Subject: Vision Surgeries for Refractive Errors

Overview: Vision surgeries are surgical procedures and/or laser treatments that alter the cornea of the eye to correct myopia, hyperopia, and astigmatism.

Policy and Coverage Criteria:
Harvard Pilgrim Health Care (HPHC) considers certain surgical procedures as medically necessary to correct refractive errors caused by surgical error, injury, or the physical inability to use both eyeglasses and contact lenses. Covered procedures may include ANY of the following:
- Astigmatic Keratotomy
- Epikeratoplasty/Lamellar Keratoplasty
- Penetrating Keratoplasty
- Intrastromal Corneal Ring Segments (INTACS)
- Laser epithelial keratomileusis (LASEK)

Harvard Pilgrim Health Care (HPHC) considers corneal collagen cross linking as reasonable and medically necessary for the treatment of progressive keratoconus and corneal ectasia after refractive surgery that is refractory to conservative treatment when documentation confirms EITHER of the following:
1. A diagnosis of progressive keratoconus supported by ANY of the following changes in a twenty-four-month period:
   - An increase of at least one diopter in either the
     o manifest cylinder or
     o steepest keratomy measurement
   - An increase of at least half a diopter in manifest refraction spherical equivalent
2. A diagnosis of corneal ectasia following refractive surgery supported by ALL of the following:
   - Consistent axial topography pattern, including relative inferior steepening with inferior-superior difference of at least 1.5 diopters,
   - Corrected distance visual acuity worse than 20/20, and
   - Corneal thickness of at least three hundred micrometers at the thinnest area.

Exclusions:
Harvard Pilgrim Healthcare (HPHC) considers corneal collagen cross-linking to be experimental and investigational when the criteria above are not met.
Harvard Pilgrim Health Care (HPHC) considers surgical procedures (including those listed above) to correct routine or natural refractive errors not medically necessary. Non-covered procedures include, but are not limited to, the following:
- Radial Keratotomy
- Hexagonal Keratotomy
- Keratophakia
- Standard Keratomileusis (ALK)
- Implantable contact lens
- Photorefractive keratectomy (PRK)
- Laser in-situ keratomileusis (LASIK)
Supporting Information:

1. Technology Assessment

Astigmatic keratotomy: Astigmatic keratotomy is a surgical procedure that reshapes the cornea from an oval shape into a spherical shape to correct astigmatism.

Radial keratotomy: Radial keratotomy is a surgical procedure that is used to correct myopia. Radial incisions are made in the cornea of the eye causing the sides of the cornea to bulge outward and flatten the center of the cornea.

Hexagonal keratotomy: Hexagonal keratotomy is a surgical procedure that is used to correct hyperopia. Circumferential connecting hexagonal incisions are made to induce central cornea steepening.

Epikeratoplasty: Epikeratoplasty is the removal of the corneal epithelium which is then replaced with a donor’s corneal disc.

Penetrating keratoplasty: Penetrating keratoplasty is the removal of the full cornea which is then replaced by a donor’s full cornea.

Keratophakia: Keratophakia is the placement of a plastic or donor lens in the cornea to correct a refractory error.

Intrastromal Corneal Ring Segments (INTACS): INTACS are inserts that are surgically implanted into the cornea resulting in the reshaping and remodeling of the cornea.

Automated Lamellar Keratoplasty (ALK): ALK is a procedure where a thin flap of the cornea is cut and tissue from the cornea stroma, under the flap, is removed and the flap is replaced.

Implantable contact lens: The Verisyse Phakic Intraocular Lens (IOL) is made of plastic, and is attached in front of the iris. It’s designed for people aged 21 years or older who have stable vision with a change in refraction of less than 0.5 diopters in six months. The Visian Implantable Collamer Lens (ICL) is made of collamer, a substance that occurs naturally in the body, and is implanted behind the iris in front of the natural lens of the eye.

Laser in situ keratomileusis: LASIK is a refractive surgery procedure that reshapes the surface of the cornea with an excimer laser to focus visual images directly onto the retina and improve visual acuity. The LASIK technique is designed to correct certain refractive errors and eliminate or reduce the need for corrective lenses.

