



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject **Corneal Remodeling**

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Computer-Assisted Corneal Topography
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INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), 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 participant'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 participant's benefit plan document **always supercedes** 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 group 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. 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. Proprietary information of CIGNA. Copyright ©2010 CIGNA

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.

CIGNA covers correction of surgically-induced astigmatism 3.00 diopters (D) or greater with a corneal relaxing incision or corneal wedge resection (i.e. astigmatic keratotomy [AK]), post-cataract or post-transplant surgery as medically necessary in an individual who is intolerant of glasses or contact lenses for EITHER of the following indications:

- previous penetrating keratoplasty (corneal transplant) within the past 60 months
- cataract surgery within the last 36 months

CIGNA covers epikeratoplasty (epikeratophakia) as medically necessary for EITHER of the following indications:

- correction of refractive errors of acquired or congenital aphakia
- hypermetropia following cataract surgery in patients unable to receive intraocular lens

CIGNA covers phototherapeutic keratectomy (PTK) 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 covers the insertion of intrastromal corneal ring segments (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 ANY of the following refractive procedures because they are considered not medically necessary (this list may not be all-inclusive):

- astigmatic keratotomy (AK) except as previously indicated
- clear lens extraction (CLE)
- conductive keratoplasty
- intrastromal corneal ring segments (e.g., INTACS) except as previously indicated
- laser in situ keratomileusis (LASIK)
- laser thermokeratoplasty (LTK)
- limbal relaxing incisions for non-surgically induced astigmatism
- phakic intraocular lens (PIOL)
- photorefractive keratectomy (PRK), and photoastigmatic keratectomy (PARK or PRK-A)
- phototherapeutic keratectomy (PTK) for the treatment of infectious keratitis
- radial keratotomy

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
- epikeratoplasty (epikeratophakia), except as previously indicated
- hexagonal keratotomy in all cases
- keratophakia for the correction of all refractive errors
- lamellar keratoplasty (nonpenetrating keratoplasty)
- laser epithelial keratomileusis (LASEK)
- minimally-invasive radial keratotomy (mini-RK) in all cases
- orthokeratology in all cases
- penetrating keratoplasty (PK) (corneal transplantation, perforating keratoplasty)
- scleral expansion surgery

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], 2007).

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, 2007). There are several refractive procedures currently in use.

Refractive Procedures

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-Buckner'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.

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, 2007). 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, 2007).

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 on ALK identified a lack of peer-reviewed literature to support the safety and efficacy of ALK. 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, 2007).

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[®] (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.

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, 2007). There is a lack of evidence in the peer-reviewed literature to support the safety and efficacy of this procedure.

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.

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. 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 (AAO, 2007).

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.

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.

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, 2007).

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.

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.

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.

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. The 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).

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

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).

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.

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, 2007). Treatment for post- LASIK ectasia is not an FDA-approved indication for intrastromal corneal ring segments.

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 ≤ 2.5 D of astigmatism, or to reduce myopia ranging from > -15.0 D to - 20.0 D with ≤ 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.

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, 2007).

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.

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, 2007).

In 2004, NICE issued a 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.

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[®] (Refractec Inc., Irvine, CA) received PMA approval from the FDA. Based on data submitted with the PMA application, the ViewPoint CK System[®] 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.

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.

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, 2007).

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.

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 a growing body of evidence indicating that intrastromal corneal ring segments are a safe and effective treatment option for a specific subset of patients with keratoconus. 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, 2007).

Coding/Billing Information

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

Covered when medically necessary:

CPT[®]* Codes	Description
65767	Epikeratoplasty
65772	Corneal relaxing incision for correction of surgically induced astigmatism
65775	Corneal wedge resection for correction of surgically induced astigmatism
0099T	Implantation of intrastromal corneal ring segments

HCPCS Codes	Description
S0812	Phototherapeutic keratectomy (PTK)

ICD-9-CM Diagnosis Codes	Description
264.6	Vitamin A deficiency with xerophthalmic scars of cornea
362.01	Background diabetic retinopathy
362.02	Proliferative diabetic retinopathy
367.0	Hypermetropia
367.1	Myopia
367.20 – 367.22	Astigmatism
367.31 – 367.32	Anisometropia and aniseikonia
367.4	Presbyopia
367.51 – 367.53	Disorders of accommodation
367.81 – 367.89	Other disorders of refraction and accommodation
367.9	Unspecified disorder of refraction and accommodation
371.00 - 371.05	Corneal scars and opacities
371.10	Unspecified corneal deposit
371.11	Anterior pigmentations of cornea
371.40 – 371.49	Corneal degenerations
371.50 – 371.58	Hereditary corneal dystrophies
371.60 – 371.62	Keratoconus
371.71	Corneal ectasia
379.31	Aphakia
743.35	Congenital aphakia
996.51	Mechanical complication due to corneal graft
996.79	Other complications due to other internal prosthetic device, implant, and graft
V42.5	Cornea replaced by transplant
V59.5	Cornea donor

