Subject: Vision Surgeries for Refractive Errors

Background: Vision surgeries are surgical procedures and/or laser treatments that alter the cornea of the eye to correct myopia, hyperopia, and astigmatism. There are many types, with most focusing on the cornea. Keratomies are surgical operations involving incisions into the cornea of the eye. Astigmatic keratotomy uses asymmetric incisions to correct the asymmetry that comprises astigmatism. Keratoplasties are the removal and replacement of part or all of a cornea. Epikeratoplasty is the removal of the corneal epithelium which is then replaced with a donor’s corneal disc. Penetrating keratoplasty is the removal and donor replacement of the full cornea. Automated lamellar keroplasty consists of the surface of the cornea being removed to allow for shaving of the corneal stroma and then reaffixed. There are several types of implants used in vision surgery. Intrastromal Corneal Ring Segments (ICRS, brand name Intacs) are ring segments inserted into the cornea to mechanically alter its shape. In laser epithelial keratomileusis (LASEK), only the epithelium of the eye is lifted, with either chemical or mechanical means being used to disengage the epithelium from the stroma. Corneal Collagen Cross-linking is a relatively new technique. 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.

Policy and Coverage Criteria:
Harvard Pilgrim Health Care (HPHC) considers vision surgeries 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 (ICRS/Intacs)
- Laser epithelial keratomileusis (LASEK)

Harvard Pilgrim Health Care (HPHC) considers corneal collagen cross linking using riboflavin and ultraviolet A 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 manifest cylinder or 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:

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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:
There is a moderately large body of evidence of low quality suggesting that implantation of Intrastromal Corneal Ring Segments (ICRS, brand name 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 comparable to the efficacy of similar ocular implants. 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.

Laser-assisted subepithelial keratomileusis (LASEK) is widely considered safe, stable, predictable, and effective for myopia. While most reviews have found a paucity of quality evidence differentiating LASEK and LASIC in terms of visual improvement, LASEK is a considerably simpler procedure that does not create a risk of higher intraoperative surgical flap complications, allows easier management of infection risk, and allows greater patient mobility.

Corneal collagen cross-linking (CXL) is the preferred treatment for corneal ectasia, supported by numerous studies. For the treatment of keratoconus, CXL is the only known treatment capable of halting disease progression. While not always effective and with effectiveness varying from moderate improvement to slowed degradation, ten and seven year studies have found CXL produces improved outcome and is capable of producing long-term stabilization of keratoconus.

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Kobashi and Rong (2017) conducted a systematic 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. Meiri 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.

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 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.

The American Academy of Ophthalmology (AAO) states in their 2017 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.”

**Coding:**

**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.**

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>65400</td>
<td>Excision of lesion, cornea (keratectomy, lamellar, partial), except pterygium</td>
</tr>
<tr>
<td>65710</td>
<td>Keratoplasty (corneal transplant); anterior lamellar</td>
</tr>
<tr>
<td>65730</td>
<td>Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia)</td>
</tr>
<tr>
<td>65750</td>
<td>Keratoplasty (corneal transplant); penetrating (in pseudophakia)</td>
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<tr>
<td>65755</td>
<td>Keratoplasty (corneal transplant); penetrating (in pseudophakia)</td>
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<tr>
<td>65756</td>
<td>Keratoplasty (corneal transplant); endothelial</td>
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<tr>
<td>65757</td>
<td>Backbench preparation of corneal endothelial allograft prior to transplantation (List separately in addition to code for primary procedure)</td>
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<tr>
<td>65767</td>
<td>Epikeratoplasty</td>
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Vision Surgeries for Refractive Errors

**HCPCS Code** | **Description**
---|---
65770 | Keratoprosthesis
65772 | Corneal relaxing incision for correction of surgically induced astigmatism
65775 | Corneal wedge resection for correction of surgically induced astigmatism
65785 | Implantation of intrastromal corneal ring segments
66999 | Unlisted procedure, anterior segment of eye [when specified as laser epithelial keratomileusis (LASEK), collagen cross linking of cornea, or photoastigmatic keratectomy (PRK-A)]

**HCPCS Code** | **Description**
---|---
J2787 | Riboflavin 5’-phosphate, ophthalmic solution, up to 3 mL

Codes considered *not* medically necessary:

**Code** | **Description**
---|---
65760 | Keratomileusis
65765 | Keratophakia
65771 | Radial keratotomy
66999 | Unlisted procedure, anterior segment of eye [when used for procedures to correct naturally occurring refraction]
S0800 | Laser in situ keratomileusis (LASIK)
S0810 | Photorefractive keratectomy (PRK)

**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:**


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Summary of Changes

<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>03/27/19</td>
<td>Annual update, policy clarified</td>
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<tr>
<td>02/20/18</td>
<td>Updated to reflect coverage of corneal collagen cross-linking</td>
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<tr>
<td>10/12/16</td>
<td>Added Corneal collagen cross linking. Updated supporting research, codes and references.</td>
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<tr>
<td>2/10/16</td>
<td>New Policy.</td>
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Approved by Medical Policy Committee: 3/12/2019
Approved by Clinical Policy Operational Committee: 2/16; 10/16, 2/18, 3/19
Policy Effective Date: 3/19
Initiated: 2/16