Anthem

Clinical UM Guideline

Subject: Refractive Surgery
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Description

This document addresses refractive surgeries which refers to various surgical procedures performed to correct refractive errors of the eye.

Note: *This document does not address PTK (phototherapeutic keratotomy) which refers to procedures to correct disorders of the cornea.*

For information concerning related topics, see:

- SURG.00061 Presbyopia and Astigmatism-Correcting Intraocular Lenses
- CG-SURG-72 Endothelial Keratoplasty
- CG-SURG-94 Keratoprosthesis
- CG-SURG-105 Corneal Collagen Cross-Linking

Clinical Indications

Medically Necessary:

Correction of surgically induced astigmatism with a corneal relaxing incision or corneal wedge resection is considered **medically necessary** when **all** of the following criteria are met:

A. The astigmatism is the result of a previous cataract surgery, medically necessary refractive surgery, scleral buckling for retinal detachment, or corneal transplant; **and**
B. The degree of astigmatism is 3.00 diopters or greater; **and**
C. The medical record documents inadequate functional vision with any of the following: (1) contact lenses, (2) spectacles, or (3) contact lenses and spectacles.

Laser in-situ keratomileusis (LASIK), laser epithelial keratomileusis (LASEK), photorefractive keratectomy (PRK), and photoastigmatic keratectomy (PARK or PRK-A) are considered **medically necessary** when **all** of the following are met:

A. Prior cataract, corneal, or scleral buckling surgery for retinal detachment has been performed on this eye; **and**
B. The medical record documents symptoms due to aniseikonia (different sizes of ocular images) or anisometropia (difference in power of refraction); **and**
C. The medical record documents inadequate functional vision with any of the following: (1) contact lenses, (2) spectacles, or (3) contact lenses and spectacles; **and**
D. The post-operative spherical equivalent refractive error has changed by 3 diopters when compared to the preoperative refractive error or the degree of astigmatism is 3 diopters or greater.

Small incision lenticule extraction (SMILE) is considered **medically necessary** when **all** of the following criteria are met:

A. Prior cataract, corneal, or scleral buckling surgery for retinal detachment has been performed on this eye; **and**
B. The medical record documents symptoms due to aniseikonia (different sizes of ocular images) or anisometropia (difference in power of refraction); **and**
C. The medical record documents inadequate functional vision with any of the following: (1) contact lenses, (2) spectacles, or (3) contact lenses and spectacles; **and**
D. The post-operative spherical equivalent refractive error has changed by 3 diopters when compared to the preoperative refractive error; **and** the following refractive error exists:
    1. Spherical refractive error (in minus cylinder format): from -1.00 diopters through –10.00 diopters; **and**
    2. Cylinder (when astigmatism is present): from -0.75 diopters through -3.00 diopters; **and**
    3. Refraction spherical equivalent: less than or equal to 10.00 diopters.

Epikeratoplasty (epikeratophakia) is considered **medically necessary** for either of the following conditions:

A. Correction of refractive errors of acquired or congenital aphakia; **or**
B. Hypermetropia following cataract surgery in individuals unable to receive intraocular lens.

Implantation of intrastromal corneal ring segments (INTACS™ Prescription Inserts, Addition Technology, Sunnyvale, CA) is considered **medically necessary** in individuals with keratoconus who meet **all** of the following criteria:

A. Progressive deterioration in vision, such that individuals can no longer achieve adequate functional vision on a daily basis with either contact lenses or spectacles; **and**
B. 21 years of age or older; **and**
C. Presence of clear central cornea; **and**
D. Corneal thickness of 450 microns or greater at the proposed incision site; **and**
E. Who have corneal transplantation as the only remaining option to improve their functional vision.

