Endothelial Keratoplasty

Policy Number: 9.03.22  Last Review: 11/2017
Origination: 11/2015  Next Review: 11/2018

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Endothelial Keratoplasty when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Endothelial keratoplasty (Descemet stripping endothelial keratoplasty [DSEK], Descemet stripping automated endothelial keratoplasty [DSAEK], Descemet membrane endothelial keratoplasty [DMEK], or Descemet membrane automated endothelial keratoplasty [DMAEK]) may be considered medically necessary for the treatment of endothelial dysfunction, including but not limited to:
- ruptures in Descemet membrane,
- endothelial dystrophy,
- aphakic, and pseudophakic bullous keratopathy,
- iridocorneal endothelial (ICE) syndrome,
- corneal edema attributed to endothelial failure,
- and failure or rejection of a previous corneal transplant.

When Policy Topic is not covered
Femtosecond laser-assisted corneal endothelial keratoplasty (FLEK) or femtosecond and excimer lasers-assisted endothelial keratoplasty (FELEK) are considered investigational.

Endothelial keratoplasty is not medically necessary when endothelial dysfunction is not the primary cause of decreased corneal clarity.

Considerations
Endothelial keratoplasty should not be used in place of PK for conditions with concurrent endothelial disease and anterior corneal disease. These situations would include concurrent anterior corneal dystrophies, anterior corneal scars from trauma or prior infection, and ectasia after previous laser vision correction surgery. Clinical input suggested that there may be cases where anterior corneal disease should not be an exclusion, particularly if endothelial disease is the primary cause of the decrease in vision. EK should be performed by surgeons who
are adequately trained and experienced in the specific techniques and devices used.

**Description of Procedure or Service**

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**Summary**

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 membrane automated endothelial keratoplasty (DMAEK). EK, and particularly DSEK, DSAEK, DMEK, and DMAEK, are becoming standard procedures. Femtosecond laser-assisted corneal endothelial keratoplasty (FLEK) and femtosecond and excimer lasers-assisted endothelial keratoplasty (FELEK) have also been reported as alternative ways to prepare the donor endothelium.

The evidence on DSEK, DSAEK, DMEK, and DMAEK in patients who have endothelial disease includes a number of within-subject cohort studies and a systematic review. Relevant outcomes include change in disease status, morbid events, and functional outcomes. The literature available at this time indicates that these procedures improve visual outcomes and reduce the serious complications associated with penetrating keratoplasty (PK). Specifically, visual recovery occurs much earlier, and because 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. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence on FLEK and FELEK in patients who have endothelial disease includes a multicenter randomized trial that compared FLEK with PK. Relevant outcomes include change in disease status, morbid events, and functional outcomes. Mean best-corrected visual acuity was worse following FLEK than PK, and endothelial cell loss was higher. With the exception of dislocation and need for repositioning of the FLEK, the percentage of complications were similar in the 2 groups. Complications in the FLEK group were due to pupillary block, graft failure, epithelial ingrowth, and elevated intraocular pressure (IOP), whereas complications in the PK group were related to sutures and elevated IOP. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input when this policy was created supported DSEK and DSAEK as the standard of care for endothelial failure, due to improved outcomes compared with PK. Subsequent clinical input was obtained on evolving techniques for EK. Clinical input uniformly considered DMEK and DMAEK to be medically necessary procedures, while most input considered FLEK and FELEK to be investigational. Input was mixed regarding the exclusion of patients with anterior corneal disease. Additional indications suggested by the reviewers were added as medically necessary.

**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 layer; the stroma, which comprises approximately 90% of the cornea; Descemet 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 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 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 (DSEK), which uses hand-dissected donor tissue, and Descemet stripping automated endothelial keratoplasty (DSAEK), which uses an automated microkeratome to assist in donor tissue dissection. These techniques include some 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 to be a potential improvement over DSEK/DSAEK. A variation of DMEK is Descemet membrane automated endothelial keratoplasty (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. A laser may also be used for stripping in a procedure called femtosecond laser-assisted corneal endothelial keratoplasty (FLEK) and femtosecond and excimer lasers-assisted endothelial keratoplasty (FELEK).

