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Subject: Keratoplasty and Keratectomy

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Keratoplasty is a generic term that includes all surgical procedures on the cornea to improve vision by changing the refractive index of the corneal surface.

Phototherapeutic keratectomy (PTK) involves the use of the excimer laser to treat visual impairment or irritative symptoms relating to diseases of the anterior cornea, by sequentially ablating uniformly thin layers of corneal tissue.

Mechanical superficial keratectomy (corneal scraping) usually involves removal of pathological epithelial and sub-epithelial tissues.

Lamellar keratoplasty (epikeratophakia) involves suturing a pre-lathed donor cornea onto the surface of the recipient's cornea, used as a means of correcting adult and pediatric aphakia.

Endothelial keratoplasty (EK), also referred to as posterior lamellar keratoplasty, is a form of corneal transplantation in which the diseased inner layer of the cornea, the endothelium, is replaced with healthy donor tissue. Specific techniques include Descemet stripping endothelial keratoplasty (DSEK), Descemet stripping automated endothelial keratoplasty (DSAEK), Descemet membrane endothelial keratoplasty (DMEK), and Descemet membrane automated endothelial keratoplasty (DMAEK).

Femtosecond laser-assisted corneal endothelial keratoplasty (FLEK) and femtosecond and excimer lasers-assisted endothelial keratoplasty (FELEK) have been proposed as alternative ways to prepare the donor endothelium.

Penetrating keratoplasty (PK), involves the creation of a large central opening through the cornea, and then filling the opening with full-thickness donor cornea that is sutured in place.

Epikeratoplasty is surgical reshaping of the cornea to correct refraction for near- or far-sightedness, either by keratomileusis, keratophakia, or radial keratotomy.

Corneal relaxing incision and corneal wedge resection are procedures performed for the correction of a surgically induced astigmatism.

Corneal collagen cross-linking (CXL) (epithelium-off method, also known as "epi-off) is a photochemical procedure approved by the Food and Drug Administration for the treatment of progressive keratoconus and corneal ectasia. Corneal collagen cross-linking (CXL) has the potential to slow the progression of disease. It is performed with the photosensitizer riboflavin (vitamin B2) and ultraviolet A (UVA) irradiation. In the epithelium-off CXL method, about 8 mm of the central corneal epithelium is removed under topical anesthesia to allow better diffusion of the photosensitizer riboflavin into the stroma. Following de-epithelialization, a solution with riboflavin is applied to the cornea (every 1-3 minutes for 30 minutes) until the stroma is completely penetrated. The cornea is then irradiated for 30 minutes with UVA 370 nm, a maximal wavelength for absorption by riboflavin, while the riboflavin continues to be applied. The interaction of riboflavin and UVA causes the formation of reactive oxygen species, leading to additional covalent bonds (crosslinking) between collagen molecules, resulting in stiffening of the cornea. The epithelium-on (transepithelial) method of CXL is a more recent technique and there is less evidence available on its safety and efficacy.

In 2016, riboflavin 5'-phosphate in 20% dextran ophthalmic solution (Photrexa Viscous®) and riboflavin 5'-phosphate ophthalmic solution (Photrexa®) were approved by the FDA for use with KXL System in corneal CXL for the treatment of progressive keratoconus and corneal ectasia after refractive surgery.

POSITION STATEMENT:

Phototherapeutic keratectomy (PTK) **meets the definition of medical necessity** when used as an alternative to lamellar keratoplasty in the treatment of any of the following:

- Visual impairment or irritative symptoms related to corneal scars
- Opacities
- Dystrophies extending beyond the epithelial layer.

Phototherapeutic keratectomy (PTK) is considered **experimental or investigational** for all other applications, and specifically for the treatment of recurrent corneal erosions and infectious keratitis. There are inadequate data regarding the effectiveness of PTK in treating recurrent corneal erosions and infectious keratitis.

Mechanical superficial keratectomy **meets the definition of medical necessity** when used for treatment of conditions affecting only the epithelial surface of the cornea.

Lamellar keratoplasty (epikeratophakia) **meets the definition of medical necessity** when used for the treatment of aphakia in an adult or child.