Not Medically Necessary:

Procedures considered **not medically necessary** include, but are not limited to, the following:

A. Correction of surgically induced astigmatism with a corneal relaxing incision or corneal wedge resection, except for the small subset of individuals noted above;
B. Laser in-situ keratomileusis (LASIK), except for the small subset of individuals noted above;

C. Laser epithelial keratomileusis (LASEK), except for the small subset of individuals noted above;
D. Epikeratoplasty (epikeratophakia), except for the small subset of individuals as noted above;
E. Laser thermal keratoplasty (LTK);
F. Photorefractive keratectomy (PRK) and photoastigmatic keratectomy (PARK or PRK-A), except for the small subset of individuals noted above;
G. Small incision lenticule extraction (SMILE) except for the small subset of individuals noted above;
H. Radial keratotomy and its variants;
I. Implantable contact lenses without lens extraction (phakic intraocular lenses) including, but not limited to, Artisan® Phakic Intraocular Lens also known as Verisyse™ Phakic Intraocular Lens (Ophtec USA, Inc., Boca Raton, FL) and Visian™ ICL Implantable Collamer Lens (Starr Surgical Company, Monravia, CA);
J. Clear lens extraction (CLE) with or without implantation of an accommodating or nonaccommodating lens;
K. Implantation of intrastromal corneal ring segments (INTACS) for the correction of myopia;
L. Conductive keratoplasty to treat presbyopia (that is, ViewPoint™ CK System [Refracrtec Inc., Irvine, CA]);
M. Keratophakia;
N. Orthokeratology;
O. Standard keratomileusis.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

LASIK, SMILE, Epikeratoplasty, PRK, Post-cataract correction
When services may be Medically Necessary when criteria are met:

CPT	
65767	Epikeratoplasty
65772	Corneal relaxing incision for correction of surgically induced astigmatism
65775	Corneal wedge resection for correction of surgically induced astigmatism
66999	Unlisted procedure, anterior segment of eye [when specified as laser epithelial keratomileusis (LASEK) or photoastigmatic keratectomy (PRK-A)]
HCPCS	
S0800	Laser in situ keratomileusis (LASIK)
S0810	Photorefractive keratectomy (PRK)
ICD-10 Procedure	
	For the following procedures when specified as LASIK, SMILE, LASEK, PRK:
08Q8XZZ-08Q9XZZ	Repair cornea, external approach [right or left; includes codes 08Q8XZZ, 08Q9XZZ]
	For the following procedures, when specified as correction of surgically induced astigmatism:
08T8XZZ-08T9XZZ	Resection of cornea, external approach [right or left; includes codes 08T8XZZ, 08T9XZZ]
	For the following procedures when specified as epikeratoplasty, epikeratophakia;
08U80KZ-08U9XKZ	Supplement cornea with nonautologous tissue substitute [left or right, by approach; includes codes 08U80KZ, 08U83KZ, 08U8XKZ, 08U90KZ, 08U93KZ, 08U9XKZ]
ICD-10 Diagnosis	
H27.00-H27.03	Aphakia
H52.00-H52.03	Hypermetropia
H52.10-H52.13	Myopia
H52.201-H52.229	Astigmatism
H52.31	Anisometropia
H52.32	Aniseikonia
Q12.3	Congenital aphakia
T85.318A-T85.318S	Breakdown (mechanical) of other ocular prosthetic devices, implants and grafts
T85.328A-T85.328S	Displacement of other ocular prosthetic devices, implants and grafts
T85.398A-T85.398S	Other mechanical complication of other ocular prosthetic devices, implants and grafts
Z96.1	Presence of intraocular lens

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed.

Implantation of intrastromal corneal ring segments
When services may be Medically Necessary when criteria are met:

CPT	
65785	Implantation of intrastromal corneal ring segments
ICD-10 Diagnosis	
H18.601-H18.629	Keratoconus
Q13.4	Other congenital corneal malformations [specified as congenital keratoconus]

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed.

Clear lens extraction
When services are Not Medically Necessary:

CPT	
	For the following codes when specified as clear lens extraction for refractive surgery:
66840	Removal of lens material; aspiration technique, one 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)
66985	Insertion of intraocular lens prosthesis (secondary implant), not associated with concurrent cataract removal

HCPCS

C1780	Lens, intraocular (new technology) [ASC billing]
Q1004	New technology intraocular lens category 4
Q1005	New technology intraocular lens category 5
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-10 Diagnosis

H52.00-H52.03	Hypermetropia
H52.10-H52.13	Myopia
H52.201-H52.229	Astigmatism
H52.31	Anisometropia
H52.32	Aniseikonia
H52.4	Presbyopia
H52.6	Other disorders of refraction
H52.7	Unspecified disorder of refraction

Other procedures

When services are Not Medically Necessary:

For the following procedure codes; or when the code describes a procedure designated in the Clinical Indications section as not medically necessary.