Photorefractive keratectomy: PRK is an effective treatment of low to moderate myopia, myopia with astigmatism, and low to moderate hyperopia without astigmatism. The corneal epithelium in the ablation zone is removed or pushed to the side and the laser treatment in then applied to the exposed corneal stroma.

Laser epithelial keratomileusis: LASEK is similar to LASIK, however, with LASEK the corneal flap is very thin which avoids the complication of corneal ectasia. Additionally, the equipment used in LASEK is not as complicated as LASIK and has lower risk of surgical flap complications. LASEK may cause greater pain than LASIK and have a slower optical recovery time.

Phototherapeutic keratectomy: PTK is a similar procedure to PRK, however, PTK is used for the correction of particular corneal diseases, whereas PRK uses an excimer laser for the correction of refractive errors in persons with otherwise non-diseased corneas.

Corneal Collagen Cross-linking: CXL is a procedure used to treat progressive keratoconus. Ultraviolet (UV) light is combined with riboflavin eye drops to create new collagen crosslinks in the cornea, strengthening and stabilizing the cornea and delaying the progression of deformation associated with keratoconus. The viscous riboflavin solution is applied to the eye topically before and during UV irradiation using the KXL System.

2. Literature Review

Hayes, Inc (2014) states that there is a moderately large body of evidence of low quality suggesting that implantation of INTACS is reasonably safe and provides some improvements in visual outcomes for patients who have keratoconus. Studies also suggest that the efficacy of INTACS is essentially the same as the efficacy of similar ocular implants.

HPHC Medical Review Criteria

Vision Surgeries for Refractive Errors

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Vega-Estrada et al. (2015) analyzed whether implantation of intrastromal corneal ring segments (ICRS) influences the progression of keratoconus in young patients. The study evaluated 18 eyes in 15 patients. Six months postoperatively, there was improvement in the uncorrected and corrected distance visual acuities and all refractive measurements and the mean keratometry was reduced by 4.48 D. The authors concluded that implantation of ICRS significantly improved the visual, refractive, and topographic parameters in the short term, however, regression at 5 years suggests that implantation of ICRS does not influence progressive keratoconus.

Al-Muammar (2015) evaluated and compared the visual and refractive outcomes, topographic keratometry and complications of Intacs and Intacs SK for mild to moderate keratoconus. At 6 months postoperatively there were significant improvements in UDVA, CDVA, manifest sphere, SE, minimum K, maximum K, and average K. There were no complications in both groups. Both models of Intacs significantly improved vision and refractive outcomes, and topographic keratometry in cases of mild to moderate keratoconus.

Ozerturk et al. (2012) compared the visual and refractive results in eyes with advanced keratoconus having deep anterior lamellar keratoplasty (DALK) with those having intrastromal corneal ring segment (ICRS) implantation. There were 36 eyes in the DALK group and 30 eyes in the ICRS group. Both groups had a significant increase in UDVA and CDVA from preoperatively to 24 months postoperatively. The DALK group had a significantly greater improvement than the ICRS group in UDVA and CDVA 24 months postoperatively. Both groups had significant improvement in spherical equivalent refractive error, manifest sphere, and manifest cylinder. The DALK group had a significantly greater mean reduction in SE and manifest cylinder than the ICRS group. Both groups had a significant postoperative reduction in the maximum and minimum K-values, however, the mean reduction was significantly greater in the DALK group.

Bedi et al. (2012) evaluated the long-term rate of progression of keratoconus in 92 eyes implanted with Intacs at 5 year follow-up. 91.3% of eyes demonstrated no progression between 1- and 5-year follow-up. No differences were noted in mean steep, flat, and average keratometry; manifest refraction spherical equivalent; and uncorrected and corrected distance visual acuity between 1- and 5-year follow-up.

Kubaloglu et al. (2011) compared astigmatic keratotomy outcomes in high astigmatism after deep anterior lamellar keratoplasty (DALK) and after penetrating keratoplasty (PK) in keratoconus patients. Visual acuity improved at 6 month follow up in both groups. The authors concluded that astigmatic keratotomy for the treatment of postkeratoplasty astigmatism after DALK and PK in keratoconus patients is safe and effective.

