MASSACHUSETTS

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Medical Policy
Endothelial Keratoplasty

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Policy Number: 180

BCBSA Reference Number: 9.03.22
NCD/LCD: N/A

Related Policies

- Keratoprosthesis, #221
- Optical Coherence Tomography of the Anterior Eye Segment, #084

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

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

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.

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

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

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)

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if medical necessity criteria are met:

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

Corneal Disease

The cornea, a clear, dome-shaped membrane that covers the front of the eye, is a key refractive element for vision. Layers of the cornea consist of the epithelium (outermost layer); Bowman layer; the stroma, which comprises approximately 90% of the cornea; Descemet membrane; and the endothelium. The endothelium removes fluid from and limits fluid into the stroma, 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.

Treatment

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 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 the 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*, 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 stripping endothelial keratoplasty, which uses hand-dissected donor tissue, and Descemet stripping automated endothelial keratoplasty, which uses an automated microkeratome to assist in donor tissue dissection. These techniques include donor stroma along with the endothelium and Descemet membrane, which results in a thickened stromal layer after transplantation. If the donor tissue comprises Descemet membrane and endothelium alone, the technique is known as Descemet membrane endothelial keratoplasty (DMEK). By eliminating the stroma on the donor tissue and possibly reducing stromal interface haze, DMEK is considered a potential improvement over Descemet stripping endothelial keratoplasty and Descemet stripping automated endothelial keratoplasty. A variation of DMEK is Descemet membrane automated endothelial keratoplasty. Descemet membrane automated endothelial keratoplasty contains a stromal rim of tissue at the periphery of the DMEK graft to improve adherence and improve handling of the donor tissue. A laser may also be used for stripping in a procedure

called femtosecond laser-assisted endothelial keratoplasty and femtosecond and excimer laser-assisted endothelial keratoplasty.

EK involves removal of the diseased host endothelium and Descemet membrane with special instruments through a small peripheral incision. A donor tissue button is prepared from the corneoscleral tissue after removing the anterior donor corneal stroma by hand (eg, DSEK) or with the assistance of an automated microkeratome (eg, Descemet stripping automated endothelial keratoplasty) or laser (femtosecond laser-assisted endothelial keratoplasty or femtosecond and excimer laser-assisted endothelial keratoplasty). 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. For minimal 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 the 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 immune-suppressants may be provided topically or orally to reduce the potential for graft rejection. Visual recovery following EK is typically 4 to 8 weeks.

Eye Bank Association of America statistics have shown the number of EK cases in the United States increased from 30,710 in 2015 to 32,221 in 2016.[1] The Eye Bank Association of America estimated that, as of 2016, nearly 40% of corneal transplants performed in the United States were endothelial grafts. As with any new surgical technique, questions have been posed about long-term efficacy and 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.

Summary

Endothelial keratoplasty, 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). Endothelial keratoplasty, and particularly DSEK, DSAEK, DMEK, and DMAEK, are becoming standard procedures. Femtosecond laser-assisted endothelial keratoplasty (FLEK) and femtosecond and excimer laser-assisted endothelial keratoplasty have also been reported as alternatives to prepare the donor endothelium.

For individuals who have endothelial disease of the cornea who receive DSEK or DSAEK, the evidence includes a number of cohort studies and a systematic review. Relevant outcomes are change in disease status, morbid events, and functional outcomes. The available literature has indicated that these procedures improve visual outcomes and reduce serious complications associated with penetrating keratoplasty (PK). Specifically, visual recovery occurs much earlier. Because endothelial keratoplasty maintains an intact globe without a sutured donor cornea, astigmatism or the risk of severe, sight-threatening complications such as expulsive suprachoroidal hemorrhage and postoperative catastrophic wound failure are eliminated. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Clinical input obtained in 2009 supported DSEK and DSAEK as the standard of care for endothelial failure, based on improved outcomes compared with PK.

For individuals who have endothelial disease of the cornea who receive DMEK or DMAEK, the evidence includes a number of cohort studies and systematic reviews. Relevant outcomes are change in disease status, morbid events, and functional outcomes. Evidence from the cohort studies and meta-analyses has consistently shown that the use of DMEK and DMAEK procedures improve visual acuity. When compared with DSEK and DSAEK, DMEK and DMAEK showed significantly greater improvements

in visual acuity, both in the short term and through 1 year of follow-up. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Clinical input obtained in 2013 on evolving techniques for endothelial keratoplasty uniformly considered DMEK and DMAEK to be medically necessary procedures.

For individuals who have endothelial disease of the cornea who receive FLEK and femtosecond and excimer laser-assisted endothelial keratoplasty, the evidence includes a multicenter randomized trial that compared FLEK with PK. Relevant outcomes are change in disease status, morbid events, and functional outcomes. Mean best-corrected visual acuity was worse after FLEK than after PK, and endothelial cell loss was higher with FLEK. With the exception of dislocation and need for repositioning of the FLEK, the percentage of complications was similar between groups. Complications in the FLEK group were due to pupillary block, graft failure, epithelial ingrowth, and elevated intraocular pressure, whereas complications in the PK group were related to sutures and elevated intraocular pressure. The evidence is insufficient to determine the effects of the technology on health outcomes.

Most input obtained in 2013 considered FLEK and femtosecond and excimer laser-assisted endothelial keratoplasty to be investigational.

Input obtained in 2013 was mixed on the exclusion of patients with anterior corneal disease. Additional indications suggested by the reviewers were added as medically necessary.

Policy History

Date	Action
4/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
4/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statement(s) unchanged.
4/2018	New references added from BCBSA National medical policy. Background and summary clarified.
2/2018	Clarified coding information.
10/2017	New references added from BCBSA National medical policy.
4/2016	New references added from BCBSA National medical policy.
11/2015	Added coding language.
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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