

02-65000-15

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Reviewed: 02/22/24

Revised: 03/15/24

Subject: Endothelial Keratoplasty and Corneal Collagen Cross-Linking

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.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

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.

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.

Summary and Analysis of Evidence: Viberg et al (2023) compared Descemet membrane endothelial keratoplasty (DMEK), Descemet stripping automated endothelial keratoplasty (DSAEK), and DSAEK with concomitant cataract surgery (phacoemulsification plus DSAEK). The study covered 1,677 participants from all Swedish corneal transplantation units treated from 2012 through 2019. The authors concluded “Visual acuity improved in most patients (90%) with all 3 surgical methods. However, DMEK and phacoemulsification plus DSAEK reached higher levels of visual acuity 2 years after surgery, and phacoemulsification plus DSAEK was superior considering graft survival rate. All 3 surgical procedures showed both strengths and weaknesses, suggesting that the choice of surgical method should be individualized, taking into consideration not only the cornea, but each patient’s complete medical status as well as the entire course of postoperative medical care. Moshirfar et al (2023) concluded that the definitive treatment for congenital hereditary endothelial dystrophy (CHED) is currently surgical, including by endothelial keratoplasty (EK). The authors stated, “EK encompasses Descemet stripping automated endothelial keratoplasty (DSAEK) and Descemet membrane endothelial keratoplasty (DMEK). DSAEK grafting, where only the endothelium and part of the posterior stroma are transplanted, has shown to be a viable option for patients with CHED.” Papaioannou et al (2016) retrospectively analyzed 377 eyes of 336 patients (mean age, 15 years) who underwent corneal collagen cross-linking for progressive keratoconus. There was a significant improvement in mean best spectacle-corrected visual acuity from 0.33 to 0.27 logMAR ($p < 0.05$). The authors found that the benefits of corneal collagen cross-linking in stabilizing keratoconus were maintained for more than 2 years in most pediatric eyes.

POSITION STATEMENT:

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]) **meets the definition of medical necessity** when used for the treatment of endothelial dysfunction, including but not limited to:

- Ruptures in Descemet membrane
- Endothelial dystrophy
- Aphakic and pseudophakic bullous keratopathy
- Iridocorneal endothelial 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.

Epithelium-off corneal collagen cross-linking **meets the definition of medical necessity**:

- As a treatment of progressive keratoconus or corneal ectasia**, 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

****NOTE: Refer to member contract. Refractive surgery and related complications may be excluded by some contracts.**

Corneal collagen cross-linking using riboflavin (Photrexa) 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. As of the last guideline revision date, epithelium-on corneal collagen cross linking has not been approved by the Food and Drug Administration.

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 (code 65771)
- Mini-RK (minimally invasive radial keratotomy)
- Laser in situ keratomileusis (LASIK) (code S0800)
- Photorefractive keratectomy (PRK) (code S0810)
- Clear lens replacement (CLR)
- Keratophakia (code 65765)
- Keratomileusis (code 65760)
- 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:

65756	Keratoplasty (corneal transplant); endothelial
65757	Backbench preparation of corneal endothelial allograft prior to transplantation (List separately in addition to code for primary procedure)
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium, when performed, and intraoperative pachymetry, when performed

ICD-10 Diagnosis Codes That Support Medical Necessity For Endothelial Keratoplasty (CPT code 65756, 65757):

H18.10 -- H18.13	Bullous keratopathy
H18.331 – H18.339	Rupture in Descemet's membrane
H18.501 -- H18.599	Hereditary corneal dystrophies
T85.390A -- T85.398S	Other mechanical complication of other ocular prosthetic devices, implants and grafts
T86.8401 -- T86.8499	Complications of corneal transplant

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

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

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](https://www.cms.gov).

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

DEFINITIONS:

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

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 long-term complication of laser in situ keratomileusis (LASIK) surgery and photorefractive keratectomy.

Descemet's membrane: an extraordinary thick basement membrane, which is unique in the body with respect to both its dimension and composition. It is built by the cells of the flat squamous epithelium that lines the posterior surface of the cornea and is designated as corneal endothelium.

Diopters: A unit of measure of the refractive power of 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.

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

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

Keratoectasia: bulging forward of the cornea.

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

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.

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

RELATED GUIDELINES:

[Implantation of Intraström Corneal Ring Segments, 09-V0000-02](#)

[Drugs and Biologics without a Medical Coverage Guideline \(Orphan Drugs and Off-Label and Labeled Use of FDA Approved Drugs\), 09-J0000-68](#)

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 02/22/24.

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.
09/15/18	Revision: updated Related Guidelines section.
05/15/19	Revision: revised statement regarding epithelial-on method of corneal cross linking. Updated references.
07/01/19	Quarterly CPT/HCPCS update. Revised code 0402T descriptor.
07/15/20	Scheduled review. Revised MCG title, description, position statement, CPT coding, ICD-10 coding, index terms, and definitions. Updated references.
10/01/20	ICD10 coding update: added H18.501 -- H18.599 and T86.8401 -- T86.8499.
05/15/22	Scheduled review. Maintained position statement and updated references.
07/01/22	Quarterly CPT/HCPCS coding update. Revised 0402T descriptor.
08/21/23	Update to Program Exceptions section.
03/15/24	Scheduled review. Revised description, maintained position statement, and updated references.