Endothelial keratoplasty (EK) (Descemet stripping endothelial keratoplasty [DSEK], Descemet stripping automated endothelial keratoplasty [DSAEK], Descemet membrane endothelial keratoplasty [DMEK], or Descemet membrane automated endothelial keratoplasty [DMAEK]) **meet the definition of medical necessity** when used for the treatment of endothelial dysfunction, including but not limited to:

- Rupture in Descemet membrane
- Endothelial dystrophy
- Aphakic and pseudophakic bullous keratopathy
- Iridocorneal endothelial (ICE) syndrome
- Corneal edema attributed to endothelial failure
- Failure or rejection of a previous corneal transplant.

Femtosecond laser-assisted corneal endothelial keratoplasty (FLEK), and femtosecond and excimer lasers-assisted endothelial keratoplasty (FELEK) are considered **experimental or investigational**. There is insufficient published clinical evidence to support safety and effectiveness.

Penetrating keratoplasty (PK) **meets the definition of medical necessity** when used for treatment of the following conditions:

- Full thickness corneal disease
- Bullous keratopathy
- Corneal opacity (vision impaired secondary to opacity, improved visual function expected after surgery)
- Corneal thinning with possible perforation
- Keratoconus (e.g., best corrected vision less than or equal to 20/50, potential corneal perforation secondary to keratoconus, corneal hydrops greater than or equal to 2 episodes, improved vision function expected after surgery)
- Fuch's endothelial dystrophy with best corrected vision less than or equal to 20/50
- Partial thickness corneal disease (e.g., superficial stromal opacification, best corrected vision less than or equal to 20/50, improved visual function expected after surgery, marginal corneal thinning/infiltration, localized corneal thinning/descemetocele formation

Epikeratoplasty **meets the definition of medical necessity** when used for the treatment of any of the following:

- Aphakia, when vision cannot be corrected with contact lenses or spectacles, and intraocular lens implantation is contraindicated
- Congenital phakia, in children over age one year, when vision cannot be corrected by use of contact lenses or spectacles
- Keratoconus, when treatment with a contact lens or treatment with penetrating keratoplasty is contraindicated
- Corneal ulcer

- Corneal degeneration.

Corneal relaxing and corneal wedge resection **meet the definition of medical necessity** when used for correction of surgically induced astigmatism.

Epithelium-off corneal collagen cross-linking using riboflavin (Photrexa® or Photrexa Viscous®) and ultraviolet A **meets the definition of medical necessity**:

- As a treatment of progressive keratoconus, demonstrated by at least one of the following:
    - An increase of 1 diopter in the steepest keratometry value, **OR**
    - An increase of 1 diopter in regular astigmatism evaluated by subjective manifest refraction, **OR**
    - A myopic shift (decrease in the spherical equivalent) of 0.50 diopter on subjective manifest refraction, **OR**
    - A decrease ≥0.1 mm in the back optical zone radius in rigid contact lens wearers where other information was not available, **AND**
    - Conservative treatment such as spectacle correction or use of rigid contact lens has failed.
- As a treatment of corneal ectasia following refractive surgery, demonstrated by at least one of the following:

    (NOTE: Refer to member contract. Refractive surgery and related complications are excluded by some contracts)

    - An increase of 1 diopter in the steepest keratometry value, **OR**
    - An increase of 1 diopter in regular astigmatism evaluated by subjective manifest refraction, **OR**
    - A myopic shift (decrease in the spherical equivalent) of 0.50 diopter on subjective manifest refraction, **OR**
    - A decrease ≥0.1 mm in the back optical zone radius in rigid contact lens wearers where other information was not available, **AND**
    - Conservative treatment such as spectacle correction or use of rigid contact lens has failed.

Corneal collagen cross-linking using riboflavin (Photrexa® or Photrexa Viscous®) and ultraviolet A is considered **experimental or investigational** for all other indications. There is insufficient published clinical evidence to support the safety and effectiveness of this procedure for any other indication.

Epithelium-on (transepithelial) corneal collagen cross-linking is considered **experimental or investigational** for all indications. There is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on safety and net health outcomes.

Computerized corneal topography (92025) **does not meet the definition of medical necessity** when performed pre or post operatively for any non-covered procedure (e.g.,refractive eye surgery).

