Medical Coverage Policy

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Coverage Policy Number..... 0141

Corneal Remodeling for Refractive Errors

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Related Coverage Resources

Intraocular Lens Implant

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses procedures used specifically for the correction of refractive errors (i.e., myopia [nearsightedness], hyperopia [farsightedness], presbyopia [loss of near vision with age], and astigmatism).

This policy is not intended to address corneal procedures, including corneal transplantation, performed for the treatment of eye diseases.

Coverage Policy

Coverage for services for or related to routine refraction and the surgical treatment of refractive errors varies across plans. Please refer to the customer's benefit plan document for coverage details.

If coverage is available for services for or related to routine refraction and the surgical treatment of refractive errors, the following conditions of coverage apply.

Corneal Relaxing Incisions

Correction of surgically-induced astigmatism 3.00 diopters (D) or greater with a corneal relaxing incision (CPT® code 65772) post-cataract or post-corneal transplant surgery is considered medically necessary in an individual who is intolerant of glasses or contact lenses.

Corneal relaxing incision (CPT® code 65772) is considered not medically necessary for any other indication.

Intrastromal Corneal Ring Segments

The insertion of intrastromal corneal ring segments (CPT® code 65785) (i.e., INTACS® prescription inserts) is considered medically necessary when provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA) for the treatment of myopia and astigmatism in individuals with keratoconus who meet ALL of the following criteria:

- progressive deterioration in vision, such that adequate functional vision on a daily basis with contact lenses or spectacles can no longer be achieved
- age 21 years of age or older
- clear central corneas
- corneal thickness of 450 microns or greater at the proposed incision site
- corneal transplantation is the only other remaining option for improving functional vision

Intrastromal corneal ring segments (CPT® code 65785) (e.g., INTACS® prescription inserts) are considered not medically necessary for any other indication.

Other Procedures

Each of the following procedures is considered not medically necessary when performed solely for the treatment of refractive errors:

- conductive keratoplasty (CPT® code 66999)
- lamellar keratoplasty (non-penetrating keratoplasty) (CPT® codes 65710; 66999)
- laser thermokeratoplasty (LTK) (CPT® code 66999)
- limbal relaxing incisions for non-surgically induced astigmatism (CPT® code 66999)
- penetrating keratoplasty (PK) (corneal transplantation, perforating keratoplasty) (CPT® code 66999)

Each of the following refractive procedures is considered experimental, investigational or unproven:

- automated lamellar keratomileusis (ALK) (i.e. standard keratomileusis) (CPT® code 65760)
- corneal allogenic intrastromal ring segments (CAIRS) (CPT® code 65785)
- corneal inlay (CPT® code 66999)
- corneal tissue addition keratoplasty (CTAK) (CPT® code 65710)
- hexagonal keratotomy (CPT® code 66999)
- laser epithelial keratomileusis (LASEK) (CPT® code 66999)
- minimally-invasive radial keratotomy (mini-RK) (CPT® code 66999)
- scleral expansion surgery (CPT® code 66999)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Corneal Relaxing Incisions

CPT®* Codes	Description
65772	Corneal relaxing incision for correction of surgically induced astigmatism

Intrastromal Corneal Ring Segments

CPT®* Codes	Description
65785†	Implantation of intrastromal corneal ring segments

†**Note: Considered Experimental/Investigational/Unproven when used to report corneal allogenic intrastromal ring segments (CAIRS).**

Considered Not Medically Necessary when used to report correction of refractive errors:

CPT®* Codes	Description
65710†	Keratoplasty (corneal transplant); anterior lamellar
66999	Unlisted procedure, anterior segment of eye

†Note: Considered Experimental/Investigational/Unproven when used to report corneal tissue addition keratoplasty (CTAK).

Considered Experimental/Investigational/Unproven when used to report correction of refractive errors:

CPT®* Codes	Description
65710†	Keratoplasty (corneal transplant); anterior lamellar
65760	Keratomileusis
65785††	Implantation of intrastromal corneal ring segments
66999	Unlisted procedure, anterior segment of eye

†Note: Considered Not Medically Necessary when used to report lamellar keratoplasty (non-penetrating keratoplasty) solely for the treatment of refractive errors.

††Note: Considered Medically Necessary when used to report intrastromal corneal ring segments (i.e., INTACS® prescription inserts).

General Background

In the normal eye, both the cornea and lens function to refract (bend) light rays and focus them on the retina to produce clear images. When there is a defect in the shape of the eyeball, cornea, or lens, light entering the non-accommodating eye does not focus on the retina. This causes blurry vision, and is known as a refractive error (or ametropia).

