



# Cigna Medical Coverage Policy

Effective Date ..... 10/15/2014  
Next Review Date ..... 10/15/2015  
Coverage Policy Number ..... 0141

Subject **Corneal Remodeling**

## Table of Contents

Coverage Policy .....	1
General Background .....	3
Coding/Billing Information .....	11
References .....	13

## Hyperlink to Related Coverage Policies

[Intraocular Lens Implant](#)

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## Coverage Policy

Coverage for services for or related to routine refraction and the surgical treatment of refractive errors is specifically excluded under many benefit plans. Please refer to the applicable benefit plan document to determine benefit availability, and the terms and conditions of coverage.

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/Corneal Wedge Resection

Cigna covers correction of surgically-induced astigmatism 3.00 diopters (D) or greater with a corneal relaxing incision (CPT® code 65772) or corneal wedge resection (CPT® code 65775) (i.e. astigmatic keratotomy [AK]), post-cataract or post-corneal transplant surgery as medically necessary in an individual who is intolerant of glasses or contact lenses.

Cigna does not cover a corneal relaxing incision (CPT® code 65772) or corneal wedge resection (CPT® code 65775) (i.e. astigmatic keratotomy [AK]) for any other indication because they are considered not medically necessary.

### Epikeratoplasty

Cigna covers epikeratoplasty (CPT® code 65767) (epikeratophakia) as medically necessary for EITHER of the following indications:

- acquired or congenital aphakia
- aphakia following cataract surgery in patients unable to receive intraocular lens

**Cigna does not cover epikeratoplasty (CPT® code 65767) (epikeratophakia) for any other indication because it is considered experimental, investigational or unproven.**

### **Phototherapeutic Keratectomy (PTK)**

**Cigna covers phototherapeutic keratectomy (PTK) (CPT® code 66999; HCPCS code S0812) as medically necessary for ANY of the following indications:**

- superficial corneal dystrophy (including granular, lattice and Reis-Bückler's dystrophy)
- epithelial membrane dystrophy
- irregular corneal surfaces due to Salzmann's nodular degeneration or keratoconus nodule
- corneal scars and opacities, including post-traumatic, postinfectious, postsurgical and secondary to pathology
- recurrent corneal erosions when more conservative measures (e.g., lubricants, hypertonic saline, patching, bandage contact lenses, gentle debridement of severely aberrant epithelium) have failed to halt the erosions

**Cigna does not cover phototherapeutic keratectomy (PTK) (CPT® code 66999; HCPCS code S0812) for any other indication because it is considered not medically necessary.**

### **Intrastromal Corneal Ring Segments**

**Cigna covers the insertion of intrastromal corneal ring segments (CPT® code 0099T) (e.g., INTACS® prescription inserts) as 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 patients 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

**Cigna does not cover intrastromal corneal ring segments (CPT® code 0099T) (e.g., INTACS® prescription inserts) for any other indication because they are considered not medically necessary.**

### **Laser In Situ Keratomileusis (LASIK) & Photorefractive Keratectomy (PRK)**

**Cigna covers correction of surgically-induced astigmatism and/or anisometropia 3.00 diopters (D) or greater with laser in situ keratomileusis (LASIK) (HCPCS code S0800), or photorefractive keratectomy (PRK) (HCPCS code S0810), as medically necessary in an individual who has documented inadequate functional vision with glasses and/or contact lenses.**

**Cigna does not cover laser in situ keratomileusis (LASIK) (HCPCS code S0800), or photorefractive keratectomy (PRK) (HCPCS code S0810) for any other indication because they are considered not medically necessary.**

### **Other Procedures**

**Cigna does not cover ANY of the following refractive procedures because they are considered not medically necessary (this list may not be all-inclusive):**

- clear lens extraction (CLE) (CPT<sup>®</sup> codes 66840; 66850; 66852; 66920; 66930; 66940; 66983; 66985; HCPCS codes C1780; Q1004; Q1005; S0596; S0800; S0810; V2630; V2631; V2632; V2687; V2688)
- conductive keratoplasty (CPT<sup>®</sup> code 65771)
- lamellar keratoplasty (nonpenetrating keratoplasty) (CPT<sup>®</sup> codes 65710; 0289T; 0290T)
- laser thermokeratoplasty (LTK) (CPT<sup>®</sup> code 66999)
- limbal relaxing incisions for non-surgically induced astigmatism (CPT<sup>®</sup> code 66999)
- penetrating keratoplasty (PK) (corneal transplantation, perforating keratoplasty) (CPT<sup>®</sup> codes 65730; 65750; 65755; 0289T; 0290T)
- phakic intraocular lens (PIOL) (HCPCS code S0596)
- radial keratotomy (CPT<sup>®</sup> code 65771)

