

# MEDICAL POLICY

<b>SUBJECT: REFRACTIVE PROCEDURES</b>	<b>EFFECTIVE DATE: 03/25/04</b> <b>REVISED DATE: 12/02/04, 12/02/05, 12/07/06, 12/13/07</b> <b>ARCHIVED DATE: 12/11/08</b> <b>EDITED DATE: 12/10/09, 12/09/10, 12/08/11, 12/06/12, 10/24/13, 10/23/14, 10/28/15, 10/27/16, 10/26/17, 10/25/18</b>
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<ul style="list-style-type: none"><li>• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i></li><li>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i></li><li>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i></li></ul>	

## POLICY STATEMENT:

- I. Based upon our criteria and assessment of the peer-reviewed literature, all forms of elective refractive keratoplasty (e.g., RK, PRK, LASEK, and LASIK) are considered **not medically necessary**. However, use of a refractive procedure in the treatment of myopia, astigmatism or hyperopia that cannot be corrected with lenses (eyeglasses, contacts, or other refractive devices) to an acuity of 20/40 will be considered medically appropriate, if there is evidence that the use of contact lenses or glasses is contraindicated (or ineffective) and documentation that other methods of conservative treatment have been attempted.
- II. Based upon our criteria and assessment of peer-reviewed literature, implantation of a phakic IOL (e.g., Artisan<sup>®</sup> or Vision ICL), an FDA-approved intracorneal inlay (e.g., Raindrop, Kamra) or intrastromal corneal ring segments for the treatment of moderate to severe myopia is considered **not medically necessary**.
- III. Based upon our criteria and assessment of peer-reviewed literature, the following refractive procedures have not been medically proven effective and are considered **investigational** as a treatment for refractive errors:
  - A. implantation of a non-FDA approved phakic intraocular lens;
  - B. a clear lens extraction with or without implantation of an intraocular lens;
  - C. non-FDA approved intracorneal inlays; or
  - D. orthokeratology.

*Refer to Corporate Medical Policy #9.01.01 Phototherapeutic Keratoplasty regarding requests for surgical treatment of medical conditions of the cornea.*

*Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.*

## POLICY GUIDELINES:

- I. For members whose contracts specifically include coverage for refractive surgery, refractive procedures are eligible for coverage provided that FDA approved indications are followed.
- II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

## DESCRIPTION:

Refractive errors include hyperopia, myopia, astigmatism and presbyopia. The term refractive surgery describes various procedures that modify the refractive error of the eye for the purpose of improving vision. Most of these procedures involve altering the cornea and are collectively referred to as keratorefractive surgery, refractive keratoplasty or refractive corneal surgery. The outcome of refractive surgery is not totally predictable; glasses or contact lenses may be necessary to obtain satisfactory distance vision after surgery and reading glasses will likely be required by postsurgical patients who are presbyopic. Refractive procedures include, but are not limited to, the following:

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

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

Minimally Invasive Radial Keratotomy (mini-RK) is intended in cases of myopia, to alter the cornea's shape and consequently the refraction by reducing the millimeters of cornea that are incised.

Astigmatic Keratotomy (AK) is a microsurgical technique used to place circumferenced incisions in the peripheral cornea to reduce astigmatism, either natural occurring, post trauma or post-surgical. AK can be divided into 2 groups: limbal relaxing incisions (LRIs) and corneal relaxing incisions (CRIs). AK is frequently in conjunction with cataract surgery.

Intrastromal Corneal Ring Segments (ICRS) procedure consists of placement of plastic segments in the peripheral corneal stroma to cause central corneal flattening. ICRS is indicated for treatment of low degrees of myopia. The ICRS can be removed, resulting in the potential for a reversible refractive effect. *Please refer to Medical Policy # 9.01.13 regarding use of intrastromal corneal ring segments for keratoconus.*

Laser Assisted In-Situ Keratomileusis (LASIK) is a two staged procedure first requiring a partial thickness flap to be made with a keratome followed by laser refractive sculpting of the exposed corneal stromal bed. It is indicated for treating myopia, astigmatism or hyperopia and may be used after cornea transplant or cataract surgery.

Laser Thermal Keratoplasty (LTK) consists of a discrete number of laser burns applied to the corneal stroma causing central steepening. It is indicated for correction of hyperopia, either natural occurring or post-surgical.

Laser-Assisted Subepithelial Keratomileusis (LASEK) is used to treat low to moderate myopia. An epithelial flap is created after exposure to 20% alcohol and following the laser ablation, the epithelium is repositioned to its original location. Like PRK, LASEK preserves more tissue for potential ablation and may have a potential indication when wavefront ablations are used. This technique could limit higher order optical aberrations compared with LASIK with creation of a standard microkeratome flap.

Conductive Keratoplasty (CK) is a surgical technique to treat low to moderate hyperopia. It delivers radio frequency (350kHz) current directly into the corneal stroma through a keratoplasty tip inserted into the peripheral cornea at 8 to 32 treatment points. A full circle of CK spots produces a cinching effect that increases the curvature of the central cornea, thereby decreasing hyperopia.

Phakic Intraocular Lens (PIOL) can be surgically placed into the anterior chamber (Vita Lens), attached to the iris (Verisyse/Artisan®) or placed in the posterior chamber anterior to the crystalline lens (STAAR Vision ICL) in the phakic eye to correct a refractive error. A phakic eye is an eye that retains the natural crystalline lens. Phakic IOLs are considered an alternative refractive treatment method for patients with high myopia or high hyperopia. These IOLs have also been used in combination with LASIK, and have sometimes been referred to as implantable contact lenses.