CPT

65760	Keratomileusis
65765	Keratophakia
65771	Radial keratotomy
66999	Unlisted procedure, anterior segment of eye [when specified as laser thermal keratoplasty, conductive keratoplasty, orthokeratology]

HCPCS

S0596	Phakic intraocular lens for correction of refractive error

ICD-10 Procedure

	For the following procedures when specified as keratomileusis, radial keratotomy, thermokeratoplasty, conductive keratoplasty, orthokeratology:
08Q8XZZ-08Q9XZZ	Repair cornea, external approach [right or left; includes codes 08Q8XZZ, 08Q9XZZ]
	For the following procedures when specified as keratophakia:
08U80KZ-08U9XKZ	Supplement cornea with nonautologous tissue substitute [left or right, by approach; includes codes 08U80KZ, 08U83KZ, 08U8XKZ, 08U90KZ, 08U93KZ, 08U9XKZ]

ICD-10 Diagnosis

	All diagnoses

Discussion/General Information

Description of Refractive Eye Conditions

Refractive errors, occurring in approximately 50% of the United States population, are disorders of the eye whereby objects, either distant, close or both, appear blurred. Refraction is the bending of light rays as they move from one transparent medium to another medium of a different density and is measured in diopters. The cornea, along with the lens, refracts light that enters the eye. Specifically, the cornea is responsible for 2/3 of the eye's total focusing power and this power is fixed – meaning that it does not change its shape to bring an object into focus. As an eye with normal vision views an object, the cornea and the lens focus the parallel light rays emitted from the object precisely on the retina and a clear image is perceived. In myopia, the most common type of refractive error (occurring in approximately 25% of individuals), the cornea is too curved or the lens too powerful for the length of the globe. Distant objects cannot be seen clearly but near objects appear clear. In hyperopia (farsightedness) the cornea is too flat or the lens too weak for the length of the globe. As a result, a distant object will appear in focus, while near vision is unclear. Presbyopia is an age related visual change, which begins between 40 and 50 years of age and results in difficulty with visual accommodation and thus objects which are nearby are blurred. In astigmatism, the refractive power of the eye is in different meridians. As a result, objects appear blurry at any distance; this can occur with myopia or hyperopia. Refractive errors are temporarily corrected by wearing eyeglasses or contact lenses; however, once the glasses or contacts are removed, blurred vision returns.

Keratoconus

Keratoconus is a progressive bilateral dystrophy that is characterized by paracentral steepening and stromal thinning that impairs visual acuity. Initial treatment often consists of hard contact lenses. A penetrating keratoplasty (that is, corneal grafting) is the next line of treatment for those individuals who develop intolerance to contact lenses. While visual acuity is typically improved with a keratoplasty, there is an associated risk of perioperative complications, long-term topical steroid use is required and endothelial cell loss occurs over time, which is a particular concern in younger individuals. As an alternative, a variety of keratorefractive procedures have been attempted, which are broadly divided into subtractive and additive techniques. Subtractive techniques include photorefractive keratectomy or LASIK but, in general, results of these techniques have been poor. Implantation of intrastromal corneal ring segments (INTACS™ Prescription Inserts) represents an additive technique where the implants are intended to reinforce the

cornea, prevent further deterioration and potentially obviate the need for a penetrating keratoplasty. This technique has primarily been studied in individuals in whom the cornea has remained transparent and who are intolerant to contact lenses.