**Cigna does not cover ANY of the following refractive procedures because they are considered experimental, investigational or unproven (this list may not be all-inclusive):**

- automated lamellar keratomileusis (ALK) (i.e. standard keratomileusis) for the treatment of all refractive errors (CPT<sup>®</sup> code 65760)
- corneal collagen cross-linking (CPT<sup>®</sup> code 66999)
- hexagonal keratotomy in all cases (CPT<sup>®</sup> code 66999)
- keratophakia for the correction of all refractive errors (CPT<sup>®</sup> code 65765)
- laser epithelial keratomileusis (LASEK) (CPT<sup>®</sup> code 66999)
- minimally-invasive radial keratotomy (mini-RK) in all cases (CPT<sup>®</sup> code 66999)
- orthokeratology in all cases (HCPCS code V2599)
- scleral expansion surgery (CPT<sup>®</sup> code 66999)

## General Background

In the normal eye, both the cornea and lens function to refract or bend light rays and focus them on the retina to produce clear images. Refractive errors are imperfections in the functioning power of the eye due to an imperfectly shaped eyeball, cornea or lens, so that regarded objects are focused either in front of or behind the retina, resulting in blurred vision. Refractive errors include myopia, or nearsightedness; hyperopia, or farsightedness; astigmatism, in which 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.

The need to correct refractive errors depends on the patient's symptoms and visual needs. Those with low refractive error may not need correction. Small changes in refractive corrections in asymptomatic patients are usually not recommended. 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. Patients with high refractive errors generally require correction to achieve satisfactory vision. Options for correcting refractive errors include spectacles, contact lenses or surgery. Spectacles should be considered before contact lenses or refractive surgery. The majority of adults can tolerate up to 3.0 D of difference in eyeglass refractive correction. Occasionally, individuals may tolerate more than 3.0 D of difference (American Academy of Ophthalmology [AAO], 2013).

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. According to the AAO, 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, 2013). There are several refractive procedures currently in use.

### Refractive Procedures

**Astigmatic Keratotomy (AK):** AK procedures are those in which either transverse or arcuate incisions are made in the paracentral cornea to change its curvature in order to reduce or eliminate corneal astigmatism. 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 postkeratoplasty astigmatism of high degree.

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. LRIs may be used to treat low to moderate degrees of astigmatism and have been performed alone or combined with cataract extraction and IOL implantation to reduce preoperative corneal astigmatism (AAO, 2013). As such, the use of LRIs to treat astigmatism that is not surgically induced is considered not medically necessary.

The effectiveness of AK for correction of other refractive errors has not been proven in the literature. The AAO Preferred Practice Pattern on Refractive Errors states: "There are few well-controlled, prospective clinical studies available on the procedure to date, performed either individually or in connection with other keratorefractive procedures" (AAO, 2013).

**Epikeratoplasty (or Epikeratophakia):** This is a refractive surgical procedure that involves placement of a precarved donor corneal lens on the surface of a patient's eye. Epikeratophakia may be considered for the treatment of childhood aphakia because contact lenses are difficult for children to use, and intraocular lens implants may result in long-term complications in children. This procedure may be used on scarred corneas and corneas affected with endothelial dystrophy. Epikeratophakia may also be considered acceptable in cases of adult aphakia when the secondary implantation of an intraocular lens might affect outcome (e.g., history of uveitis, significant corneal endothelial disease, gross corneal irregularity after trauma). The effectiveness of this procedure for the correction of refractive errors in other disorders has not been proven in the literature. The AAO Preferred Practice Pattern on Refractive Errors and Refractive Surgery states that epikeratoplasty results have been widely variable and there have been significant complications including poor wound healing, irregular astigmatism and infectious keratitis. According to the AAO, this procedure has largely been abandoned.

**Phototherapeutic Keratectomy (PTK):** PTK is used to correct refractive errors caused by a diseased cornea (e.g., granular, lattice, and Reis-Bucher's dystrophy; epithelial membrane dystrophy; irregular corneal surfaces due to Salzmann's nodular degeneration; or keratoconus nodules, corneal scars and opacities, and recurrent corneal erosions) or for the correction of visual impairment after cataract surgery. PTK uses an excimer laser, but does not alter the final refractive state of the eye. PTK should not be confused with photorefractive keratectomy (PRK). Although technically the same procedure, PTK is used for the correction of particular corneal diseases; whereas, PRK is used for the correction of refractive errors (e.g., myopia, hyperopia, astigmatism and presbyopia) in persons with otherwise nondiseased corneas.

**Intrastromal Corneal Ring Segments (INTACS):** This procedure involves inserting a flexible ring beneath the surface of the cornea to elevate the edge of the cornea. This effectively flattens 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.