Correction of refractive errors is generally a contract exclusion. Therefore, the following services are **not eligible for coverage**:

- Radial keratotomy

- Mini-RK (minimally invasive radial keratotomy)
- Laser in situ keratomileusis (LASIK)
- Photorefractive keratectomy (PRK)
- Clear lens replacement (CLR)
- Keratophakia
- Keratomileusis
- Hexagonal keratotomy
- Automated lamellar keratoplasty (ALK)
- Conductive Keratoplasty (CK)
- Laser Thermoplasty (same as conductive keratoplasty).

Documentation that supports medical necessity may be needed in order to determine if the stated criteria have been met. The following information may be required documentation to support medical necessity: physician history and physical, physician operative report, and physician procedure note.

LOINC Codes:

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician operative note	28573-4	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician procedure note	11505-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

BILLING/CODING INFORMATION:

CPT Coding:

65435	Removal of corneal epithelium; with or without chemocauterization (abrasion, curettage)
65436	Removal of corneal epithelium; with application of chelating agent (eg, EDTA)

65710	Keratoplasty (corneal transplant); anterior lamellar
65730	Keratoplasty penetrating (except in aphakia or pseudophakia)
65750	Keratoplasty (corneal transplant); penetrating (in aphakia)
65755	Keratoplasty (corneal transplant); penetrating (in pseudoaphakia)
65756	Keratoplasty (corneal transplant); endothelial
65757	Backbench preparation of corneal endothelial allograft prior to transplantation (List separately in addition to code for primary procedure)
65760	Keratomileusis (non-covered)
65765	Keratophakia (non-covered)
65767	Epikeratoplasty
65771	Radial keratotomy (non-covered)
65772	Corneal relaxing incision for correction of surgically induced astigmatism
65775	Corneal wedge resection for correction of surgically induced astigmatism
0290T	Corneal incisions in the recipient cornea created using a laser, in preparation for penetrating or lamellar keratoplasty (List separately in addition to code for primary procedure)
0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)

HCPCS Coding:

S0800	Laser in situ keratomileusis (LASIK) **(non-covered)**
S0810	Photorefractive keratectomy (PRK) **(non-covered)**
S0812	Phototherapeutic keratectomy (PTK)

ICD-10 Diagnosis Codes That Support Medical Necessity For CPT Code 65435, 65436, 65710, 65730, 65750, 65755, 65756, 65757, and 0290T:

H16.001 – H16.079	Corneal ulcer
H17.01 – H17.823	Corneal scars and opacities

H18.011 – H18.019	Anterior corneal pigmentations
H18.031 – H18.033	Corneal deposits in metabolic disorders
H18.041 – H18.043	Kayser-Fleischer ring
H18.051 – H18.069	Posterior corneal and stromal corneal pigmentations
H18.10 – H18.13	Bullous keratopathy
H18.40 – H18.49	Corneal degeneration
H18.50 – H18.59	Hereditary corneal dystrophies
H18.601 – H18.629	Keratoconus
H18.731 – H18.739	Descemetocele
H18.831 – H18.839	Specified disorders of cornea

ICD-10 Diagnosis Codes That Support Medical Necessity For CPT Code 65767:

H16.001 – H16.079	Corneal ulcer
H18.40 – H18.49	Corneal degenerations
H18.601 – H18.629	Keratoconus
H18.831 – H18.839	Recurrent erosion of cornea
H27.00 – H27.03	Aphakia
Q12.3	Congenital aphakia
Q13.4	Other congenital corneal malformations
T85.21xA – T85. 29xS	Mechanical complication of intraocular lens

ICD-10 Diagnosis Codes That Support Medical Necessity For CPT Code 0402T:

H18.601 – H18.629	Keratoconus
H18.711 - H18.719	Corneal ectasia

ICD-10 Diagnosis Codes That Support Medical Necessity For CPT Code S0812:

H17.00 – H17.9	Corneal scar and opacities
H18.59	Other hereditary corneal dystrophies

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Refractive Keratoplasty (80.7) located at cms.gov.

The following Local Coverage Determinations (LCDs) were reviewed on the last guideline review date: Computerized Corneal Topography (L33810) and Non-Covered Services (L33777), located at fcso.com.

DEFINITIONS:

Aphakia: absence of the crystalline lens of the eye (e.g., after surgical removal of cataracts).

