies. It should not be performed as an initial form of treatment. Surgical methods include debridement/superficial keratectomy and phototherapeutic keratectomy (PTK).

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## Supplemental Information

**PRACTICE GUIDELINES AND POSITION STATEMENTS**
The National Institute for Health and Care Excellence issued guidance in 2007 on corneal implants for keratoconus. The guidance, based on nine case series, a nonrandomized controlled trial, and specialists' opinions, concluded that "[c]urrent evidence on the safety and efficacy of corneal implants for keratoconus appears adequate to support the use of this procedure…."

## Government Regulations

## National Coverage Determination:

Longstanding: "**Refractive Keratoplasty",** Pub 100-3, V.1 Sec. 80.7; Effective date 5/1/97.

**Indications and Limitations of Coverage**

The correction of common refractive errors by eyeglasses, contact lenses or other prosthetic devices is specifically excluded from coverage. The use of radial keratotomy and/or keratoplasty for the purpose of refractive error compensation is considered a substitute or alternative to eye glasses or contact lenses, which are specifically excluded by §1862 (a)(7) of the Act (except in certain cases in connection with cataract surgery). In addition, many in the medical community consider such procedures cosmetic surgery, which is excluded. Therefore, radial keratotomy and keratoplasty to treat refractive defects are not covered.

The use of lasers to treat ophthalmic disease constitutes ophthalmologic surgery. Coverage is restricted to practitioners who have completed an approved training program in ophthalmologic surgery.

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*

## Related Policies

- Corneal Collagen Cross-linking
- Femtosecond Laser in Keratoplasty

## References


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*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through July 2024, the date the research was completed.*

## Joint BCBSM/BCN Medical Policy History

| Policy Effective Date | BCBSM Signature Date | BCN Signature Date | Comments |
|---|---|---|---|
| 4/24/02 | 4/24/02 | 4/24/02 | Joint policy established |
| 11/7/02 | 11/7/02 | 10/17/02 | Criteria revised |
| 11/18/03 | 11/18/03 | 11/18/03 | Policy retired |
| 8/25/05 | 8/25/05 | 8/27/05 | Policy reactivated; added information regarding the FDA humanitarian device approval for Intacs® for the treatment of keratoconus |
| 11/1/07 | 8/21/07 | 10/30/07 | Routine maintenance |
| 11/1/10 | 8/17/10 | 8/17/10 | Routine maintenance; combined information on policy titled “Insertion of Intracorneal Ring Segments” into this policy so it could be moved to “replaced.” |
| 3/1/13 | 12/11/12 | 12/31/12 | Routine maintenance; revised Medical Policy Statement, Inclusions/Exclusions, and Rationale sections for better clarity; updated Regulatory Status section |
| 9/1/14 | 6/20/14 | 6/23/14 | Routine maintenance |
| 1/1/16 | 10/13/15 | 10/27/15 | Routine maintenance |
| 1/1/17 | 10/11/16 | 10/11/16 | Routine maintenance<br>Deleted CPT code 0099T; added CPT code 65785 |
| 1/1/18 | 10/19/17 | 10/19/17 | • Routine maintenance<br>• Correction: procedure code 65767 moved under established code section per Inclusion/exclusion criteria<br>• Background paragraph added distinguishing PTK from PRK<br>• Terms in MPS and Inclusion/Exclusion criteria clarified |
| 1/1/19 | 10/16/18 | 10/16/18 | • Routine maintenance |

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|---|---|---|---|
| 1/1/20 | 10/15/19 | | • Incorporation of PTK for corneal erosion – S0812 moved to EST<br>• Title updated to include Phototherapeutic Keratectomy<br>Clarification of inclusions<br>• Under intrastromal rings, removal of reference to progressive keratoconus and failure of conservative therapy (glasses and contacts) |
| 1/1/21 | 10/20/20 | | • Routine maintenance |
| 1/1/22 | 10/19/21 | | • Routine maintenance |
| 1/1/23 | 10/18/22 | | • Routine maintenance (ky) |
| 1/1/24 | 10/17/23 | | • Routine maintenance<br>• Vendor: NA (ky) |
| 1/1/25 | 10/15/24 | | • Routine maintenance<br>• Vendor: N/A (ky) |

Next Review Date: 4th Qtr, 2025

# BLUE CARE NETWORK BENEFIT COVERAGE
# POLICY: REFRACTIVE KERATOPLASTIES, PHOTOTHERAPEUTIC KERATECTOMY AND IMPLANTATION OF INTRASTROMAL CORNEAL RING SEGMENTS

## I. Coverage Determination:

| | |
|---|---|
| **Commercial HMO (includes Self-Funded groups unless otherwise specified)** | Covered; criteria apply |
| **BCNA (Medicare Advantage)** | Refer to the Medicare information under the Government Regulations section of this policy. |
| **BCN65 (Medicare Complementary)** | Coinsurance covered if primary Medicare covers the service. |

## II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.