**Myopia:** On April 9, 1999, INTACS™ (Keravision Inc., Fremont, CA) 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 less than 1.0 D of astigmatism. Intrastromal corneal ring segments are considered not medically necessary for patients with mild myopia. They are considered investigational for children, for patients with moderate to severe myopia (greater than -3.0 D), for patients with more than 1.0 D of astigmatism, and for hyperopia.

The National Institute for Health and Clinical Excellence (NICE) has issued guidance on the use of corneal implants for the correction of refractive error. NICE states that the available evidence on the efficacy of corneal implants for the correction of refractive error shows limited and unpredictable benefit. In addition, NICE states there are concerns about the safety of the procedure for patients with refractive error which can be corrected by other means, such as spectacles, contact lenses, or laser refractive surgery. Therefore, corneal implants should not be used for the treatment of refractive error in the absence of other ocular pathology such as keratoconus (NICE, 2007b).

**Keratoconus:** On July 26, 2004, INTACS® prescription inserts for keratoconus (Addition Technology, Sunnyvale, CA) 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 patients 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:** A number of 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, et al., 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.

The NICE guidance on the use of corneal implants for the management of keratoconus states that current evidence on the safety and efficacy of corneal implants for keratoconus appears adequate to support the use of this procedure, provided that normal arrangements are in place for consent, audit and clinical governance (NICE, 2007a).

**Miscellaneous:** Intrastromal corneal ring segments have been investigated as a treatment for ectasia after LASIK. 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, 2013). Treatment for post- LASIK ectasia is not an FDA-approved indication for intrastromal corneal ring segments.

**Clear Lens Extraction (CLE):** CLE, also referred to as refractive lens exchange, has been performed to correct refractive errors such as myopia, hyperopia, and presbyopia. The CLE technique is very similar to cataract extraction. The eye's natural lens is removed and replaced with a prescription intraocular lens. The replacement lens may be monofocal, multifocal or accommodating. Several studies have supported the safety and effectiveness of clear lens extraction using multifocal intraocular lenses (Leyland and Pringle, 2006; Dick, et al., 2002; Jacobi, et al., 2002). The AAO Preferred Practice Pattern on Refractive Errors and Refractive Surgery states that refractive lens exchange for myopia and hyperopia has been demonstrated to be predictable and effective, but no large-scale investigations on complications have been reported. Complications that may result in a permanent loss of vision are rare and include infectious endophthalmitis, intraoperative suprachoroidal hemorrhage, cystoid macular edema (CME), retinal detachment, corneal edema, and IOL dislocation (AAO, 2013).

CLE for the treatment of refractive errors is considered not medically necessary because the correction of refractive errors can be achieved with eyeglasses or contact lenses.

**Conductive Keratoplasty (CK):** CK is the application of radiofrequency thermal energy to increase the curvature of the cornea and thereby reduce hyperopia. On April 11, 2002, ViewPoint CK System<sup>®</sup> (Refractec Inc., Irvine, CA) received PMA approval from the FDA. Based on data submitted with the PMA application, the ViewPoint CK System<sup>®</sup> is approved for the treatment of patients who are at least 40 years of age, who have mild to moderate hyperopia (0.75 D to 3.25 D), 0.75 D or less astigmatism, and whose eyesight has changed very little over the previous 12 months, as demonstrated by a change of less than 0.50 D in refraction. According to the FDA, CK improves distance vision in farsighted people, but the amount of farsightedness correction is not always permanent. Those who require very acute vision for work-related activities may still need glasses, and glasses will also be needed for reading. CK is considered not medically necessary for its FDA-approved indications, and is considered investigational for all other indications.

Few case series with small sample sizes (n=10-27) and follow-up of 1-3 years have reported conductive keratoplasty to be safe and effective for symptomatic presbyopia (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 patients 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 patients 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.

Currently, there is insufficient evidence in the peer-reviewed literature to support the effectiveness of this procedure for the treatment of presbyopia.

**Laser in Situ Keratomileusis (LASIK):** LASIK is a type of laser surgery of the cornea to correct refractive errors, during which a slice of the patient'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 PRK to treat myopia and, later, to treat astigmatism. Physicians then began using these lasers for LASIK surgery as well 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 a patient's refraction and corneal topography, controls the laser beam to precisely remove corneal tissue.

The FDA has granted approval to some laser manufacturers of LASIK laser systems, to treat myopia, hyperopia, and astigmatism, and for PRK to treat hyperopia and astigmatism. On July 30, 1998, the Kremer Excimer Laser System<sup>®</sup> (PhotoMed, Inc., King of Prussia, PA) was granted premarket approval by the FDA for treatment of myopia and astigmatism. However, LASIK is considered not medically necessary for the treatment of myopia between -1.0 and -15.0 diopters (D), with or without astigmatism up to 5.0 D because this can be corrected satisfactorily with eyeglasses or contact lenses. LASIK has not been shown to be effective for the treatment of high myopia greater than -15.0 D, hyperopic astigmatism greater than 5.0 D, and for all other refractive errors.