Refractive errors include myopia, or nearsightedness; hyperopia, or farsightedness; astigmatism, where an uneven curvature of the cornea blurs vision for both near and far objects; and presbyopia, which is associated with aging and loss of flexibility of the lens, limiting the ability of the eye to change its point of focus from far to near.

Corneal ectasia, also known as keratectasia or iatrogenic keratoconus, is caused by irregularities in the cornea that lead to disturbances of vision due to astigmatism. The term corneal ectasia can refer to a group of conditions, most notably keratoconus, but can also be related to irregular astigmatism that can develop after an individual undergoes refractive surgery (such as laser in situ keratomileusis [LASIK] or photorefractive keratectomy [PRK]). Keratoconus is a non-inflammatory degenerative condition in which collagen fibers within the cornea weaken and progressively thin. As a result, the thinning the fibers can no longer maintain the normal round shape of the cornea. Consequently, the cornea bulges outward, steepens and develops a progressive conical shape. This abnormality prevents light that is entering the eye from focusing directly on the retina, resulting in irregular astigmatism and progressive myopia or visual loss (American Academy of Ophthalmology [AAO], 2023).

Surgical Treatment of Refractive Errors
The need to correct refractive errors depends on the individual's symptoms and visual needs. People with low or monocular refractive errors may not need correction, and small changes in refractive corrections in asymptomatic individuals are usually not recommended (AAO, 2022b). The major reasons for treating refractive errors are to improve visual acuity, function and comfort. Other reasons for treatment include enhancing binocular vision and decreasing strabismus.

The AAO has defined degrees of refractive errors to include (AAO, 2022b):

- Low to moderate refractive errors:
  - spherical equivalents of less than 6.00 diopters (D) of myopia, less than 3.00 D of hyperopia, and less than 3.00 D of regular astigmatism
- High refractive errors:
  - spherical equivalents of 6.00 D or more of myopia, 3.00 D or more of hyperopia, and 3.00 D or more of regular astigmatism

Individuals with high refractive errors generally require correction to achieve satisfactory vision. Options for correcting refractive errors include spectacles (glasses), contact lenses, or surgery. Spectacles should be considered before contact lenses or refractive surgery. Most adults can tolerate up to 3.0 diopters (D) of difference in eyeglass refractive correction between both eyes. Occasionally, individuals may tolerate more than 3.0 D of difference (AAO, 2022b).

Refractive surgery refers to surgical procedures designed to correct refractive errors by reshaping the corneal surface, and to improve the focusing power of the eye, thus reducing or eliminating the need for corrective lenses. Refractive surgery is an elective procedure which may be considered by those who wish to become less dependent on spectacles or contact lenses, or when there is an occupational or cosmetic reason to not wear spectacles (AAO, 2022a).

Refractive Procedures

Corneal Relaxing Incisions/Corneal Wedge Resection (Arcuate Keratotomy [AK])
Corneal relaxing incisions are a type of incisional treatment used in the management of astigmatism and include arcuate (or "astigmatic") keratotomy (AK) and limbal relaxing incisions (LRIs). In AK, either transverse or arcuate incisions are made in the paracentral cornea to change its curvature in order to reduce or eliminate corneal astigmatism by allowing the cornea to become more rounded when it heals. AK is often performed for the correction of surgically-induced astigmatism and following medically indicated cataract removal or corneal transplant surgery. Variations of AK include the Ruiz procedure and the Troutman Wedge Resection also referred to as a corneal wedge resection. The wedge resection, often used with corneal relaxing incisions, effectively decreases astigmatism. However, clinical results have been reported to be unpredictable, therefore, the technique is typically reserved for the correction of post-keratoplasty astigmatism of high degree (i.e. ≥ 3.00 D).

Limbal relaxing incisions (LRIs) or peripheral corneal relaxing incisions are also a variant of AK in which incisions are placed just on the far peripheral aspect of the cornea. The incisions are created with blades designed to achieve a consistent depth. Femtosecond lasers may also be used to create arcuate incisions. LRIs may be used to treat astigmatism and have been performed alone or combined with cataract extraction and intraocular lens implantation to reduce preoperative corneal astigmatism (AAO, 2022a). The correction of iatrogenic astigmatism is generally supported, while the use of LRIs to treat astigmatism not resulting from a prior surgery (e.g., correction of pre-existing, non-surgically induced astigmatism during cataract surgery) is considered not medically necessary.