Kymionis et al. (2007) evaluated long-term follow-up of Intacs microthin prescription inserts for the management of keratoconus in 17 eyes. At five year follow-up, the spherical equivalent error was significantly reduced. After five years, intracorneal ring segments implantation improved UCVA, BSCVA, and refraction in the majority of the keratoconus patients.

Colin et al. (2007) evaluated the long-term safety and efficacy of Intacs segments for the treatment of keratoconus in terms of intraoperative and postoperative complications, visual outcome, restoration of contact lens tolerance, and inhibition of disease progression. At 2 years, UCVA and BCVA significantly improved in 80.5% and 68.3% of eyes. The proportion of eyes with a BCVA >0.85 increased from 22.0% at baseline to 51.2% and 53.7% at 1 year and 2 years. The mean keratometry readings decreased from 50.1 +/- 5.6 D preoperatively to 46.4 +/- 5.3 D at 1 year and 46.8 +/- 4.9 D at 2 years. Contact lens tolerance was restored in over 80% of cases. The authors concluded that Intacs implantation is a safe and efficacious treatment for keratoconus. Significant and sustained improvements in objective visual outcomes were achieved in most cases, with restoration of contact lens tolerance.

Allo et al. (2006) conducted a retrospective study comprising of 13 eyes to evaluate the long-term results and stability of Intacs implantation for keratoconus correction. There was a significant increase in mean BSCVA and significant decrease in mean inferior-superior asymmetry. The authors concluded that Intacs increased the BSCVA and decreased inferior-superior asymmetry with stability up to 36 months.

Goosey et al. (1991) compared penetrating keratoplasty to epikeratoplasty in the surgical management of keratoconus. Of 47 eyes with keratoconus, 31 were treated with epikeratoplasty and 16 with penetrating keratoplasty.

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keratoplasty. The penetrating keratoplasty procedure resulted in a higher percentage of eyes that had visual acuity of 20/20 than the epikeratoplasty group. 31% of the eyes in the penetrating keratoplasty group had graft failures while no serious complications were noted in the epikeratoplasty group.

Laser Surgeries:
Hayes, Inc. (2007) reports there is a moderate level of evidence to support the safety and efficacy of LASIK. LASIK is most appropriate in patients with low or moderate myopia or myopic astigmatism who choose to undergo surgical refraction correction. There is less evidence for the use of LASIK in hyperopia, and very little evidence about overall patient satisfaction regarding visual acuity, side effects, or need for corrective lenses after surgery. More research is needed to evaluate the long-term clinical efficacy, predictability, safety, and stability of LASIK for various levels of myopia and hyperopia.

Chao et al. (2015) evaluated changes in nerve morphology, tear neuropeptide, and dry eye to establish the relationship between reinnervation and dry eye and to assess the role of tear neuropeptides in reinnervation in 20 patients post-LASIK. Corneal nerve morphology, tear neuropeptide concentration, and dry eye were monitored prior to LASIK and 1 day, 1 week, 1, 3, and 6 months post-LASIK. There was no change in dry eye symptoms and tear function, except for osmolarity, post-LASIK. There was an immediate decrease in corneal nerve morphology that remained by 6 months post-LASIK. The concentration of the tear neuropeptide SP increased at 3 months post-LASIK. The authors found an inverse relationship between reinnervation and dry eye symptoms post-LASIK, confirming that post-LASIK dry eye is a neuropathic disease.

Bamashmus et al. (2015) evaluated subjective quality of vision and patient satisfaction after LASIK for myopia and myopic astigmatism in 200 patients. Seven scales were formulated to cover specific aspects of the quality of vision including; global satisfaction; quality of uncorrected and corrected vision; quality of night vision; glare; daytime driving and; night driving. The preoperative myopic sphere was -3.50 ± 1.70 D and myopic astigmatism was 0.90 ± 0.82 D. There were 96% of eyes within ± 1.00 D of the targeted correction. The uncorrected visual acuity was 20/40 or better in 99% of eyes postoperatively. A total of 98.5% of patients was satisfied or very satisfied with their surgery, 98.5% considered their main goal for surgery was achieved. Night driving was rating more difficult preoperatively by 6.2%, whereas 79% had less difficulty driving at night. The authors concluded that patient satisfaction with uncorrected vision after LASIK for myopia and myopic astigmatism appears to be excellent and is related to the residual refractive error postoperatively.