Refractive Surgery

Refractive surgery has emerged as an option to permanently eliminate the use of glasses or contact lenses. The goals of refractive surgery are to reduce or eliminate refractive error, attain normal vision, and reduce or eliminate the need for glasses or contact lenses for distant vision through the incision or excision of corneal tissue by a surgical instrument. Refractive keratoplasty is a generic term, which includes all surgical procedures on the cornea to improve vision by changing the refractive index of the corneal surface, although they involve different methods. Refractive procedures include the following surgeries:

1. Corneal relaxing incision and corneal wedge resection for surgically induced astigmatism are procedures to correct an astigmatism resulting from a previous surgery (for example, cataract surgery or a corneal transplant). In corneal relaxing, an “X” cut is made on the corneal surface. Slices along the “X” are removed and its edges are sutured. In the corneal wedge resection, a wedge is cut from the cornea and the edges sutured.
2. Laser in-situ keratomileusis (LASIK) is a variation on the PRK method. LASIK is a type of laser surgery of the cornea to correct refractive errors. During LASIK, a surgeon uses lasers and a cutting tool called a microkeratome that works similar to a carpenter’s plane, to form a circular flap on the cornea, which is flipped back to expose the inner layers of the cornea. An excimer laser is then used to shape the interior portions of the cornea to the desired curvature. The flap is then sewn back in place and allowed to heal. LASIK procedures have emerged as the most frequently used option.
3. Automated lamellar keratoplasty (ALK) is a procedure similar in technique to LASIK, where a flap is made in the upper surface of the eye and the interior structure is altered to change the curvature of the cornea, but no lasers are used. Instead of a laser to reshape the inner eye structure, a microkeratome is used. ALK is used for the treatment of moderate farsightedness.
4. Small-incision lenticule extraction (SMILE): This is an alternative to flap-based procedures. It is a minimally invasive technique using a femtosecond laser and involves creating a refractive lenticulecule in the corneal stroma and mechanically removing it through a small peripheral incision.
5. Radial keratotomy (RK) is a procedure in which a surgeon uses a delicate diamond-tipped surgical blade, a microscope, and microscopic instruments to make several spoke-like, "radial" incisions in the non-viewing (peripheral) portion of the cornea. The slits surgically alter the curve of the cornea, making it flatter, which may improve the focus of images onto the retina. Variants are known as mini RK, hexagonal RK and astigmatic RK.
6. Photorefractive keratectomy (PRK) is a refractive surgical procedure involving the reshaping of the surface with the use of a computer to measure the shape of the cornea. Using these measurements, the surgeon applies a computer-controlled excimer laser to make modifications to the cornea for correction of refractive errors (for example, myopia, hyperopia, astigmatism, and presbyopia in individuals with otherwise non-diseased corneas). The PRK procedure flattens the cornea by vaporizing small amounts of tissue from the cornea's surface to correct mild to moderate myopia. A similar procedure, photoastigmatic keratectomy (PARK or PRK-A) is a refractive surgical procedure to correct myopia with astigmatism. Photorefractive keratectomy should not be confused with phototherapeutic keratectomy (PTK). Phototherapeutic keratectomy refers to procedures to correct disorders of the cornea. PTK in not addressed in this document.
7. Laser epithelial keratomileusis (LASEK) is a modification of PRK that attempts to preserve the epithelium. A trephine and spatula are used sequentially to score, loosen, and roll up the epithelium, which remains attached at a nasal or superior hinge. Photoablation is then performed, and the epithelium is unrolled back over the central, lasered corneal stroma. A bandage contact lens is used for several days until the epithelium is intact.
8. Epikeratoplasty (or epikeratophakia - lamellar keratoplasty) is a refractive surgical procedure that involves shaving a portion of the cornea and then replacing it with a pre-shaped donor cornea; (also called non-penetrating or layered).
9. Keratophakia involves implantation of a donor cornea, plastic lens, or a slice of the individual’s own cornea, (which is removed and reshaped), underneath the person’s own cornea to improve the shape of the corneal area.
10. Orthokeratology (Ortho-K) involves the application of sequentially flatter hard contact lenses to flatten the cornea and, thereby, reduce myopic refractive error. Unlike traditional contact lenses, the lenses involved in Ortho-K do not refract like glasses do, but only serve to alter the shape of the cornea to achieve normal vision.
11. Laser thermal keratoplasty describes the use of a holmium: YAG laser that is applied to the periphery of the cornea, causing shrinkage of the collagen fibrils, thus steepening its shape and improving its refractive power.
12. Clear lens extraction (CLE) is a surgical procedure in which the non-cataractous crystalline lens is removed and replaced with an intraocular lens for refractive purposes.