Clear Lens Extraction has been performed to correct high hyperopic or myopic refractive errors. An aphakic intraocular lens is usually implanted after removal of the crystalline lens. *Please refer to Medical Policy # 9.01.14 regarding intraocular lens implants.*

An Intracorneal Inlay consists of a polysulfone or hydrogel lenticule that is placed in the optic zone of the central corneal stroma to correct refractive errors by acting as a supplemental lens to focus images clearly within the eye.

Orthokeratology utilizes the application of sequentially flatter PMMA hard contact lenses to flatten the cornea, thereby reducing the myopic refractive error.

Automated Lamellar Keratoplasty (ALK) has been performed to correct high degrees of nearsightedness, or myopia and to correct low to moderate amounts of hyperopia. It is performed utilizing a microkeratome to slice off a thin layer of the

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center of the cornea. This flattens the central optical zone, thereby reducing myopia.

**RATIONALE:**

The U.S. Food and Drug Administration (FDA) regulates the sale of medical devices such as the lasers used for refractive and phototherapeutic keratoplasty. The FDA has approved several laser devices for LASIK, PRK, LASEK, CK and other refractive surgeries, including Laser Thermal Keratoplasty (LTK), and has also approved Intrastromal Corneal Ring Segments (e.g., INTACS®). The Artisan® phakic IOL received FDA approval in September 2004 for moderate to severe myopia. Staar’s Vision ICL phakic IOL received FDA approval in December 2005. The Vision ICL is intended for use in adults aged 21 to 45 years with an anterior chamber depth of 3 mm or greater for the correction of myopia. The Kamara corneal inlay (AcuFocus) which received FDA approval in 2015 is designed to reduce or eliminate the need for reading glasses for people (ages 54-60 years of age) who have good distance vision without glasses but have problems seeing up close due to presbyopia. The raindrop near vision inlay, developed by Revision Optics gained FDA approval in 2016.

Short-term studies on phakic intraocular lenses indicate that these lenses produce an equal or sometimes even better improvement in vision compared to LASIK, but long-term follow-up in regards to tolerance and continued vision correction is lacking. These implants have also been associated with multiple complications such as retinal detachment, pupillary ovalization, endothelial cell loss, cataract formation, induced astigmatism, glaucoma, halos and glare, depending on the location of the IOL placement. The FDA approval of the Artisan® lens was based on review of multicenter clinical studies involving 662 patients. After 3 years, 92% of patients had a 20/40 or better vision and 44% had 20/20 vision or better. The data also showed a continual loss of corneal epithelial cells at a rate of 1.8% per year over the 3 years. The FDA noted that it is unknown whether the cell loss will continue or what the long-term effects will be.

The American Academy of Ophthalmology (AAO) Preferred Practice Pattern on Refractive Errors 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. The AAO does not recommend this approach to correct refractive errors.

Intrastromal corneal ring segments (INTACS) received FDA clearance for use in patients with low myopia in April of 1999. An ophthalmic technology assessment by the American Academy of Ophthalmology concluded the following: At 1 year, 97% of patients who completed follow-up had 20/40 or better uncorrected visual acuity (UCVA). Seventy-four percent of patients had 20/20 or better UCVA. Ninety-two percent of eyes were within +/-1 D of intended refractive correction, and 69% were within 0.5 D of intended refractive correction. The ocular complication rate, which was defined as clinically significant events but not resulting in permanent sequelae, was 11% at 12 months. The adverse event rate was 1.1%, defined as a serious event if untreated. Evidence suggests that low myopia (-1 to -3 D) in a well-defined group of patients who have a stable manifest refraction and less than +1.0 D of astigmatism can be treated with Intacs inserts with a reasonable assurance of safety and effectiveness. Additional clinical research is needed to determine the long-term effectiveness of treatment and the comparative safety, effectiveness, and costs with other treatment modalities, including laser-assisted in-situ keratomileusis (LASIK) and photorefractive keratectomy (PRK).

Clinical evidence in peer-reviewed literature has demonstrated that refractive procedures such as PRK, LASIK and LASEK are safe and effective treatments that provide stable correction of myopia, hyperopia or astigmatism when performed by experienced ophthalmologic surgeons. The FDA has become increasingly concerned about reports of severe complications of LASIK, but has acknowledged that it does not have enough studies to know how often severe complications occur. In April 2008, the FDA convened a public advisory panel to listen to patient experiences with LASIK (due to the many complications reported e.g., dry eyes, double vision, corneal infection, blindness) and consider how to improve information for patients and physicians about LASIK. The FDA has launched a new national study of patient outcomes, along with the National Eye Institute and American Society of Cataract and Refractive Surgery (ASCRS) to try to compile more information on the rate of poor LASIK results.

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Spectacles and contact lenses have been shown to provide more accurate corrections of refractive errors than refractive surgery. According to the American Academy of Ophthalmology, spectacles are the simplest and safest means of correcting a refractive error.

**CODES:**      Number                      Description

*Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

**CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

**All codes are considered not medically necessary when used as refractive procedures.**

<b><u>CPT:</u></b>	65760	Keratomileusis
	65765	Keratophakia
	65767	Epikeratoplasty
	65771	Radial Keratotomy
	65785	Implantation of intrastromal corneal ring segments ( <i>effective 01/01/16</i> )

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<b><u>HCPCS:</u></b>	S0596	Phakic intraocular lens for correction of refractive error
	S0800	Laser in Situ Keratomileusis (LASIK)
	S0810	Photorefractive Keratectomy (PRK)

<b><u>ICD10:</u></b>	H52.00-H52.4	Disorders of refraction (code range)
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\*key articles

**KEY WORDS:**

LASIK, Photorefractive keratectomy (PRK), phakic intraocular lens, intracorneal inlay.

## CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for refractive keratoplasty. Please refer to the following NCD website for Medicare Members: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=72&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAA&>