Kato et al. (2008) investigated the safety and efficacy of LASIK over a 5-year postoperative period in 779 eyes with myopia or myopic astigmatism. Preoperative uncorrected visual acuity showed significant improvements at day 1 and 1 month after surgery. Improvements continued at a significant level thereafter. Postoperative manifest refraction improved with minimal but significant regression after 1 year. There was a significant decrease in corneal endothelial cell counts at 5 years after surgery. The authors concluded that LASIK is an effective and safe procedure for correcting myopia and myopic astigmatism as long as inclusion and exclusion criteria are strictly followed.

Alio et al. (2008) evaluated the long-term outcomes of LASIK for high myopia in 196 myopic eyes. All patients were evaluated at 3 months, 1, 2, 5, and 10 years postoperatively with the outcome measures being refractive predictability and stability, mean corneal keratometry, topographical cylinder, safety, efficacy, stability of visual acuity, and postoperative complications. At 10 years, 42% of eyes were within +/-1.00 D and 61% were within +/- 2.00 D. 27.5% of eyes underwent retreatment due to under correction and/or regression. 40% showed a postoperatively uncorrected visual acuity of 20/40 or better. The authors concluded that LASIK for myopia over -10 D is a safe procedure with myopic regression that slows down with time and a high rate of best spectacle-corrected visual acuity increase in the long-term. Zadok et al. (2000) evaluated the efficacy, safety, and predictability of hyperopic LASIK in 72 eyes in patients with up to +5.00 diopters hyperopia. Groups were split into a low hyperopia group (<3.00D) and moderate hyperopia group (>=3.00D). At 6 months, in the low hyperopia group had a mean MSE of +0.30 +/- 0.71 D, with 88.9% eyes within 1 D of emmetropia compared with +1.09 +/- 0.92 D and 51.8% within 1 D of emmetropia in the moderate hyperopia group. Uncorrected visual acuity was 20/40 to 5/200.

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or better in 95.6% and in 77.8% eyes in the low and moderate hyperopia groups. 25% required
retreatment to correct residual hyperopia, 20.0% in the low hyperopia group and 33.3% in the moderate
hyperopia group. Retreatments resulted in an MSE of +0.02 +/- 0.45 D and +0.04 +/- 0.73 D in the low
and moderate hyperopia groups.

Lindstrom et al. (2000) assessed the safety and efficacy of LASIK for secondary hyperopia and hyperopic
astigmatism in a prospective, nonrandomized, self-controlled interventional study including 30 patients.
Spherical equivalent (SE) was +1.73 +/- 0.79D before surgery, -0.13 +/- 1.00D at 6 months post
surgery, and -0.18 +/- 1.08D at 1 year post surgery. At 6 months, 84% of patients with secondary
hyperopia had uncorrected visual acuity of 20/40 or better, 76% were within +/-1D of emmetropia. At 1
year, 85% had uncorrected visual acuity of 20/40 or better and 85% were within +/-1D of emmetropia.
The authors concluded that he data suggests that LASIK for consecutive hyperopia from +0.5 to +5.50 D
and astigmatism from 0 to +2.75 D using the VISX STAR S2 is safe and effective.

El-Maghryaby et al. (1999) compared the effectiveness, safety, and stability of excimer LASIK and PRK for
low-to-moderate myopia in a prospective, randomized, bilateral study involving 33 patients with a
manifest refraction of -2.50 to -8.00 diopters. For each patient, one eye received LASIK and the other
received PRK. At day one post surgery, 81% of patients reported no pain in the LASIK treated eye,
whereas 0% reported being pain free in the PRK treated eye. At 3 to 4 days post surgery, 80% of LASIK
treated eyes and 45% of PRK treated eyes improved or remained within 1 line of baseline spectacle-
corrected visual. At 2 year follow up, 61% of LASIK and 36% of PRK treated eyes achieved an
uncorrected visual acuity of 20/20 or better, with no difference in refractive outcome between
techniques. Patients initially showed a preference for LASIK by a 2 to 1 margin at 1 year follow up, but no
preference was shown at 2 year follow up.