Intrastromal Corneal Ring Segments (ICRS)

This procedure involves inserting a flexible ring beneath the surface of the cornea to elevate the edge of the cornea to flatten the front of the eye, decreasing nearsightedness. Different size rings are used to correct different degrees of nearsightedness. Intrastromal corneal ring segments have been investigated for two indications—as a refractive procedure to correct mild myopia and as a treatment of keratoconus.

U.S. Food and Drug Administration (FDA): On April 9, 1999, INTACS™ (Keravision Inc.) received premarket application (PMA) approval from the FDA for the treatment of adults with mild myopia (from -1.0 to -3.0 D) who have ≤ 1.0 D of astigmatism. Intrastromal corneal ring segments are considered not medically necessary for individuals with mild myopia. They are unsupported for children, for individuals with moderate to severe myopia (greater than -3.0 D), for individuals with more than 1.0 D of astigmatism, and for hyperopia.

On July 26, 2004, INTACS® prescription inserts for keratoconus (Addition Technology) received humanitarian device exempt (HDE) approval from the FDA. A humanitarian use device (HUD) is exempt from the effectiveness requirements of a PMA. According to the FDA, INTACS prescription inserts are indicated for the reduction or elimination of myopia and astigmatism in a specific subset of individuals with keratoconus who meet all of the following criteria:

- progressive deterioration in vision, such that adequate functional vision on a daily basis with contact lenses or spectacles can no longer be achieved
- 21 years of age or older
- clear central corneas
- corneal thickness of 450 microns or greater at the proposed incision site
- corneal transplantation is the only remaining option to improve functional vision

Literature Review: Case series and comparative trials have evaluated the safety and effectiveness of intrastromal corneal implants for keratoconus (Torquetti, et al., 2009; Kymionos, et al., 2007; Colin and Malet, 2007; Ertan and Bahadir, 2006; Colin, 2006; Kanellopoulos, et al., 2006; Siganos, et al., 2003; Boxer, et al., 2003; Colin, et al., 2001). Some studies have had limitations including retrospective design, small sample size, and short-term follow-up. However, results of the available evidence indicate that the use of intrastromal corneal implants for individuals with keratoconus is associated with improved functional vision and can defer or possibly eliminate the need for corneal transplantation.

Intrastromal corneal ring segments have been investigated as a treatment for corneal ectasia after laser in situ keratomileusis (LASIK) surgery. According to the AAO, reported techniques vary in the size, number, and symmetry of the implants as well as the location of the incision. Although early results show potential, long-term efficacy for this procedure remains to be determined (AAO, 2022a). Treatment for post- LASIK ectasia is not an FDA-approved indication for intrastromal corneal ring segments.

Laser in Situ Keratomileusis (LASIK)
LASIK is a type of laser surgery of the cornea performed to correct refractive errors. A slice of the individual's cornea is removed, shaped to the desired curvature with an excimer laser, and then sewn back to the remaining cornea. In recent years, LASIK surgery has become the procedure of choice for treating moderate to high levels of myopia, with or without astigmatism. In 1995, the first refractive laser systems approved by the U.S. Food and Drug Administration (FDA) were the excimer lasers for use in photorefractive keratectomy (PRK) to treat myopia and, later, to treat astigmatism. Physicians then began using these lasers for LASIK surgery and to treat refractive disorders other than myopia. The laser emits an ultraviolet beam that is able to reshape the cornea. Refractive errors are minimized with the aid of a programmed computer that, using an individual’s refraction and corneal topography, controls the laser beam to precisely remove corneal tissue.

Photorefractive Keratectomy (PRK)
PRK involves the reshaping of the surface of the cornea with an excimer laser to correct mild-to-moderate myopia. The laser alters the anterior curvature to modify a particular refractive error by varying the ablation pattern. Photoastigmatic keratectomy (PARK or PRK-A) is a refractive surgical procedure used to correct myopia with astigmatism.

Other Procedures

Conductive Keratoplasty (CK): CK is the application of radiofrequency thermal energy to correct presbyopia and low hyperopia with or without astigmatism; or to correct residual refractive error after LASIK or cataract surgery.

In April 2002, the ViewPoint™ CK® System (Refractec Inc.) received premarket approval (PMA) from the FDA, as a Class III device. The March 2004 updated FDA-approved indications were for the temporary induction of myopia (-1.00 D to -2.00 D) to improve near vision in the non-dominant eye of presbyopic hyperopes or presbyopic emmetropes, via spherical hyperopic treatment of 1.00 to 2.25 D, in individuals:

- age ≥ 40 years of age
- with a documented stability of refraction for the prior 12 months, as demonstrated by a change of <0.50 D in spherical and cylindrical components of the manifest refraction
- with <0.75 D of cycloplegic refractive cylinder; and
- with a successful preoperative trial of monovision or history of monovision wear (i.e., dominant eye corrected for distance vision and non-dominant eye corrected for near vision).