Not Medically Necessary/Not Covered:

CPT* Codes	Description
65771	Radial Keratotomy

HCPCS Codes	Description
S0800	Laser in situ keratomileusis (LASIK)
S0810	Photorefractive keratectomy (PRK)

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
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)
65760	Keratomileusis
65765	Keratophakia

[†] **Note:** Experimental/Investigational/Unproven and Not Covered when used to report penetrating or lamellar keratoplasty for the treatment of refractive errors.

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

References

1. American Academy of Ophthalmology. Policy Statement. Laser surgery. February 2001. Accessed July 11, 2009. Available at URL address: http://one.aao.org/CE/PracticeGuidelines/ClinicalStatements_Content.aspx?cid=7dcf9ccd-1253-4296-a372-b5024cb414fb
2. American Academy of Ophthalmology. Preferred Practice Pattern. Refractive Errors & Refractive Surgery. September 2007. Accessed July 11, 2009. Available at URL address: http://10.33.192.56:8080/___Finjan_Substitute_Data_ARAGABALDDEBSS.asp?Page=Main&Action=Finish&ID=21155617
3. Boxer Wachler BS, Christis JP, Chandra NS, Chou B, Korn T, Nepomuceno R. Intacs for keratoconus. *Ophthalmology*. 2003 May;110(5):1031-1040.
4. Chang DH, Davis EA. Phakic intraocular lenses. *Curr Opin Ophthalmol*. 2006 Feb;17(1):99-104.
5. CIGNA HealthCare Medicare Administration. Corneal Transplant Wound Revisions. Medicare Part B Carrier - Tennessee Local Medical Review Policy. Accessed June 4, 2005. Available at URL address: http://www.cignamedicare.com/partb/lmp_lcd/tn/cms_fu/9619-02.htm
6. Colin J. European clinical evaluation: Use of Intacs for the treatment of keratoconus. *J Cataract Refract Surg*. 2006 May;32(5):747-55.
7. Colin J, Cochener B, Savary G, Malet F, Holmes-Higgin D. INTACS inserts for treating keratoconus: one-year results. *Ophthalmology*. 2001 Aug;108(8):1409-14.
8. Colin J, Malet FJ. Intacs for the correction of keratoconus: two-year follow-up. *J Cataract Refract Surg*. 2007 Jan;33(1):69-74.
9. Das S, Link B, Seitz B. Salzmann's nodular degeneration of the cornea: a review and case series. *Cornea*. 2005 Oct;24(7):772-7.

