MASSACHUSETTS

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Medical Policy

Endothelial Keratoplasty

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Policy Number: 180

BCBSA Reference Number: 9.03.22

Related Policies

- Keratoprosthesis, #221

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Endothelial keratoplasty [Descemet's stripping endothelial keratoplasty (DSEK) Descemet's stripping automated endothelial keratoplasty (DSAEK)], Descemet's membrane endothelial keratoplasty [DMEK], or Descemet's membrane automated endothelial keratoplasty [DMAEK]) may be considered **MEDICALLY NECESSARY** for the treatment of endothelial dysfunction, including but not limited to:

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

Femtosecond laser-assisted corneal endothelial keratoplasty (FLEK) or femtosecond and excimer lasers-assisted endothelial keratoplasty (FELEK) are **INVESTIGATIONAL**.

Endothelial keratoplasty is **NOT MEDICALLY NECESSARY** when endothelial dysfunction is not the primary cause of decreased corneal clarity.

Prior Authorization Information

Commercial Members: Managed Care (HMO and POS)

Prior authorization is **NOT** required.

Commercial Members: PPO, and Indemnity
Prior authorization is **NOT** required.

Medicare Members: HMO Blue[SM]
Prior authorization is **NOT** required.

Medicare Members: PPO Blue[SM]
Prior authorization is **NOT** required.

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

CPT codes:	Code Description
65756	Keratoplasty (corneal transplant); endothelial
65757	Backbench preparation of corneal endothelial allograft prior to transplantation (List separately in addition to code for primary procedure)

ICD-9 Diagnosis Codes

ICD-9-CM diagnosis codes:	Code Description
371.20	Corneal edema, unspecified
371.21	Idiopathic corneal edema
371.22	Secondary corneal edema
371.23	Bullous keratopathy
371.24	Corneal edema due to wearing of contact lenses
371.33	Rupture in descemet's membrane
371.57	Endothelial corneal dystrophy
371.58	Other posterior corneal dystrophies
996.51	Mechanical complication due to corneal graft
996.53	Mechanical complication due to ocular lens prosthesis

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
H18.10	Bullous keratopathy, unspecified eye
H18.11	Bullous keratopathy, right eye
H18.12	Bullous keratopathy, left eye
H18.13	Bullous keratopathy, bilateral
H18.20	Unspecified corneal edema
H18.211	Corneal edema secondary to contact lens, right eye

H18.212	Corneal edema secondary to contact lens, left eye
H18.213	Corneal edema secondary to contact lens, bilateral
H18.219	Corneal edema secondary to contact lens, unspecified eye
H18.221	Idiopathic corneal edema, right eye
H18.222	Idiopathic corneal edema, left eye
H18.223	Idiopathic corneal edema, bilateral
H18.229	Idiopathic corneal edema, unspecified eye
H18.231	Secondary corneal edema, right eye
H18.232	Secondary corneal edema, left eye
H18.233	Secondary corneal edema, bilateral
H18.239	Secondary corneal edema, unspecified eye
H18.331	Rupture in Descemet's membrane, right eye
H18.332	Rupture in Descemet's membrane, left eye
H18.333	Rupture in Descemet's membrane, bilateral
H18.339	Rupture in Descemet's membrane, unspecified eye
H18.51	Endothelial corneal dystrophy
H18.59	Other hereditary corneal dystrophies
T86.840	Corneal transplant rejection
T86.841	Corneal transplant failure
T85.21XA	Breakdown (mechanical) of intraocular lens, initial encounter
T85.22XA	Displacement of intraocular lens, initial encounter
T85.29XA	Other mechanical complication of intraocular lens, initial encounter

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's stripping endothelial keratoplasty, Descemet's stripping automated endothelial keratoplasty, or Descemet's membrane endothelial keratoplasty.

Background

The cornea, a clear, dome-shaped membrane that covers the front of the eye, is a key refractive element of the eye. Layers of the cornea consist of the epithelium (outermost layer); Bowman's layer; the stroma, which comprises approximately 90% of the cornea; Descemet's membrane; and the endothelium. The endothelium removes fluid from the stroma and limits entry of fluid as well, thereby maintaining the ordered arrangement of collagen and preserving the cornea's transparency. Diseases that affect the endothelial layer include Fuchs' endothelial dystrophy, aphakic and pseudophakic bullous keratopathy (corneal edema following cataract extraction), and failure or rejection of a previous corneal transplant.

The established surgical treatment for corneal disease is penetrating keratoplasty (PK), which 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. Visual recovery after PK may take 1 year or more due to slow wound healing of the avascular full-thickness incision, and the procedure frequently results in irregular astigmatism due to the sutures and the full-thickness vertical corneal wound. PK is associated with an increased risk of wound dehiscence, endophthalmitis, and total visual loss after relatively minor trauma for years after the index procedure. There is also risk of severe, sight-threatening complications such as expulsive suprachoroidal hemorrhage, in which the ocular contents are expelled during the operative procedure, as well as postoperative catastrophic wound failure.