Literature Review: Currently, there is insufficient evidence in the peer-reviewed literature to support the effectiveness of CK for the treatment of presbyopia. Studies are primarily in the form of case series with small sample sizes (n=10-27) and follow-ups of 1-3 years (Ye, et al., 2011; Stahl, 2007). A larger series by McDonald and colleagues (2004) reported preliminary results of a multicenter clinical trial supported by the FDA to evaluate the effectiveness of CK for the treatment of presbyopic symptoms of emmetropic and hyperopic eyes. A total of 143 individuals with presbyopic symptoms were enrolled in this one-year study and treated to improve near vision in one eye (unilateral treatment). In addition, 33 fellow eyes were treated to improve distance vision (bilateral treatment). At six months follow-up, 77% of examined eyes had J3 or better monocular UCVA, and 85% of individuals had binocular UCVA of 20/25 or better distance along with J3 or better near, a combination that represents functional acuity for a presbyopic individual. Of eyes treated with CK, 92% had an uncorrected binocular vision of 20/32 and J5, which also allows a high degree of uncorrected visual function. It was noted that follow-up was too short for meaningful determination of refractive stability; follow-up to three years and beyond is needed for accurate evaluation of stability.

According to the AAO (2022a) disadvantages of CK include early overcorrection, regression and induced astigmatism. The procedure is not frequently used today.

Lamellar Keratoplasty (Non-Penetrating Keratoplasty): This is a corneal transplant procedure in which a partial thickness of the cornea is removed. The diseased tissue is replaced with a partial-thickness donor cornea. There are two types of lamellar keratoplasty: anterior lamellar keratoplasty (including the subtype deep anterior lamellar keratoplasty [DALK]) and posterior lamellar keratoplasty (also referred to as endothelial keratoplasty). Lamellar keratoplasty may be indicated for a number of corneal diseases, including scarring, edema, thinning, distortion, dystrophies, degenerations and keratoconus. However, it is considered not medically necessary when performed solely to correct astigmatism and other refractive errors.

Laser Thermokeratoplasty (LTK) (Other Than Conductive Keratoplasty): Multiple types of lasers have been investigated for use in LTK, including hydrogen fluoride, cobalt:magnesium fluoride, erbium:glass, carbon dioxide, and the Ho: Yag diode (McDonald and Azar, 2020). Laser thermokeratoplasty has largely been abandoned in current refractive surgery practice, as the corneal wound healing response produces postoperative scarring and instability.

Limbal Relaxing Incisions (LRIs): LRIs, or peripheral corneal relaxing incisions, are a variant of arcuate (astigmatic) keratotomy (AK) (see above) in which incisions are placed just on the far peripheral aspect of the cornea. LRIs may be used to treat low to moderate degrees of astigmatism and have been performed alone or combined with cataract extraction and intraocular lens implantation to reduce preoperative corneal astigmatism (AAO, 2022a). As such, the use of LRIs to treat astigmatism that is not surgically induced is considered not medically necessary.

Penetrating Keratoplasty (PK) (Corneal Transplantation, Perforating Keratoplasty): PK involves replacement of the full-thickness cornea with a donor cornea, but retains the peripheral cornea. As with lamellar keratoplasty, this procedure may be indicated for a number of corneal diseases. Most PKs are performed to improve poor visual acuity caused by an opaque cornea. PK has also been used to remove active corneal disease, such as persistent severe bacterial, fungal, or amebic inflammation of the cornea (keratitis) after appropriate antibiotic therapy. The most common indications for PK are: bullous keratopathy, keratoconus, corneal scar with opacity, keratitis, corneal transplant rejection, Fuch's dystrophy, corneal degeneration, other corneal dystrophies, corneal edema, and herpes simplex keratitis. PK is considered not medically necessary when performed solely to correct astigmatism or other refractive errors. Surgically induced astigmatism is a potential complication of PK that may require refractive surgery.

Automated Lamellar Keratoplasty (ALK): ALK, also referred to as standard keratomileusis, is a technique that shapes the cornea with a microkeratome, an oscillating sharp blade used to incise the corneal stroma beneath the Bowman membrane, rather than with a laser. It is considered investigational for treatment of all refractive errors. The AAO Refractive Surgery Preferred Practice Pattern assessment stated that ALK had only fair predictability. Complications of ALK include irregular astigmatism, thin flaps, free or displaced caps, anterior chamber perforation, interface opacities, infectious keratitis, and epithelial ingrowth. The AAO has further stated that ALK has been largely abandoned due to the advent of laser-in-situ keratomileusis (LASIK) (AAO, 2022a).