The use of refractive eye surgery as an alternative to eyeglasses or contact lenses is considered to be predominately for comfort and convenience. A medical rationale for refractive surgery must rest on the demonstration that refractive surgery results in a clinically significant improvement in vision, as compared to that achieved with eyeglasses or contact lenses.

The available peer-reviewed literature has failed to establish the superiority of refractive surgical procedures, in terms of safety and long-term benefit over conventional eyewear including glasses and contact lenses, for the indications listed in this document as not medically necessary.

The most recent American Academy of Ophthalmology (AAO) Preferred Practice Pattern on Refractive Surgery (2022) states, “Refractive surgery may be considered when a patient wishes to be less dependent on eyeglasses or contact lenses, or when there are occupational or cosmetic reasons not to wear eyeglasses.” The AAO Preferred Practice Pattern does not discuss vision outcomes after refractive surgery compared with eyeglasses or contact lenses.

The research on the relative effectiveness of different types of refractive surgery compared with no surgery was summarized in a network meta-analysis published in 2017 by Wen and colleagues. Trials were included if they treated individuals with PRK, T-PRK, LASEK, Epi-LASIK, LASIK, femtosecond (FS)-based LASIK, femtosecond lenticule extraction (FLEx), or SMILE. The authors identified 48 randomized controlled trials (RCTs) comparing two or more types of refractive surgery in individuals with myopia. A total of 4234 study participants (5256 eyes) were included in the analysis. For specific procedures, this involved 1036 individuals (1174 eyes) undergoing LASIK, 500 individuals (594 eyes) undergoing FS-LASIK, 1392 individuals (1737 eyes) undergoing PRK, 900 individuals (1326 eyes) undergoing LASEK, 131 individuals (150 eyes) undergoing Epi-LASIK, 105 individuals (105 eyes) undergoing T-PRK, 110 individuals (110 eyes) undergoing SMILE, and 60 individuals (60 eyes) undergoing FLEx. Their network meta-analysis indirectly comparing techniques to one another did not find any statistically significant differences among procedures in efficacy (uncorrected distance visual acuity [UDVA] of 20/20 or better) or safety (losing 2 or more lines of best spectacle-corrected visual acuity [BSCVA] at 6 months post-surgery). For predictability (refractive spherical equivalent within ± 0.50D of the target), FS-LASIK was significantly better than any other type of surgery. The Wen analysis did not address the relative efficacy of refractive surgery and eyeglasses or contact lenses.

Meta-analyses have been published of literature comparing clinical outcomes after SMILE and FS-LASIK. Yan (2017) included comparative studies conducted with adults who had myopia or myopic astigmatism. The primary efficacy outcome was the proportion of eyes achieving an uncorrected distance visual acuity (UDVA) of 20/20 or better. A total of 2 RCTs and 25 non-randomized

comparative studies met the inclusion criteria. In a pooled analysis of the 7 studies reporting this outcome, no significant difference was found in the proportion of eyes with an uncorrected visual acuity (UCVA) of 20/20 or better (odds ratio [OR]: 0.77; 95% confidence interval [CI], 0.54 to 1.09; p=0.04). Among other outcomes, there were no significant differences between groups in the percentage of eyes losing at least 1 line of BSCVA (7 studies), in the proportion of individuals with postoperative refraction within 1.0D of the target refraction (6 studies), or in the mean refractive spherical equivalent outcomes (11 studies).

A meta-analysis by Fu and colleagues (2021) included comparative studies in adults with high myopia (preoperative spherical equivalent refractive error of -6.00 D or worse, or spherical refractive error worse than -5.00 D and cylindrical refractive error worse than -1.00). The authors identified 12 studies, 1 of which was an RCT. In a pooled analysis of 6 studies, there was no significant difference in UDVA between the SMILE and FS-LASIK groups. At the 3 month follow-up, the weighted mean difference (WMD)=-0.00, 95% CI, -0.01 to 0.00, p=0.33). Another pooled analysis of 6 studies did not find a significant difference between groups for postoperative mean refractive SE (WMD, -0.03, 95% CI, -0.09 to 0.03, p=0.30). A meta-analysis of 5 studies found significantly better postoperative corrected distance visual acuity (CDVA) in the SMILE group compared with the FS-LASIK group (WMD, -0.04, 95% CI, -0.05 to -0.02, p<0.00001).