Dulaney et al. (1998) evaluated the visual and refractive results of LASIK for mild to moderate myopia
with or without astigmatism in 124 eyes. Eyes with a preoperative spherical equivalent from -1.35 to -
10.00 diopters were included in the study. All eyes were completely re-epithelialized by the first
postoperative day. Uncorrected visual acuity was 20/40 or better in 81% of eyes at day 1 and 91% at 6
months. 72% of eyes were included in 6 month follow up. The authors concluded that LASIK provided
rapid visual recovery with satisfactory visual and refractive outcomes in eyes with myopia with or without
astigmatism.

Zhao et al. (2010) examined the differences between LASEK and PRK for myopia in a systematic review
and meta-analysis. They identified 12 studies comparing PRK with LASEK for myopia. No differences in
outcomes were observed between the two procedures and LASEK showed no benefit over PRK.

Teus et al. (2008) compared the visual results after LASEK and epi-LASIK to correct myopia in 94 eyes.
The groups were matched for age and refraction. The authors concluded that their results suggested a
faster visual rehabilitation and better safety and efficacy outcomes after LASEK compared to epi-LASIK.

Pop et al. (2000) compared PRK with LASIK in 107 eyes at 1, 3, 6, and 12 months postoperatively. 70%
of eyes were evaluated at 12-month follow-up. At 12 month follow-up, 83% of LASIK and 86% of PRK
cases had uncorrected visual acuities of 20/20 or better. Refractions within +/- 0.5 D represented 78% of
the LASIK eyes and 83% of the PRK eyes. LASIK patients reported halos twice as often as PRK patients.
The authors concluded that PRK and LASIK achieved equal refractive outcomes at all postoperative
follow-ups.

Hersh et al. (1998) conducted a randomized clinical trial of PRK and LASIK in 220 eyes to analyze visual
acuity, predictability, and stability of refraction, corneal haze, and flap complications. One day after
surgery, 0.0% and 4.5% eyes in the PRK group saw 20/20 and 20/40 or better uncorrected while 10%
and 68.6% eyes in the LASIK group saw 20/20 and 20/40 or better. At 6 months after PRK, 19.1% and
66.2% eyes saw 20/20 and 20/40 or better while after LASIK, 26.2% and 55.7% eyes saw 20/20 and
20/40 or better, respectively. After PRK, 57.4% were within 1.0 D of attempted correction compared with
40.7% in the LASIK group; however, the standard deviation of the predictability was similar between
groups: 1.01 D for PRK and 1.22 D for LASIK. From months 1 to 6, there was an average regression of
0.89 D in the PRK group and 0.55 D in the LASIK group. After PRK, 11.8% had a decrease in spectacle-

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corrected visual acuity of two Snellen lines or more; after LASIK, 3.2% had a decrease of two lines or more. Only two eyes had postoperative spectacle-corrected visual acuity less than 20/32. The authors concluded that although improvement in uncorrected visual acuity is more rapid in LASIK than in PRK, efficacy outcomes in the longer term generally are similar between the two procedures.

CXL: The evidence for corneal cross-linking is promising and there are currently numerous clinical trials in progress. Kobashi and Rong (2017) conducted a systemic review of one-year efficacy of keratoconus treatment, identifying five randomized controlled trials involving 289 eyes that met inclusion criteria. They found that CXL can be effective in halting keratoconus progression for at least a year in certain circumstances, although the ability to establish magnitude of benefit was compromised by factors inherent to keratoconus. Meli et al. (2016) conducted a meta-analysis of keratoconus treatment, finding that CXL was safe and effective, halts keratoconus progression out to twenty-four months, and improves visual function to a limited degree. Ucakhan et al. (2016) evaluated the long-term visual, refractive, and topographic outcomes of CXL in the management of pediatric keratoconus. The study included 40 eyes of 40 consecutive patients under the age of 19 with progressive keratoconus. All 40 eyes underwent CXL with the Dresden protocol. Evaluation of uncorrected distance visual acuity, best spectacle-corrected distance visual acuity, manifest refraction, slit-lamp biomicroscopy, corneal topography, corneal aberrometry, and endothelial cell counts were done at baseline and all postoperative follow-up exams until 48 months. Results showed a significant mean improvement in uncorrected distance visual acuity and best spectacle-corrected distance visual acuity at 48 months. There was a significant decrease in mean Kmax at month 48 and a significant improvement in topographic and elevation indices and corneal aberrations after 6 months. No change was seen in mean endothelial density. The authors concluded that corneal CXL seems to be safe and effective in halting the progression of keratoconus in pediatric patients at 4-year follow-up and the procedure improves visual, refractive, topographic, and corneal aberrometric measurements. Lang et al. (2015) conducted a prospective, randomized, blinded, placebo-controlled trial to determine the efficacy and safety of corneal CXL for halting progression of keratoconus. The study included 29 keratoconus patients who were randomized to either the treatment group (15 eyes) or the control group (14 eyes). Corneal refractive power decreased on average by 0.35 +/- 0.58 dioptres/year in the treatment group. Corneal refraction increased power increased 0.11 +/- 0.61 diopters/year in the control group. The authors concluded that CXL is an effective treatment for some patients to halt the progression of keratoconus. Some of the patients still progressed and some untreated controls improved. Further investigations are necessary.