Residual refractive errors after penetrating keratoplasty are usually responsible for decreased visual acuity despite a clear graft. The mean amount of astigmatism that has been reported after penetrating keratoplasty for keratoconus is usually between 2 and 6 D. Correction with spectacles or contact lenses should be considered initially, followed by the possibility of incisional refractive surgery if the patient is intolerant to either of these alternatives. The primary goal of LASIK after penetrating keratoplasty is to reduce the refractive error (e.g., astigmatism, anisometropia) to levels at which spectacle correction or contact lenses can be tolerated. The uncorrected visual acuity should remain a secondary goal (Wilkinson, et al., 2008).

**Laser thermokeratoplasty (LTK) (other than CK):** LTK utilizes the following methods: superficial treatment of Gassett and Kaufman for keratoconus, holmium, YAG laser thermokeratoplasty, or the hot needle of Fyodorov. Based on review of the literature, all of these methods of thermokeratoplasty have been abandoned in current refractive surgery because the corneal wound-healing response produces postoperative scarring and instability.

#### **Laser Treatment for Refractive Errors**

While use of the laser has minimized the potential adverse events from earlier forms of refractive surgery, not every patient is a candidate for treatment using the excimer laser. Age, high refractive error, ocular and medical disease may prevent a patient from obtaining a predictable refractive outcome. Despite increased efficacy in recent years, the refractive outcome may not always result in uncorrected vision acuity, or BSCVA of 20/20 or better; and some patients may develop a worsening of vision clarity and acuity, secondary to scarring, glare and halos. Patients may have a postoperative overcorrection, undercorrection and astigmatism that may need an enhancement to correct residual refractive error. Finally, there is a possibility that patients may still require correction with eyeglasses or contact lenses to obtain the best vision acuity and, over time, postoperative refractive-error regression may require additional laser treatment.

**Phakic Intraocular Lens (PIOL):** PIOL are synthetic lenses that are placed within the eye, along with the normal lens of the eye, to correct refractive errors. The PIOLs have a refractive power that exerts its effect on the overall refractive power of the eye. This results in improvement of refractive errors. PIOLs have the advantage of leaving the natural corneal curvature unchanged, whereas corneal refractive surgery creates

abnormal corneal shapes, which may induce visual aberrations. While there is evidence to support short-term safety and efficacy, there are limited long-term data on potential complications such as the increased risk of cataract, corneal damage or retinal detachment (National Institute for Clinical Excellence [NICE], 2009). Other potential complications of PIOL implantation include endophthalmitis, chronic iridocyclitis, iris distortion, pigment dispersion, glaucoma, and intraocular lens (IOL) dislocation.

FDA-approved devices include Visian ICL (implantable collamer lens) (Staar Surgical Co., Aliso Viejo, CA) and Artisan (Model 206 and 204) PIOL, also known as Verisyse (VRSM5US and VRSM6US) (Ophtec BV, Groningen, Netherlands). According to the FDA, the Visian ICL is indicated for adults 21–45 years of age to correct myopia ranging from -3.0 D to < -15.0 D with  $\leq 2.5$  D of astigmatism, or to reduce myopia ranging from > -15.0 D to -20.0 D with  $\leq 2.5$  D of astigmatism. The Artisan Myopia IOLs are indicated for the reduction or elimination of myopia in adults with myopia ranging from -5 to -20 D with less than or equal to 2.5 D of astigmatism.

PIOLs are considered not medically necessary for FDA-approved indications and investigational for all other indications.

**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. Both procedures are considered not medically necessary for patients with hyperopia of up to 6.0 D, and myopia of up to -10.0 D, with or without astigmatism up to 4.0 D, because the refractive corrections achieved with PRK and PARK are less precise than that achieved by eyeglasses or contact lenses. PRK and PARK are considered investigational for patients with hyperopia greater than 6.0 D, myopia greater than -10.0 D, astigmatism greater than 4.0 D, and for all other refractive errors. This is based on the FDA-approved indications for PRK and PARK.

The AAO Ophthalmic Procedure Assessment of PRK concluded that "it appears to be a safe and effective procedure for the treatment of low to moderate degrees of myopia and astigmatism. Results for high degrees of myopia are associated with poorer outcomes, that is, longer stabilization periods, greater need for re-treatment, and increased loss of lines of BSCVA" (No authors listed, 1999). The AAO Preferred Practice Pattern on Refractive Errors states that published reports of PRK document a median rate of 92% of patients achieving 20/40 uncorrected vision and 70% of patients achieving 20/20 uncorrected vision at 12 or more months following PRK for myopia (AAO, 2013).