A 2023 RCT by Ma and Manche compared FS-LASIK and SMILE surgeries. A total of 80 individuals were randomized to receive one of these procedures in their dominant eye and the other procedure in the contralateral eye. Eligibility criteria included -0.75 to -8.00 D of spherical myopia and less than 3.00 D of astigmatism. All procedures were done by a single surgeon. At months 1,3, 6 and 12 after surgery, there were no significant differences in scores on the validated Patient-Reported Outcomes With Laser In Kitu Karatomileusis (PROWL) questionnaire (p>0.85 for each comparison). At month 12, 97% of participants reported that they were ‘overall happy’ with the results of the surgery.

Several systematic reviews have addressed biomechanical changes after flap-based refractive surgery (e.g. LASIK, FS-LASIK and FLEx) and the non-flap-based SMILE procedure in individuals with myopia. Guo 2019 reviewed 22 studies; 6 RCTs 15 cohort studies and 2 cross-sectonal studies. A total of 17 studies addressed the SMILE procedure and there were 14 on LASIK, 4 on FLEX, 2 on LASEK, and 1 on PRK. In an analysis of corneal hysteresis [CH] and corneal resistence factor [CRF]), the pooled Hedges’ g was significantly better with the SMIILE procedure compared with FS-LASIK and LASIK and was not significantly different that LASEK or PRK. Raevdal, 2018 included 9 studies, 3 RCTs and 6 non-randomized observational studies. Pre-treatment to post-treatment comparisons found statistically significant reductions in corneal viscoclassic properties in all studies, regardless of the type of procedure. The RCTs did not find significant differences between SMILE and flap-based procedures in biomechanical outcomes (CH and CRF). However, among observational studies, 2 found significant differences in change in CH, favoring the SMILE procedure, and 5 studies found significant differences in CRF, in favor of SMILE. These systematic reviews did not address differences in vision outcomes.

A systematic review of RCTs comparing LASIK and the SMILE and reporting vision outcomes was published by Yao and colleagues in 2022. A total of 11 RCTs met the eligibility criteria, which included follow-up of more than 3 months and being conducted in adults with myopia or myopic astigmatism. In a meta-analysis of 8 RCTs, there was no significant differences between the LASIK and SMILE groups in the proportion of eyes losing one or more eyes of CDVA (RR, 1.14, 95% CI, 0.58 to 2.27, p=0.70) or in the proportion of eyes achieving UCVA of 20/20 or better at follow-up (RR, 9.99, 95% CI, 0.94 to 1.05, p=0.71). The study also investigated the predictability measures, postoperative refraction within 0.5 and 1.0D and postoperative astigmatism within 0.25, 0.5 and 1.0D. the proportion of eyes with refraction within 0.5D was significantly higher in the LASIK group than the SMILE group (RR, 0.91, 95% CI, 0.83 to 0.99, p=0.04) and there was no significant difference between groups for refraction within 1.0D. There was no significant difference between groups for the postoperative astigmatism outcomes.