Corneal Allogenic Intrastromal Ring Segments (CAIRS): The CAIRS technique uses allogenic tissue as a spacer graft to produce effects similar to synthetic intrastromal corneal ring segments (i.e., INTACS). In this procedure, a deepithelialized and deendothelialized donor cornea is cut into two semicircles, and the segments are then inserted into intrastromal channels which are typically created via femtosecond laser. Corneal collagen cross linking may then be performed. CAIRS has been proposed for the treatment of corneal ectatic disorders, including keratoconus (Patel and Jacob, 2023).

Literature Review: There is insufficient evidence in the published, peer-reviewed literature to support the long-term safety and efficacy of CAIRS for the treatment of keratoconus or any other condition. The evidence consists primarily of case reports and small prospective and retrospective case series with small patient populations, varied methodologies, and short term follow-ups (Asfar, et al., 2024; Bteich, et al., 2024; Coscarelli, et al., 2024; Kirgiz, et al., 2024; Susanna, et al., 2024; Yucekul, et al., 2024; Bteich, et al., 2023a; Bteich, et al., 2023b; Jacob, et al., 2023; Nacaroglu, et al., 2023; Haciagaoglu, et al., 2022; Jacob, et al., 2018). While improvements in uncorrected and corrected distance visual acuity, and topographic and tomographic measurements have been reported, long-term outcomes and safety have not been established. Reported complications have included graft dislocation; yellow-white deposits in segment tunnels; dry eye

symptoms; and worsening visual acuity. Additional well-designed, comparative trials with larger patient populations and long term follow-ups are needed.

Keskin Perk et al. (2024) conducted a prospective study to evaluate the efficacy, safety, and stability of sterile corneal allograft ring segments in individuals with keratoconus. The study included 62 eyes from 49 subjects, aged 18 to 52 years, with stage 1 to 3 keratoconus, contact lens intolerance, and corrected visual acuity less than 0.5 Snellen. Individuals with central or paracentral corneal scarring, history of herpetic keratitis, severe dry eye, previous ocular surgery, autoimmune or connective tissue disease, pregnancy, lactation, prior cross-linking treatment, and double-ring segment implantation were excluded. All subjects underwent implantation of sterile corneal allograft ring segments (KeraNatural, VisionGift), with outcomes measured including uncorrected and corrected distance visual acuity, spherical equivalent, spherical and cylindrical refraction, keratometric values, and corneal thickness. The mean follow-up period was 23.23 ± 13.46 months, with up to 36 months of observation (32 eyes, 52%). At three-year follow up, statistically significant improvements were observed in uncorrected distance visual acuity (from 0.96 ± 0.50 to 0.41 ± 0.34, $p<0.001$), corrected distance visual acuity (from 0.72 ± 0.47 to 0.22 ± 0.19, $p<0.001$), spherical equivalent, spherical refraction, and keratometric values (all $p<0.001$). No significant changes were found in cylindrical refraction ($p=0.333$) or thinnest corneal thickness ($p=0.154$). Minor adverse events included transient dry eye symptoms and yellow-white segment tunnel deposits. Study limitations included the small subject population, absence of a control group, 48% loss to follow up at three years, and lack of specific assessments for visual symptoms such as halo and glare.

Professional Societies/Organizations: The American Academy of Ophthalmology (AAO) preferred practice pattern for the treatment of corneal ectasia stated that "long-term results on CAIRS…are awaited", and no recommendation for or against CAIRS was given (AAO, 2023).

Corneal Inlay: Corneal inlays have been proposed as a treatment for presbyopia. The device is a thin disc shaped lens with micro-perforations proposed to help focus images clearly within the eye like glasses or contact lenses. Although the inlay has no refractive power, the goal of the device is to have the central opening function as a pinhole to increase depth of focus and improve near vision without changing distance vision. The inlay is implanted through a pocket-shaped laser incision of the cornea.

U.S. Food and Drug Administration (FDA): Several refractive corneal inlays have received FDA approval via the premarket approval (PMA) process, as Class III devices. In addition to Intacs®, inlays have been approved for intrastromal implantation to improve near vision in phakic, presbyopic individuals who do not require correction for clear distance vision, but require near correction of +1.00 D to +2.50 D of reading add.