Eye disorders such as keratoconus, where the cornea becomes progressively thinner and cone shaped, may result in a large amount of astigmatism resulting in poor vision that cannot be clearly corrected with spectacles. Keratoconus usually requires contact lenses for clear vision, and it may eventually progress to a point where a corneal transplant is necessary. If glasses and contact lenses are ineffective in correcting the refractive error, two commonly used procedures are photorefractive keratectomy (PRK) and LASIK (American Optometric Association [AOA], 2011).

**Radial Keratotomy (RK):** RK involves the use of radial incisions in the cornea to correct mild to moderate myopia. RK is considered not medically necessary for treatment of myopia ranging from -2.00 to -8.00 D, because this refractive error can be corrected satisfactorily with eyeglasses or contact lenses. Radial keratotomy is considered investigational for treatment of myopia greater than -8.00 D. It is also considered investigational for the treatment of all other refractive errors because of the high rate of complications that include starbursts, anterior chamber perforation and infectious keratitis. The established indications for RK were based on the 1992 AAO Ophthalmic Procedures Assessment of Radial Keratotomy for Myopia. The AAO's position on RK was reaffirmed in the 2007 AAO Preferred Practice Pattern on Refractive Errors and Refractive Surgery. RK has been performed infrequently since the advent of photorefractive keratectomy (PRK) and LASIK (AAO, 2013).

**Automated Lamellar Keratoplasty (ALK):** ALK, also referred to as standard keratomileusis, is a technique that shapes the cornea with a microkeratome rather than with a laser. It is considered investigational for treatment of all refractive errors. The AAO Preferred Practice Pattern on Refractive Errors 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, 2013).

### **Corneal Collagen Cross-linking**

Corneal collagen cross-linking using riboflavin and ultraviolet A is under investigation for the treatment of the progressive ectasia associated with keratoconus. The progressive changes are a result of weakened collagen that leads to herniation of the cone. The goal of the procedure is to induce cross-linkage between the corneal collagen fibers, increasing the stability of the cornea and halting the progression of keratoconus. The original procedure, referred to as epithelium-off, involves removal of the epithelium prior the administration of riboflavin and ultraviolet A. In a modification of the procedure, epithelium-on collagen cross-linking, the epithelium remains intact, potentially decreasing the risk for adverse effects such as infection and scarring. Corneal collagen cross-linking has been used in the earlier stages of keratoconus, and has also been used in combination with corneal ring implantation or radial keratotomy, or to treat post-LASIK ectasia.

The available evidence in the published peer-reviewed medical literature evaluating the safety and effectiveness of primarily epithelial-off corneal collagen cross-linking consists of prospective and retrospective case series and RCTs. Wittig-Silva et al. (2014) published their results of a randomized, controlled trial (n=100 eyes) of corneal collagen cross-linking (n=50 eyes) in patients with keratoconus. Eyes randomized to the control group (n=50) did not receive sham treatment. Patients between the ages of 16 and 50 years with a confirmed diagnosis of progressive keratoconus were included. Exclusion criteria were a minimum corneal thickness less than 400 µm, axial corneal scarring, previous refractive or other corneal surgery, a history of chemical burns, severe infections, and other corneal or ocular surface disorders. The primary outcome measure was the maximum simulated keratometry value (Kmax). Other outcome measures included uncorrected visual acuity (UCVA) and best spectacle-corrected visual acuity (BSCVA). At 36 months of follow-up, 27 eyes remained in the control group and 41 eyes in the experimental group. Overall, there was improvement in treated eyes with a flattening of Kmax by  $-1.03 \pm 0.19$  D at 36 months. An improvement of at least  $-2.00$  D between baseline and 36 months was observed in six eyes with a maximum improvement of  $-2.90$  D in 2 eyes. In the control group, no eyes improved by 2.00 D or more, and 19 eyes had documented progression of 2.00 D or more, with seven eyes in this group progressing by 4.00 D or more over 36 months. A comparison of the changes between control and treatment groups demonstrated statistically significant differences for all evaluated time points ( $p < 0.001$ ). For UCVA, the difference between the changes in both groups also was significant in favor of the treatment group at each follow-up ( $p < 0.001$ ). Compared to baseline values treated eyes significantly improved in BSCVA throughout 36 months of follow-up. The mean change in BSCVA for the control group was not significant at 36 months, and there was no significant difference in BSCVA between the 2 groups at any time point. Adverse events (n=2 eyes) of mild, diffuse corneal edema and a small paracentral infiltrate occurred in one week after CXL treatment. Study limitations include loss to follow-up and compassionate CXL being offered to select patients in the control group after a minimum of six months of follow-up. The authors noted that "this could lead to masking of progression in the control group and an underestimation of the treatment effect demonstrated in this study" (Wittig-Silva, et al., 2014). The results of this study suggest that CXL is associated with improved UCVA and BSCVA compared to no treatment for progressive keratoconus.