For individuals with keratoconus, there are several case series on intrastromal corneal implants. Boxer Wachler (2003) reported on the outcomes in 74 eyes of 50 subjects with a mean follow-up of 9 months. A total of 45% gained at least 2 lines of BSCVA, 51% of individuals had no change, and 4% lost BSCVA. Siganos (2003) studied 33 eyes in 26 individuals at a mean follow-up of 11.3 months. In this study, 25 eyes recorded a 1- to 6-line gain in BSCVA, while 4 eyes remained unchanged and 4 eyes experienced a loss. Colin (2001) reported the 1-year results in a series of 10 individuals. The mean values for BSCVA improved progressively over time, and at the 12 month follow-up, average visual acuity was 2 lines better than baseline. Alio (2006) reported the outcomes of 13 eyes with a follow-up of 36 months in all eyes. Mean best BSCVA increased from 0.46 (20/50) preoperatively to 0.66 (20/30) postoperatively (p≤0.001). Colin and Malet (2007) reported outcomes of a 2-year follow-up study comprised of 100 eyes after INTACS implantation. At 2 years, the UCVA and BCVA improved in 80.5% and 68.3% of eyes, respectively (p<0.001). The proportion of eyes with a BCVA greater than or equal to 0.5 (20/40) increased from 22.0% at baseline to 51.2% and 53.7% at 1 year and 2 years, respectively (p<0.001). Contact lens tolerance was restored in over 80% of cases. Additional recent case series and retrospective reviews continue to show promising results for intrastromal corneal implants for the treatment of refractory keratoconus (Bedi, 2012; Ozerturk, 2012; Torquetti, 2014).

A systematic review by Afsharpaiman and colleagues (2020) evaluated the published literature and found a low rate of infectious keratitis complications after refractive surgery. The authors identified 14 studies, which included over 2 million eyes. In a pooled analysis, the incidence of infectious keratitis after refractive surgery was 0.00015%. By procedure, incidence was 0.0006 after LASIK, 0.0005 after LASEK and 0.00012 after PRK.

Definitions

Aniseikonia: The condition in which an image in one eye differs in size or shape from the same image in the other eye.

Anisometropia: The condition in which both eyes have an unequal refractive power; one eye may be myopic (nearsighted) and the other hyperopic (farsighted).

Aphakia: Absence or loss of the eye's natural crystalline lens, as after cataract removal.

Astigmatism: A common form of visual impairment in which part of an image is blurred, due to an irregularity in the curvature of the front surface of the eye, the cornea.

Hyperopia (farsightedness): The ability to see distant objects more clearly than close objects.

Keratoconus: Cone-shaped cornea with the apex of the cone being forward; this is also called conical cornea.

Myopia (nearsightedness): The ability to see close objects more clearly than distant objects.

Presbyopia: Age related visual changes affecting near vision.

Refraction: In ophthalmology, this term refers to the bending of light that takes place within the human eye; this results in vision ability, such as “20/20.”

Refractive error (ametropia): A disorder that occurs when parallel rays of light entering the non-accommodating eye are not focused

on the retina; this includes nearsightedness (myopia), farsightedness (hyperopia), and astigmatism; lenses can be used to control the amount of refraction, correcting these errors.

Spectacle prescription abbreviations:

- Sphere (SPH): This refers to a correction that is spherical, meaning the same in all meridians of the eye. A positive number indicates hyperopia (farsightedness) and a negative number indicates myopia (nearsightedness).
- Cylinder (CYL): Refers to a correction for astigmatism for which the corneal shape differs by meridian. A positive number indicates a farsighted astigmatism and a negative number indicates a nearsighted astigmatism.
- Axis: Refers to the axis of the astigmatism and is written as a number between 1 and 180. An axis of 90 refers to the vertical meridian of the eye and 180 is the horizontal meridian.

Stroma: The supportive framework of an organ (or gland or other structure); the stroma is usually composed of connective tissue.

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Websites for Additional Information

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion/General Information and References sections.
Reviewed	11/10/2022	MPTAC review. Discussion/General Information and References sections updated.
Reviewed	11/11/2021	MPTAC review. Discussion/General Information and References sections updated.
Reviewed	11/05/2020	MPTAC review. Discussion/General Information and References sections updated. Reformatted Coding section.
Reviewed	11/07/2019	MPTAC review. Discussion/General Information and References sections updated.
Revised	01/24/2019	MPTAC review. Medically necessary indications added for small incision lenticule extraction (SMILE). SMILE added to not medically necessary indications when medically necessary criteria are not met. Discussion/General Information and References sections updated.
New	05/03/2018	MPTAC review. Initial document development. Moved content of SURG.00009 Refractive Surgery to new clinical utilization management guideline document with the same title. Updated Discussion, References and Index sections.