Device or Product	Identifier	Manufacturer	Decision Date
KeraVision Intacs	P980031	KeraVision, Inc. (Addition Technology)	4/9/1999
KAMRA® Inlay	P120023	CorneaGen (AcuFocus, Inc.)	4/17/2015
Raindrop® Near Vision Inlay†	P150034	ReVision Optics, Inc.	6/29/2016

*FDA product code: LQE

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

[†]In March 2019, the FDA issued a Class 1 Device Recall of the Raindrop Near Vision Inlay, due to an increased risk of corneal haze. The inlay is not currently commercially available.

The Presbia Flexivue Microlens™ (PresbiBio, LLC., Sandyford Dublin) is a refractive optic corneal inlay that functions by altering the corneal index of refraction to improve near vision performance, by the means of a bifocal optic which separates distance and near focal points. The basic principle is corneal multifocality, providing distance vision through a plano central zone surrounded by one or more rings of varying additional power for intermediate and near vision. The Flexivue Microlens is a 3 mm diameter, transparent hydrogel-based implant made from a hydrophilic acrylic material and contains an ultraviolet blocker. Depending on the add power, the thickness of the inlay varies from 15 µm to 20 µm. The Microlens received its CE Mark for the European Economic Area. It is not currently FDA-approved and is not commercially available in the U.S. (Beer, et al., 2020; Moarefi, et al., 2017).

Additional options in corneal inlays are being studied with the Presbyopic Allogenic Refractive Lenticule (PEARL) techniques. PEARL is a procedure that places a small piece of tissue from one part of the cornea into another part. The inlay is proposed to change the shape of the cornea with the goal of improving near vision. The surgeon uses a laser to make a small cut in the cornea. A lenticule (a small disc of corneal tissue) is removed through the cut. The lenticule is sculpted and reshaped with a laser, then placed into a small pocket made in the individual's cornea. Because the inlay is made of the person's own tissue, it is biologically compatible, making it less likely to cause complications of artificial corneal inlays. The procedure is still under investigation (Moarefi, et al., 2017; Boyd, 2016).

Literature Review: Evidence in the published peer-reviewed medical literature evaluating the safety and effectiveness of corneal inlays is primarily in the form of case reports and case series (Darian-Smith, et al., 2022; Linn, et al., 2017; Verdoorn, 2017; Whang, et al., 2017; Jalali, et al., 2016; Dexl, et al., 2015; Yoo, et al., 2015; Yilmaz, et al., 2011; Seyeddain, et al., 2010). These studies included small patient populations with follow-up periods ranging from six months to four years. Adverse events included cataract progression and device explantation.

Vukich et al. (2018) conducted a prospective nonrandomized multicenter open-label single-arm study (n=507) to evaluate the safety and efficacy of the KAMRA corneal inlay. Individuals aged 45–60 years, with presbyopia and corrected distance visual acuity (CDVA) to 20/20 in both eyes were included in the study. The eye to be implanted had uncorrected near visual acuity (UNVA) between 20/40 and 20/100 and cycloplegic refractive spherical equivalent of +0.50 diopters (D) to -0.75 D with 0.75 D or less of refractive cylinder, and required a near correction of +1.00 to +2.50 D of reading addition (add). The eyes also had a minimum central corneal thickness of ≥ 500 µm, corneal power ≥ 41.00 D and ≤ 47.00 D in all meridians and an endothelial cell count of more than 2000 cells/mm^2. The primary outcome was the percentage of eyes with a UNVA ≥ 20/40. Several subgroups were predetermined before study initiation to measure contrast sensitivity (n=335), defocus curve (n=114), and visual fields (n=224). The corneal inlay was implanted under a lamellar resection, either a corneal pocket created by a femtosecond laser (n=471) or under a corneal flap (n=37) created by a mechanical microkeratome. The mechanism of action of the KAMRA (increase in depth of focus by blocking peripheral unfocused rays of light) was reflected in the defocus curves. Reported outcomes at 36 months included the following:

- The implanted eyes exhibited 3.5 diopters of defocus range above 20/40, with 363/417 individuals (87.1%) and 391/417 individuals (93.8%) having 20/40 or better monocular and binocular uncorrected near visual acuity (UNVA). The mean visual acuities significantly improved for both positive and negative defocus after implantation.
- Individuals implanted via a femtosecond laser pocket procedure demonstrated further improved near vision, with 131/145 individuals (90.3%), 137/145 individuals (94.5%) having 20/40 or better monocular and binocular UNVA, respectively.

- UDVA of 20/25 or better was maintained in 135/145 subjects (93.1%) and 100% of implanted eyes.
- The results of a patient questionnaire showed that for those in the pocket group, near vision tasks were all graded as much easier to perform postoperatively than preoperatively ($p<0.001$). Minimal change was reported in ease of performing distance vision tasks. There was a significant reduction in the ease of watching television and driving at night ($p<0.05$).