Hersh et al. (2011) conducted an RCT (n=58 patients/71 eyes) to evaluate corneal collagen crosslinking for treatment of keratoconus and corneal ectasia. The treatment group received standard corneal collagen crosslinking and the sham control group received riboflavin alone. Primary outcomes included uncorrected and corrected distance visual acuities, refraction, and astigmatism. At one year of follow-up, improvements were found in uncorrected ( $p=0.04$ ) and corrected ( $p<0.001$ ) distance visual acuities. Keratoconus patients had more improvement in topographic measurements than patients with ectasia. Limitations to this study include small sample size and short-term follow-up.

A prospective series by Caporrossi et al. (2011) presented a functional analysis after Riboflavin UV A corneal cross-linking in three different age groups of patients with progressive keratoconus. At 48 months of follow-up pediatric (n=152), intermediate (n=286), and adult patients (n=78) showed a mean gain in UCVA of +0.2, +0.14 and +0.12 Snellen lines respectively. BSCVA gained by a mean of +0.21, +0.2, and +0.1 Snellen lines.

A case series (n=55) by Kymionis et al. (2010) reported a statistically significant increase in the measured intraocular pressure (IOP) 12 months after cross-linking for keratoconus ( $p<0.001$ ). The change in IOP measurements at both postoperative examinations was not correlated with patient age, preoperative pachymetry, or preoperative keratometry readings.

A prospective RCT (n=66 eyes/49 patients) by Wittig-Silva et al. (2008) evaluated the efficacy and safety of corneal collagen cross-linking for the management of progressive keratoconus. Eyes were separately randomized into either treatment or control groups. Interim analysis of treated eyes showed a statistically significant flattening of the steepest simulated keratometry value (K-max) by an average of 1.45 D (p=0.002) at 12 months. A trend toward improvement in BSCVA was also observed. In the control group the mean K-max steepened by 1.28 D (p<0.0001) after 12 months. BSCVA decreased over 12 months (p=0.036).

The National Institute for Health and Clinical Excellence (NICE) (2013) conducted a review of the evidence on photochemical corneal collagen cross-linkage (CXL). According to NICE, the majority of the published evidence on the procedure using riboflavin and ultraviolet A (UVA) for keratoconus and keratectasia relates to the epithelium-off technique. NICE (2013) stated that the “current evidence on the safety and efficacy of epithelium-off CXL for keratoconus and keratectasia is adequate in quality and quantity. Therefore, this procedure can be used provided that normal arrangements are in place for clinical governance, consent and audit.” NICE found the safety and efficacy evidence for epithelium-on CXL and the combination (CXL-plus) procedures to be of inadequate quantity and quality and therefore recommended that the procedures only be used with special arrangements for clinical governance, consent and audit or research (NICE, 2013).

Although initial study results are promising, there is currently insufficient evidence in the published peer-reviewed medical literature to support the use of corneal collagen cross-linking using riboflavin and ultraviolet A. Additional large, well-designed clinical trials with longer-term follow-up are needed to further elucidate the role of this procedure in the treatment for keratoconus or for any other indication.

**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, as newer techniques in refractive surgery have been developed.

**Keratophakia:** This technique involves the insertion of a donor cornea lens into the corneal stroma to change the shape of the cornea and modify its refractive power. Keratophakia was not addressed in the AAO Preferred Practice Pattern on Refractive Errors and Refractive Surgery, and there is a paucity of studies evaluating keratophakia for refractive errors. The effectiveness of keratophakia for correction of refractive errors has not been proven in the peer-reviewed medical literature.

**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. Lamellar keratoplasty may be indicated for a number of corneal diseases, including scarring, edema, thinning, distortion, dystrophies, degenerations and keratoconus. However, it is considered investigational and not medically necessary when performed solely to correct astigmatism and other refractive errors. There is insufficient evidence in the peer-reviewed medical literature regarding the effectiveness of lamellar keratoplasty for the treatment of refractive errors.

**Laser Epithelial Keratomileusis (LASEK):** LASEK, a modification of 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. Advantages of LASEK compared to LASIK are that more stromal tissue is reserved, and flap-related complications do not occur. Patients undergoing LASEK experience more postoperative discomfort and slower recovery of vision than those who have had LASIK. The AAO Preferred Practice Pattern on Refractive Errors and Refractive Surgery states that the potential for the development of corneal haze remains a concern since LASEK is a modification of PRK (AAO, 2013). There is a lack of evidence in the peer-reviewed literature to support the safety and efficacy of this procedure.