10. Dick HB, Gross S, Tehrani M, Eisenmann D, Pfeiffer N. Refractive lens exchange with an array multifocal intraocular lens. *J Refract Surg.* 2002 Sep-Oct;18(5):509-18.
11. Ertan A, Kamburoğlu G, Bahadır M. Intacs insertion with the femtosecond laser for the management of keratoconus: one-year results. *J Cataract Refract Surg.* 2006 Dec;32(12):2039-42.
12. Jacobi PC, Dietlein TS, Lüke C, Jacobi FK. Multifocal intraocular lens implantation in prepresbyopic patients with unilateral cataract. *Ophthalmology.* 2002 Apr;109(4):680-6.
13. Kanellopoulos AJ, Pe LH, Perry HD, Donnenfeld ED. Modified intracorneal ring segment implantations (INTACS) for the management of moderate to advanced keratoconus: efficacy and complications. *Cornea.* 2006 Jan;25(1):29-33.
14. Kymionis GD, Siganos CS, Tsiklis NS, Anastasakis A, Yoo SH, Pallikaris AI, et al. Long-term follow-up of Intacs in keratoconus. *Am J Ophthalmol.* 2007 Feb;143(2):236-244. Epub 2006 Nov 30.
15. Leyland M, Pringle E. Multifocal versus monofocal intraocular lenses after cataract extraction. *Cochrane Database Syst Rev.* 2006 Oct 18;(4):CD003169.
16. McDonald MB, Durrie D, Asbell P, Maloney R, Nichamin L. Treatment of presbyopia with conductive keratoplasty: six-month results of the 1-year United States FDA clinical trial. *Cornea.* 2004 Oct;23(7):661-8.
17. Mimura T, Azar DT. Refractive Surgery. In: Yanoff M, Duker JS, editors. *Ophthalmology.* 3rd ed. St. Louis, MO; Mosby, Inc.; 2008.
18. National Institute for Health and Clinical Excellence (NICE). IPG164 Photorefractive (laser) surgery for the correction of refractive error: Guidance. March 2006. Accessed June 14, 2006. Available at URL address: <http://www.nice.org.uk/page.aspx?o=IPG164guidance>
19. National Institute for Health and Clinical Excellence (NICE). IPG227 Corneal implants for keratoconus: Guidance July 2007a. Accessed July 11, 2009. Available at URL address: <http://www.nice.org.uk/nicemedia/pdf/IPG227guidance.pdf>
20. National Institute for Health and Clinical Excellence (NICE). IPG225 Corneal implants for the correction of refractive error: Guidance July 2007b. Accessed July 11, 2009. Available at URL address: <http://www.nice.org.uk/nicemedia/pdf/IPG225Guidance.pdf>
21. National Institute for Health and Clinical Excellence (NICE). IPG70 Scleral expansion surgery for presbyopia: guidance. July, 2004. Accessed July 11, 2009. Available at URL address: <http://www.nice.org.uk/nicemedia/pdf/ip/IPG070guidance.pdf>
22. No authors listed. Excimer laser photorefractive keratectomy (PRK) for myopia and astigmatism. *American Academy of Ophthalmology. Ophthalmology.* 1999 Feb;106(2):422-37.
23. No authors listed. Radial keratotomy for myopia. *American Academy of Ophthalmology. Ophthalmology.* 1993 Jul;100(7):1103-15.
24. No authors listed. Keratophakia and keratomileusis: safety and effectiveness. *American Academy of Ophthalmology. Ophthalmology.* 1992 Aug;99(8):1332-41.
25. Rapuano CJ, Sugar A, Koch DD, Agapitos PJ, Culbertson WW, de Luise VP, et al. Intrastromal corneal ring segments for low myopia: a report by the American Academy of Ophthalmology. *Ophthalmology.* 2001 Oct;108(10):1922-8.
26. Shortt AJ, Allan BD. Photorefractive keratectomy (PRK) versus laser-assisted in-situ keratomileusis (LASIK) for myopia. *Cochrane Database Syst Rev.* 2006 Apr 19;(2):CD005135.

27. Siganos CS, Kymionis GD, Kartakis N, Theodorakis MA, Astyrakakis N, Pallikaris IG. Management of keratoconus with Intacs. *Am J Ophthalmol*. 2003 Jan;135(1):64-70.
28. Sugar A, Rapuano CJ, Culbertson WW, Huang D, Varley GA, Agapitos PJ, et al. Laser in situ keratomileusis for myopia and astigmatism: safety and efficacy: a report by the American Academy of Ophthalmology. *Ophthalmology*. 2002 Jan;109(1):175-87.
29. Swarbrick HA. Orthokeratology review and update. *Clin Exp Optom*. 2006 May;89(3):124-43.
30. Torquetti L, Berbel RF, Ferrara P. Long-term follow-up of intrastromal corneal ring segments in keratoconus. *J Cataract Refract Surg*. 2009 Oct;35(10):1768-73.
31. U.S. Food and Drug Administration (FDA). Update on excimer lasers for nearsightedness. Accessed June 28, 2004. Available at URL address: <http://www.fda.gov/bbs/topics/ANSWERS/ANS00737.html>
32. U.S. Food and Drug Administration (FDA). FDA approves implant to correct mild nearsightedness. Accessed June 28, 2004. Available at URL address: <http://www.fda.gov/bbs/topics/ANSWERS/ANS00948.html>
33. U.S. Food and Drug Administration (FDA). FDA-approved lasers for LASIK. Accessed June 29, 2004. Available at URL address: <http://www.fda.gov/cdrh/LASIK/lasers.htm>
34. U.S. Food and Drug Administration (FDA). New Humanitarian Device Approval. INTACS® Prescription Inserts for Keratoconus - H040002. Updated September 21, 2004. Accessed June 6, 2005. Available at URL address: <http://www.fda.gov/cdrh/mda/docs/h040002.html>
35. Van Meter WS, Musch DC, Jacobs DS, Kaufman SC, Reinhart WJ, Udell IJ; American Academy of Ophthalmology. Safety of overnight orthokeratology for myopia: a report by the American Academy of Ophthalmology. *Ophthalmology*. 2008 Dec;115(12):2301-2313.e1. Epub 2008 Sep 20.
36. Varley GA, Huang D, Rapuano CJ, Schallhorn S, Boxer Wachler BS, Sugar A; Ophthalmic Technology Assessment Committee Refractive Surgery Panel, American Academy of Ophthalmology. LASIK for hyperopia, hyperopic astigmatism, and mixed astigmatism: a report by the American Academy of Ophthalmology. *Ophthalmology*. 2004 Aug;111(8):1604-17.

Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	8/15/2008	0141	Corneal Remodeling

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.