Ocular adverse events included decreases in CDVA of ≥ 2 lines and secondary surgical interventions which included six inlay repositionings and 44 removals (8.7%). The removal rate was significantly less in the pocket group and further reduced with deeper implantation. There was also one event each of corneal edema, corneal haze, amorphous material around a fold in the inlay, and stromal thinning secondary to abnormal healing response to corneal trauma. Less than 1.0% of the subjects reported severe glare or halos postoperatively. Author-noted limitations of the study included the fact that the questionnaire was not validated before the study; the deep implantation cohort was small relative to the whole cohort size; and the subgroups of lamellar resection and implantation depth were created following the study, which limited the statistical power of the analyses on these variables. Another limitation was the number of subjects lost to follow-up (n=49; 8.7%).

Corneal Tissue Addition Keratoplasty (CTAK): Corneal tissue addition keratoplasty (CTAK) has been proposed for the management of corneal ectasia. During CTAK, preserved irradiated donor corneal tissue is cut to individual-customized size specifications with a femtosecond laser, then placed in a laser-created channel in the recipient cornea, with the aim of reshaping the cornea and improving vision. The reported potential benefits of CTAK over corneal transplantation are shorter recovery time and a reduced risk of complications. The technique is currently under investigation.

Literature Review: The evidence in the published, peer-reviewed literature is insufficient to support the safety, efficacy, and long-term outcomes of CTAK for the treatment of keratoconus or any other condition.

Greenstein et al. (2023) conducted a single center prospective open label clinical trial of CTAK for the treatment of keratoconus and ectasia after laser in situ keratomileusis. The study included 18 adults (21 eyes). All subjects underwent placement of gamma-irradiated, sterilized, preserved corneal tissue (CorneaGen) cut to individual specifications with a femtosecond laser. At six months postoperatively, the average uncorrected distance visual acuity (UDVA) improved from 1.21 ± 0.35 logMAR lines (LL) (20/327) to 0.61 ± 0.25 LL (20/82) ($p<0.001$). The average corrected distance visual acuity (CDVA) improved from 0.62 ± 0.33 LL (20/82) to 0.34 ± 0.21 LL (20/43) ($p=0.002$), and the average manifest refraction spherical equivalent (MRSE) improved from -6.25 ± 5.45 diopters (D) to -1.61 ± 3.33 D ($p=0.002$). Twenty eyes (95.2%) gained more than two lines of UDVA, with 10 eyes (47.6%) gaining more than six lines, with no eyes worsening. Twelve eyes (57.1%) gained at least two lines of CDVA, with one eye worsening by more than two lines. At six months, the average topographic mean keratometry (Kmean) flattened by -8.44 D ($p=0.002$), the maximum keratometry (Kmax) flattened by -6.91 D ($p=0.096$ [NS]), and the mean point of maximum flattening (Kmaxflat) was -16.03 D. One subject experienced a partial tear of the channel wall during inlay insertion, requiring suturing and loss of three lines of CDVA. Limitations of the study included the small sample size, lack of control/comparator group, and short term follow-up.

Hexagonal Keratotomy: This technique uses a computer-assisted microkeratome to reshape the cornea. It works similarly to a carpenter's plane, making a hexagonal pattern of cuts versus the radial cuts seen in radial keratotomy (RK). Hexagonal keratotomy has been used to treat hyperopia which occurs naturally and also to treat presbyopia after RK. Hexagonal keratotomy is

now rarely used, due to complications like poor healing and irregular astigmatism, and as newer techniques in refractive surgery have been developed (Mercer, et al., 2023).

Laser Epithelial Keratomileusis (LASEK): LASEK, a modification of photorefractive keratectomy (PRK), is a surface ablation procedure that attempts to preserve the epithelium. The postoperative outcomes of LASEK have been reported to be similar to those of PRK. Proposed advantages of LASEK compared to LASIK are that more stromal tissue is reserved, and flap-related complications do not occur. However, individuals undergoing LASEK experience more postoperative discomfort and slower recovery of vision than those who have had LASIK. The AAO Preferred Practice Pattern Refractive Surgery stated that the potential for the development of corneal haze remains a concern since LASEK is a modification of PRK (AAO, 2022a). There is a lack of evidence in the peer-reviewed literature to support the safety and efficacy of this procedure.