**Orthokeratology:** Sequentially flatter, hard contact lenses are applied to flatten the cornea and thereby reduce myopic refractive error. The AAO Preferred Practice Pattern on Refractive Errors and Refractive Surgery states that attempts to predict which patients will respond to orthokeratology based on ocular biomechanical or biometric parameters have not been successful. According to the AAO, the effects of orthokeratology have been unpredictable and poorly controlled. More recently, the use of reverse geometry gas-permeable rigid contact

lenses for temporary corneal reshaping in patients with myopia is being investigated. The center of the contact lens worn during sleep is deliberately fitted flatter than central corneal curvature to transiently induce central corneal flattening, which will reverse myopia during the day when the lens is not worn. The most serious complication that has been associated with orthokeratology is microbial keratitis. The AAO states that there is insufficient evidence to support the use of orthokeratology for the prevention of myopia in children (AAO, 2013).

Van Meter et al. (2008) performed a technology assessment of case reports and noncomparative case series (n=75) to evaluate the safety of overnight orthokeratology for the treatment of myopia. It was found that overnight orthokeratology is associated with complications including infectious keratitis and induced astigmatism, however the prevalence and incidence of complications have not been determined. The authors summarized that "because overnight orthokeratology puts patients at risk for vision-threatening complications they may not encounter otherwise, sufficiently large well-designed cohort or randomized controlled studies are needed to provide a more reliable measure of the risks of treatment and to identify risk factors for complications. Overnight orthokeratology for slowing the progression of myopia in children also needs well-designed and properly conducted controlled trials to investigate efficacy" (Van Meter, et al., 2008).

There is insufficient evidence in the published, peer-reviewed literature to support the effectiveness of orthokeratology for the treatment of myopia.

**Penetrating Keratoplasty (PK) (Corneal Transplantation, Perforating Keratoplasty):** PK involves replacement of the full-thickness of the 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.

**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). According to the AAO, 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 (AAO, 2013).

In 2004, NICE issued guidance on the use of scleral expansion bands in which it was stated that the current evidence on the safety and efficacy of scleral expansion surgery for presbyopia is very limited. NICE found no evidence of efficacy in the majority of patients and also noted that there were concerns about the potential risks of the procedure. It was recommended that the procedure not be used (NICE, 2004).

Qazi et al. (2002) conducted a multicenter, prospective, nonrandomized, clinical trial (n=29) to assess the effects of scleral expansion band (SEB) segments on accommodation. The non-operated eye served as the control. A statistically significant increase in accommodative amplitude was noted in both the operated eye and the control eye ( $p < 0.0001$ ) at six-month follow-up. A modest improvement in near vision was noted in approximately half of the patients using subjective methods of testing. Adverse effects included a transient elevation of intraocular pressure (n=1) and misalignment of individual SEB segments (n=3). Study limitations include small sample size and the use of subjective testing methods.

There is insufficient evidence in the peer-reviewed literature to support the effectiveness of scleral expansion surgery for the treatment of presbyopia.

#### **Use Outside of the US**

No relevant information.

## Summary

The safety and effectiveness of refractive surgical procedures are improving; however, these procedures are associated with significant risks of degradation of best corrected visual acuity (BCVA), as well as induced regular or irregular astigmatism, regression of effect, visual aberrations (e.g., transient or permanent glare, or starburst/halo effect), and decreased contrast sensitivity. While the evidence is not robust, there is an adequate body of evidence indicating that intrastromal corneal ring segments are a safe and effective treatment option for a specific subset of patients with keratoconus. The evidence in the published peer-reviewed medical literature on the treatment of progressive keratoconus with corneal collagen cross-linking using riboflavin and ultraviolet is evolving. Additional results of well-designed controlled clinical trials are needed to firmly establish the role of this procedure in treating ectasia associated with keratoconus, and to determine the preferred technique i.e., epithelium-off, epithelium-on).

For other U.S. Food and Drug Administration (FDA)-approved indications and indications accepted by the American Academy of Ophthalmology (AAO), refractive surgical procedures are considered not medically necessary because spectacles or contact lenses have been shown to provide more accurate corrections of refractive errors than refractive surgery. According to the AAO Preferred Practice Pattern on refractive surgery "eyeglasses are the simplest and safest means of correcting a refractive error, therefore eyeglasses should be considered before contact lenses or refractive surgery" (AAO, 2013).

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## Coding/Billing Information

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

3) ICD-10-CM Diagnosis Codes are for informational purposes only and are not effective until 10/01/2015.