Alnawaiseh et al. (2015) conducted a review to determine long-term changes in corneal transparency after riboflavin-UV A-induced corneal CXL. Charts and data of 28 patients (42 eyes) who had undergone CXL for progressive keratoconus were retrospectively reviewed. Results showed that total corneal light backscatter was significantly higher 1 to 3 months after CXL compared to before CXL. There were significant differences in the anterior and central layer at total diameter and posterior layer and the 3 central annuli at total corneal thickness. Total corneal light backscatter at total corneal thickness and total diameter faded over time following CXL. Backscatter was significantly lower 24 to 36 months following CXL. The authors concluded that corneal densitometry peaks in the first months after CXL and returns to preoperative values approximately 1 year after CXL. Two years following CXL, corneal densitometry reaches values obtained for healthy, untreated corneas, thus achieving an improvement in corneal clarity over untreated keratoconic corneas. Poli et al. (2015) evaluated 6-year results of standardized epithelium-off corneal collagen CXL for treatment of progressive corneal ectasia. A total of 25 consecutive patients and 36 eyes with progressive primary or iatrogenic corneal ectasia underwent CXL following the Siena protocol. Main outcome measures included uncorrected (UDVA) and corrected (CDVA) distance visual acuities, biomicroscopy and fundus appearance, topography-derived steep and flat keratometry, central corneal thickness, intraocular pressure with Goldmann applanation tonometer, and endothelial cell density. Measures were recorded at

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baseline, 1, 3, 6, 12, 24, 36, and 72 months. Bilateral macular OCT was performed at the endpoint visit. The results showed, at 6 years, CXL stabilized primary and iatrogenic corneal ectasia in 89% of the patients. In bilateral CXL, the progression of the first eye was highly predictive of the fellow eye’s outcome. The authors concluded that CXL maintains long-term results in halting the progression of corneal ectasia, with significant improvement in CDVA and long-term stability of keratometry. Further clinical studies with longer follow-up and larger series are needed to confirm these results.

Hashemi et al. (2015) compared the long-term outcomes of accelerated and standard corneal cross-linking protocols in the treatment of progressive keratoconus. A total of 31 eyes with keratoconus were treated with an accelerated protocol (18 mW/cm(2), 5 min) and all contralateral eyes were treated with the standard method (3 mW/cm(2), 30 min) using the same overall fluence of 5.4 J/cm(2). At 18 month follow-up post procedure, the standard group showed significant improvement in spherical equivalent, K-readings, Q value, index of surface variance, and keratoconus index. A significant decline in central corneal thickness was seen, however, no change in visual acuity, corneal hysteresis, corneal resistance factor, P2 area, or endothelial density was seen. Central corneal thickness was the only significant change seen in the accelerated group. The only parameters that showed significant differences between the standard and accelerated protocols were K-reading and index surface variance. The authors concluded that accelerated cross-linking, using 18 mW/cm(2) for 5 minutes, shows a comparable outcome and safety profile when compared to the standard protocol. Examination of long-term results are needed.

3. Professional/Governmental Agencies

The American Academy of Ophthalmology (AAO) stated in their 2013 Preferred Practice Pattern on Refractive Surgery that “eyeglasses are the simplest and safest means of correcting a refractive error; therefore, eyeglasses should be considered before contact lenses or refractive surgery.”