Kuryan et al. (2017) published results of a Cochrane review (n=3 RCTs/154 subjects) to assess the effects of LASEK versus LASIK for correcting myopia. RCTs were selected in which myopic subjects were assigned randomly to receive either LASEK or LASIK in one or both eyes. Participants were included in the studies who were between the ages of 18 and 60 years with myopia up to 12 D and/or myopic astigmatism of severity up to 3 D, and who did not have a history of prior refractive surgery. All trials enrolled participants with mild to moderate myopia (< -6.50 D); only one trial included subjects with severe myopia (> -6.00 D). The primary outcome measure was uncorrected visual acuity (UCVA) at 12 months. The evidence showed uncertainty as to whether there was a difference between LASEK and LASIK in UCVA at 12 months. People receiving LASEK were less likely to achieve a refractive error within 0.5 diopters of the target at 12 months follow-up (RR 0.69, 95% CI 0.48 to 0.99; 57 eyes; very low-certainty evidence). One trial reported mild corneal haze at six months in one eye in the LASEK group and none in the LASIK group (RR 2.11, 95% CI 0.57 to 7.82; 76 eyes; very low-certainty evidence). None of the included trials reported postoperative pain score or loss of visual acuity, spherical equivalent of the refractive error, or quality of life at 12 months. Individuals receiving LASEK were less likely to achieve a refractive error within 0.5 diopters of the target at 12 months follow-up (very low-certainty evidence). In terms of adverse events, refractive regression was reported only in the LASEK group (8/37 eyes) compared to 0/39 eyes in the LASIK group in one trial (low-certainty evidence). Likewise, low-certainty evidence of one trial reported adverse events of corneal flap striae and refractive over-correction only in the LASIK group (5/39 eyes) compared to 0/37 eyes in the LASEK group. This review was limited by the small sample sizes in studies and the low quality of the available evidence. The authors concluded that large, well-designed RCTs are needed to estimate the magnitude of any difference in efficacy or adverse effects between LASEK and LASIK for treating myopia or myopic astigmatism.

Minimally Invasive RK (mini-RK): Radial keratotomy involves the use of radial incisions in the cornea to correct mild to moderate myopia. Mini-RK is a modified radial keratotomy procedure that reduces the millimeters of cornea incised. The goal is to maximize corneal flattening with a minimum length and number of incisions. Mini-RK is considered an investigational procedure.

Scleral Expansion Surgery: Scleral expansion surgery involves the use of scleral expansion band segments which are inserted beneath partial thickness scleral incisions (scleral belt loops) in each of the oblique quadrants. The procedure is claimed to improve accommodation and has been proposed as a treatment for presbyopia. The infrared laser has also been used to make deep scleral incisions to treat presbyopia presumably by mechanisms similar to scleral expansion bands (Kleinmann, et al., 2006). Many investigators dispute the proposed mechanism of scleral expansion to treat presbyopia, and the results of these various surgeries have not shown predictable or consistent effects on distance corrected near acuity or accommodative amplitude

(Mercer, et al., 2023; AAO, 2022a). There is insufficient evidence in the peer-reviewed literature to support the effectiveness of scleral expansion surgery for the treatment of presbyopia.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

By 2050, it is estimated that the majority of total visual impairment will be due to uncorrected refractive error. Undiagnosed and uncorrected refractive errors contribute to the developmental, academic and social challenges in children, and, in some cases, vision loss. The presence and type of uncorrected refractive error varies by race and ethnicity. For example, Black and Hispanic children are more likely to be myopic than white children, while white and Hispanic children are more likely to be hyperopic than Black children. Racial and ethnic differences exist for astigmatism as well. The Multi-Ethnic Pediatric Eye Disease Study found a higher prevalence of presenting refractive error–related visual impairment in both Black children and Hispanic children than in either Asian American or non-Hispanic white children (Elam, et al., 2022).

In a 2016 study, Woodward et al. found that Black and Latino Americans had significantly higher odds of being diagnosed with keratoconus than white Americans (57% and 43%, respectively), while Asian Americans were 39% less likely to develop the condition than white individuals. Other factors which have been found to increase the risk of development of keratoconus include asthma, sleep apnea, Down syndrome, connective tissue disorders, allergic eye disease, a family history of keratoconus, and Leber congenital amaurosis (Oyeniran and Tauqeer, 2021; Woodward, et al., 2016; Gomes, et al., 2015).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Refractive Keratoplasty (80.7)	5/1/1997
LCD		No Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• Removed keratophakia and orthokeratology from policy statement.	11/15/2025
Annual Review	• Removed policy statements for corneal collagen crosslinking and corneal wedge resection. • Added corneal allogenic intrastromal ring segments and corneal tissue addition keratoplasty to policy statement.	12/15/2024
Annual Review	• Removed laser in situ keratomileusis, photorefractive keratectomy, and radial keratotomy from policy statement.	10/15/2023