Astigmatism: a defect of vision due to corneal irregularity in which the image is blurred or distorted, usually in either the vertical or the horizontal axis; not the same as near-sightedness (myopia) or far-sightedness (hyperopia), but can be in addition to near- or far-sightedness. Surgically-induced astigmatism usually occurs following cataract surgery.

Automated lamellar keratoplasty (ALK): surgical procedure to improve far-sightedness; the outer area of the cornea is opened and replaced; scar tissue creates a bulging of the cornea, thereby correcting vision in some cases.

Cataract: an opacity of loss of optical uniformity of the crystalline lens with cataract development located on a continuum extending from minimal changes of original transparency in the crystalline lens to the extreme stage of total opacity; usually associated with aging, although they may be associated with other causes (i.e., acquired or congenital childhood cataracts, traumatic, complicated, toxic and secondary after-cataract); there is no medical treatment for cataracts; treatment requires lens extraction.

Clear lens replacement (CLR): this procedure entails removing the natural lens of the eye and replacing it with an intraocular lens (IOL) implant. This procedure is essentially the same as a cataract operation

with lens implant. CLR is completed prior to cataract development for the refractive advantage. CLR is a procedure that is more invasive than LASIK, PRK, and Intacs, with consequent greater potential risks.

Conductive keratoplasty (Refractec's CK): a procedure for farsightedness (hyperopia) in people over age 40. CK utilizes the controlled release of radiofrequency (RF) energy.

Cornea: responsible for focusing light rays to the back of the eye.

Corneal ectasia (also known as keratectasia, iatrogenic keratoconus, or secondary keratoconus): thinning of the cornea causing a cone-shaped bulging of the cornea (keratoconus) that occurs after refractive surgery; a serious longterm complication of laser in situ keratomileusis (LASIK) surgery and photorefractive keratectomy.

Descemetocele: an out pouching of the cornea. It causes loss of structural integrity, which may lead to perforation if untreated.

Diopters: A unit of measure of the refractive power if a lens. A one-diopter lens will focus parallel light rays one meter from the lens and a two-diopter lens will focus one-half of a meter from the lens. A plus 1.0-diopter lens is convex and will converge the light rays so they focus as a visible image 1 meter past the lens. A minus 1.0-diopter lens is concave and will diverge or spread light. The minus lens will not actually focus as a visible image on an optics table. Its image is known as a virtual image and if the diverging rays were followed to their point of origin, they would focus one meter in front of the minus lens.

Farsightedness: see hyperopia.

Fuchs' endothelial dystrophy: an inherited eye disorder that can lead to decreased vision and blindness.

Hyperopia: far-sightedness; occurs when rays of light entering the eye are brought to a focus behind the retina, as a result of the eyeball being too short from front to back.

Implantable contact lenses (phakic intraocular lenses [IOL]): under investigation as a refractive procedure that can potentially correct refractive errors (nearsightedness and farsightedness). The thin IOL implant is placed in the eye without removing the natural lens of the eye.

Intra-LASIK: an advance in LASIK surgery; it is a computer guided laser that is applied to the cornea to create a flap.

Iridocorneal endothelial (ICE) syndrome: an irregular corneal endothelium that can lead to varying degrees of corneal edema, iris atrophy, and secondary angle-closure glaucoma.

Kerato: cornea (the clear outer layer of the center of the eye).

Keratoconus: thinning of the cornea causing a cone-shaped bulging of the cornea, usually bilaterally; can by corrected by glasses, contact lenses, or surgery.

Keratoectasia: bulging forward of the cornea.

keratomileusis: involves removing, freezing, and lathing the patient's cornea, followed by its replacement onto the corneal bed. This surgery ahs been proposed for myopia and aphakic hyperopia.

Keratopathy: any non-inflammatory disease of the eye (cornea).

Keratophakia: involves removing the patient's cornea followed by placement of a lathed donor cornea within the recipient's cornea stroma. This surgery has been proposed for aphakia.

Keratoplasty: the replacement of abnormal host tissue by donor corneal tissue.

Keratoprosthesis: an artificial cornea intended to provide vision to patients with severe bilateral corneal disease.

Lamellar: thin layer, refers to the outermost layers of the cornea.

Laser thermal keratoplasty (LTK): similar to conductive keratoplasty, but is done with a laser.