A number of related techniques have been, or are being, developed to selectively replace the diseased endothelial layer. One of the first endothelial keratoplasty (EK) techniques was termed deep lamellar endothelial keratoplasty (DLEK), which used a smaller incision than PK, allowed more rapid visual rehabilitation, and reduced postoperative irregular astigmatism and suture complications. Modified EK techniques include endothelial lamellar keratoplasty, endokeratoplasty, posterior corneal grafting, and

microkeratome-assisted posterior keratoplasty. Most frequently used at this time are Descemet's stripping endothelial keratoplasty (DSEK), which uses hand-dissected donor tissue, and Descemet's stripping automated endothelial keratoplasty (DSAEK), which uses an automated microkeratome to assist in donor tissue dissection. A laser may also be utilized for stripping in a procedure called femtosecond laser-assisted corneal endothelial keratoplasty (FLEK) or femtosecond and excimer lasers-assisted endothelial keratoplasty (FELEK). These techniques include some donor stroma along with the endothelium and Descemet's membrane, which results in a thickened stromal layer after transplantation. If the donor tissue comprises Descemet's membrane and endothelium alone, the technique is known as Descemet's membrane endothelial keratoplasty (DMEK). By eliminating the stroma on the donor tissue and possibly reducing stromal interface haze, DMEK is considered to be a potential improvement over DSEK/DSAEK. A variation of DMEK is Descemet's membrane automated EK (DMAEK). DMAEK contains a stromal rim of tissue at the periphery of the DMEK graft to improve adherence and increase ease of handling of the donor tissue.

EK involves removal of the diseased host endothelium and Descemet's membrane with special instruments through a small peripheral incision. A donor tissue button is prepared from corneoscleral tissue after removing the anterior donor corneal stroma by hand (e.g., DSEK) or with the assistance of an automated microkeratome (e.g., DSAEK) or laser (FLEK or FELEK). Several microkeratomes have received clearance for marketing through the U.S. Food and Drug Administration (FDA) 510(k) process. Donor tissue preparation may be performed by the surgeon in the operating room, or by the eye bank and then transported to the operating room for final punch out of the donor tissue button. To minimize endothelial damage, the donor tissue must be carefully positioned in the anterior chamber. An air bubble is frequently used to center the donor tissue and facilitate adhesion between the stromal side of the donor lenticule and the host posterior corneal stroma. Repositioning of the donor tissue with application of another air bubble may be required in the first week if the donor tissue dislocates. The small corneal incision is closed with one or more sutures, and steroids or immunosuppressants may be provided either topically or orally to reduce the potential for graft rejection. Visual recovery following EK is typically achieved in 4-8 weeks, in comparison with the year or more that may be needed following PK.

Eye Bank Association of America (EBAA) statistics show the number of EK cases in the United States increased from 1,429 in 2005 to 23,409 in 2012. The EBAA report estimates that approximately 1/2 of corneal transplants performed in the U.S. were endothelial grafts. As with any new surgical technique, questions have been posed about long-term efficacy and the risk of complications. EK-specific complications include graft dislocations, endothelial cell loss, and rate of failed grafts. Long-term complications include increased intraocular pressure, graft rejection, and late endothelial failure. Also of interest is the impact of the surgeon's learning curve on the risk of complications.

Summary

Endothelial keratoplasty, and particularly Descemet's stripping endothelial keratoplasty (DSEK), Descemet's stripping automated endothelial keratoplasty (DSAEK), Descemet's membrane endothelial keratoplasty (DMEK) and Descemet's membrane automated endothelial keratoplasty (DMAEK), are relatively new procedures. Femtosecond laser-assisted corneal endothelial keratoplasty (FLEK) and femtosecond and excimer lasers-assisted endothelial keratoplasty (FELEK) have been reported as alternative ways to prepare the donor endothelium. The literature and clinical input available at this time indicates that endothelial keratoplasty reduces the serious complications associated with penetrating keratoplasty. Specifically, visual recovery occurs much earlier, and because endothelial keratoplasty (EK) maintains an intact globe without a sutured donor cornea, astigmatism and the risk of severe, sight-threatening complications such as expulsive suprachoroidal hemorrhage and postoperative catastrophic wound failure are eliminated. These improvements appear to have resulted in rapid acceptance of this procedure with a trend toward intervention at an earlier stage of endothelial disease.

Long-term graft survival with these new techniques is presently unknown. However, current procedures result in acceptable short-term survival, and additional surgical intervention can be performed with a low risk of visual loss. Due to the marked reduction in serious complications compared to the alternative, DSEK/DSAEK has become the preferred approach for endothelial dysfunction among corneal surgeons.

DMEK/DMAEK have also become accepted approaches to EK, due to a reduction in stromal haze and improvement in visual acuity. Therefore, these techniques may be considered medically necessary.

FLEK and FELEK have not been shown to have improved outcomes compared to existing techniques; therefore, these techniques are considered investigational.

EK will continue to evolve as techniques are modified in an attempt to improve donor tissue adherence and increase endothelial survival. Randomized controlled studies and/or long-term prospective studies will be needed to adequately evaluate these new procedures.

Policy History

Date	Action
5/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
3/2014	BCBSA National medical policy review. New medically necessary, not medically necessary and investigational indications described. Effective 3/1/2014. Clarified coding information.
1/2014	Clarified coding information
11/2011- 4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
2/2011	Reviewed - Medical Policy Group – Psychiatry and Ophthalmology. No changes to policy statements.
5/1/2010	Medical Policy 180 effective 5/1/2010 created.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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