CMS:

The correction of common refractive errors by eyeglasses, contact lenses or other prosthetic devices is specifically excluded from coverage. The use of radial keratotomy and/or keratoplasty for the purpose of refractive error compensation is considered a substitute or alternative to eyeglasses or contact lenses, which are specifically excluded by §1862(a)(7) of the Act (except in certain cases in connection with cataract surgery). In addition, many in the medical community consider such procedures cosmetic surgery, which is excluded by section §1862(a)(10) of the Act. Therefore, radial keratotomy and keratoplasty to treat refractive defects are not covered.

Keratoplasty that treats specific lesions of the cornea, such as phototherapeutic keratectomy that removes scar tissue from the visual field, deals with an abnormality of the eye and is not cosmetic surgery. Such cases may be covered under §1862(a)(1)(A) of the Act.

The use of lasers to treat ophthalmic disease constitutes ophthalmologic surgery. Coverage is restricted to practitioners who have completed an approved training program in ophthalmologic surgery.


FDA: INTACS – Indications for Use

INTACS® prescription inserts are intended for the reduction or elimination of myopia and astigmatism in patients with keratoconus, who are no longer able to achieve adequate vision with their contact lenses or
spectacles, so that their functional vision may be restored and the need for a corneal transplant procedure may potentially be deferred.

The specific subset of keratoconic patients proposed to be treated with INTACS prescription inserts are those patients:

- Who have experienced a progressive deterioration in their vision, such that they can no longer achieve adequate functional vision on a daily basis with their contact lenses or spectacles;
- Who are 21 years of age or older;
- Who have clear central corneas;
- Who have a corneal thickness of 450 microns or greater at the proposed incision site; and
- Who have corneal transplantation as the only remaining option to improve their functional vision.

**Codes:**

**Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.**

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<th>Description</th>
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<td>Keratoplasty (corneal transplant); anterior lamellar</td>
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<td>65730</td>
<td>Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia)</td>
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<td>65750</td>
<td>Keratoplasty (corneal transplant); penetrating (in pseudophakia)</td>
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<td>Implantation of intrastromal corneal ring segments</td>
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<td>66999</td>
<td>Unlisted procedure, anterior segment of eye [when specified as laser epithelial keratomileusis (LASEK), collagen cross linking of cornea, or photoastigmatic keratectomy (PRK-A)]</td>
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**Codes considered not medically necessary:**

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<th>Description</th>
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</thead>
<tbody>
<tr>
<td>65760</td>
<td>Keratomileusis</td>
</tr>
<tr>
<td>65765</td>
<td>Keratophakia</td>
</tr>
<tr>
<td>65771</td>
<td>Radial keratotomy</td>
</tr>
<tr>
<td>66999</td>
<td>Unlisted procedure, anterior segment of eye [when used for procedures to correct naturally occurring refraction]</td>
</tr>
<tr>
<td>S0800</td>
<td>Laser in situ keratomileusis (LASIK)</td>
</tr>
<tr>
<td>S0810</td>
<td>Photorefractive keratectomy (PRK)</td>
</tr>
</tbody>
</table>

**HPHC Medical Review Criteria**

Vision Surgeries for Refractive Errors

*HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members’ unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.*

*Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.*
Billing Guidelines:
Member's medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

References:

HPHC Medical Review Criteria

Vision Surgeries for Refractive Errors

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Active Clinical Trials for Collagen Crosslinking for Keratoconus:

HPHC Medical Review Criteria

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**Summary of Changes**

<table>
<thead>
<tr>
<th>Date</th>
<th>Changes</th>
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</thead>
<tbody>
<tr>
<td>02/20/18</td>
<td>Updated to reflect coverage of corneal collagen cross-linking</td>
</tr>
<tr>
<td>10/12/16</td>
<td>Added Corneal collagen cross linking. Updated supporting research, codes and references.</td>
</tr>
<tr>
<td>2/10/16</td>
<td>New Policy.</td>
</tr>
</tbody>
</table>

Approved by Medical Policy Review Committee: 02/20/2018  
Reviewed/Revised: 2/16; 10/16, 2/18  
Initiated: 2/16

**HPHC Medical Review Criteria**

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