LASIK® (laser in situ keratomileusis): reshapes the surface of the cornea with an excimer laser to focus visual images directly onto the retina and improve visual acuity.

Limbal relaxing incisions (LRI): a modification of astigmatic keratotomy (AK), which is a procedure to treat astigmatism.

Myopia: near-sightedness; a condition of the eye in which images are formed in front of the retina, resulting in a blurred image.

Nearsightedness: see myopia.

Photorefractive keratectomy (PRK): laser surgery to improve myopia by removing small amounts of tissue to flatten the cornea; lasts 10-20 minutes.

Phototherapeutic keratectomy (PTK): laser surgery to treat visual impairment or irritating symptoms relating to diseases of the cornea, by removing thin layers of corneal tissue.

Presbyopia: alteration of vision occurring with age, difficulty accommodating easily when changing focus between near objects and distant objects.

Radial keratotomy (RK): surgical treatment for myopia where approximately eight slits are made on the surface of the cornea, i.e., spokes of a wheel, resulting in flattening of the cornea.

Refraction: the measure of refractive error, which can be used to prescribe glasses and contacts.

Refractive keratoplasty: any surgical procedure performed to improve vision, involving changing the shape of the cornea.

Retina: the layer of tissue lining the inside of the back of the eye. The retina contains millions of photoreceptor cells, which convert light into images.

RELATED GUIDELINES:

Implantation of Intrastromal Corneal Ring Segments, 09-V0000-02

OTHER:

Other names used to report refractive keratoplasty:

Note: 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.

Automated Keratotomy
Conductive Keratoplasty (CK)
Keratoplasty, endothelial
Epikeratophakia
Epikeratoplasty
Excimer Laser Photorefractive Keratectomy
Hexagonal Keratotomy
Intra-Lasik
Keratectomy, Excimer Laser Photorefractive
Keratomileusis
Keratophakia
Keratoplasty, Refractive
Lamellar Keratoplasty
Laser In Situ Keratomileusis (LASIK)
Laser Thermoplasty
Mini-RK (Minimally Invasive Radial Keratotomy)
Ocular Implants
Photorefractive Keratectomy (PRK)
Radial Keratotomy (RK)

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 04/26/18.

GUIDELINE UPDATE INFORMATION:

09/15/01	Medical Coverage Guideline reformatted and revised.
11/15/01	MCG revised to include references to phototherapeutic keratectomy (PTK).
08/15/03	Annual review. Revised/new MCG; developed separate guideline for Refractive Keratoplasty.
08/15/05	Review. Deleted info on correction of post-surgical astigmatism; updated references.
02/15/06	Revision consisting of removal of information regarding INTACS and intrastromal corneal rings (new MCG 09-V0000-02 was developed for Implantation of Intrastromal Corneal Ring Segments).
11/15/06	Added coverage statement for 65772 and 65775. Added 4th and 5th digit to 370. Added 4th digit to 371.3 and 371.4. Updated references.
07/15/07	Scheduled review; reformatted guideline; updated references.

07/30/08	Added code 65755.
01/01/09	Annual HCPCS coding update: added codes 65710 and 65730.
04/29/09	Add CPT code 92025 and statement for computerized corneal topography.
07/15/09	Scheduled review; add CPT code 65756 and 65757, and add endothelial keratoplasty to position statement. Update references. Revise description section. Revise guideline title.
10/15/10	Revision; related ICD-10 codes added.
06/15/11	Scheduled review; position statements maintained and references updated.
07/15/11	Revision; formatting changes.
01/01/12	Annual HCPCS coding update. Added 0289T and 0290T.
05/11/14	Revision: Program Exceptions section updated.
10/01/15	Revision; updated ICD9 and ICD10 coding sections.
11/01/15	Revision: ICD-9 Codes deleted.
05/15/16	Scheduled review, Revise MCG title, description, position statement, CPT, HCPCS, and ICD10 coding sections, and definitions.. Update references.
01/01/17	Annual CPT/HCPCS update. Deleted 0289T.
02/15/17	Revision; added statement regarding computerized corneal topography.
05/15/18	Revision: added criteria for coverage of corneal collagen cross-linking. Revised description, CPT coding, ICD10 coding, program exception section, and definitions. Updated references.