### Corneal Relaxing Incision/Corneal Wedge Resection

Covered when medically necessary:

CPT <sup>®</sup> * Codes	Description
65772	Corneal relaxing incision for correction of surgically induced astigmatism
65775	Corneal wedge resection for correction of surgically induced astigmatism

### Epikeratoplasty (epikeratophakia)

Covered when medically necessary:

CPT <sup>®</sup> * Codes	Description
65767	Epikeratoplasty

### Phototherapeutic Keratectomy (PTK)

Covered when medically necessary when used to report phototherapeutic keratectomy (PTK):

CPT* Codes	Description
66999	Unlisted procedure, anterior segment of eye

HCPCS Codes	Description
S0812	Phototherapeutic keratectomy (PTK)

### Intrastromal Corneal Ring Segments

**Covered when medically necessary:**

<b>CPT®*</b> <b>Codes</b>	<b>Description</b>
0099T	Implantation of intrastromal corneal ring segments

**Laser In Situ Keratomileusis (LASIK), Photorefractive Keratectomy (PRK)**

**Covered when medically necessary:**

<b>HCPCS</b> <b>Codes</b>	<b>Description</b>
S0800	Laser in situ keratomileusis (LASIK)
S0810	Photorefractive keratectomy (PRK)

**Not Medically Necessary/Not Covered when used to report correction of refractive errors:**

<b>CPT* Codes</b>	<b>Description</b>
65710	Keratoplasty (corneal transplant); anterior lamellar
65730	Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia)
65750	Keratoplasty (corneal transplant); penetrating (in aphakia)
65755	Keratoplasty (corneal transplant); penetrating (in pseudophakia)
65771	Radial Keratotomy
66840	Removal of lens material; aspiration technique, 1 or more stages
66850	Removal of lens material; phacofragmentation technique (mechanical or ultrasonic) (eg, phacoemulsification), with aspiration
66852	Removal of lens material; pars plana approach, with or without vitrectomy
66920	Removal of lens material; intracapsular
66930	Removal of lens material; intracapsular, for dislocated lens
66940	Removal of lens material; extracapsular (other than 66840, 66850, 66852)
66983	Intracapsular cataract extraction with insertion of intraocular lens prosthesis (1 stage procedure)
66985	Insertion of intraocular lens prosthesis (secondary implant), not associated with concurrent cataract removal
66999†	Unlisted procedure, anterior segment of eye
0289T	Corneal incisions in the donor cornea created using a laser, in preparation for penetrating or lamellar keratoplasty (List separately in addition to code for primary procedure)
0290T	Corneal incisions in the recipient cornea created using a laser, in preparation for penetrating or lamellar keratoplasty (List separately in addition to code for primary procedure)

†**Note:** Not Medically Necessary/Not Covered when used to report those procedures outlined in this medical coverage policy.

<b>HCPCS</b> <b>Codes</b>	<b>Description</b>
C1780	Lens, intraocular (new technology)
Q1004	New technology, intraocular lens, category 4 as defined in Federal Register notice
Q1005	New technology, intraocular lens, category 5 as defined in Federal Register notice
S0596	Phakic intraocular lens for correction of refractive error
S0800	Laser in situ keratomileusis (LASIK)

S0810	Photorefractive keratectomy (PRK)
V2630	Anterior chamber intraocular lens
V2631	Iris supported intraocular lens
V2632	Posterior chamber intraocular lens
V2787	Astigmatism correcting function of intraocular lens
V2788	Presbyopia correcting function of intraocular lens

ICD-9-CM Diagnosis Codes	Description
367.0-367.9	Disorders of refraction and accommodation

ICD-10-CM Diagnosis Codes (effective 10/01/2015)	Description
H52.00- H52.03	Hypermetropia
H52.10- H52.13	Myopia
H52.201- H52.209	Unspecified astigmatism
H52.211- H52.219	Irregular astigmatism
H52.221- H52.229	Regular astigmatism
H52.31- H52.32	Anisometropia and aniseikonia
H52.4	Presbyopia
H52.511- H52.519	Internal ophthalmoplegia (complete) (total)
H52.521- H52.529	Paresis of accommodation
H52.531- H52.539	Spasm of accommodation
H52.6	Other disorders of refraction
H52.7	Unspecified disorder of refraction

**Experimental/Investigational/Unproven/Not Covered when used to report correction of refractive error:**

CPT* Codes	Description
65760	Keratomileusis
65765	Keratophakia
66999 <sup>†</sup>	Unlisted procedure, anterior segment of eye

HCPCS Codes	Description
V2599	Contact lens, other type

\*Current Procedural Terminology (CPT®) © 2013 American Medical Association: Chicago, IL.

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