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 corneoscleral tissue after removing the anterior donor corneal stroma by hand (eg, DSEK) or with the assistance of an automated microkeratome (eg, DSAEK) or laser (FLEK or FELEK). 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 1 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 to 8 weeks.
Eye Bank Association of America (EBAA) statistics show the number of EK cases in the United States increased from 1429 in 2005 to 23,409 in 2012. EBAA estimated that as of 2012, approximately one-half 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 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.

**Rationale**

This evidence review was created in August 2009 and has been updated regularly using the MEDLINE database. The most recent literature update was performed through July 20, 2017.

Assessment of efficacy for therapeutic intervention involves a determination of whether the intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

**DESCEMET STRIPPING ENDOTHELIAL KERATOPLASTY AND DESCemet STRIPPING AUTOMATED ENDOTHELIAL KERATOPLASTY**

In 2009, the American Academy of Ophthalmology’s Ophthalmic Technology Assessment Committee performed a review of the safety and efficacy of Descemet stripping automated endothelial keratoplasty (DSAEK), identifying 1 level I study (randomized controlled trial of precut vs surgeon dissected) along with 9 level II (well-designed observational studies) and 21 level III studies (mostly retrospective case series).(1) Although more than 2000 eyes treated with DSAEK were reported in different publications, most were reported by 1 research group with some overlap in patients. The main results of this review are as follows:

- DSAEK-induced hyperopia ranged from 0.7 to 1.5 diopters (D), with minimal induction of astigmatism (range, -0.4 to 0.6 D).
- The reporting of visual acuity was not standardized in studies reviewed. The average best-corrected visual acuity (BCVA) ranged from 20/34 to 20/66, and the percentage of patients seeing 20/40 or better ranged from 38% to 100%.
- The most common complication from DSAEK was posterior graft dislocation (mean, 14%; range, 0%-82%), with a lack of adherence of the donor posterior lenticule to the recipient stroma, typically occurring within the first week. It was noted that this percentage might be skewed by multiple publications from 1 research group with low complication rates. Graft dislocation required additional surgical procedures (rebubble procedures), but did not lead to sight-threatening vision loss in the articles reviewed.
Endothelial graft rejection occurred in a mean of 10% of patients (range, 0%-45%); most were reversed with topical or oral immunosuppression, with some cases progressing to graft failure. Primary graft failure, defined as unhealthy tissue that has not cleared within 2 months, occurred in a mean of 5% of patients (range, 0%-29%). Iatrogenic glaucoma occurred in mean of 3% of patients (range, 0%-15%) due to a pupil block induced from the air bubble in the immediate postoperative period or delayed glaucoma from topical corticosteroid adverse effects.

Endothelial cell loss, which provides an estimate of long-term graft survival, was on mean 37% at 6 months and 41% at 12 months. These percentages of cell loss were reported to be similar to those observed with penetrating keratoplasty (PK).

Reviewers concluded that DSAEK appeared to be at least equivalent to PK regarding safety, efficacy, surgical risks, and complication rates, although long-term results were not yet available. The evidence also indicated that endothelial keratoplasty (EK) is superior to PK regarding refractive stability, postoperative refractive outcomes, wound- and suture-related complications, and risk of intraoperative choroidal hemorrhage. The reduction in serious and occasionally catastrophic adverse events associated with PK has led to the rapid adoption of EK for treatment of corneal endothelial failure.

More recently, in 2016, Heinzelmann et al reported on outcomes in patients who underwent EK or PK for Fuchs endothelial dystrophy or bullous keratopathy. The study included 89 eyes undergoing DSAEK and 329 eyes undergoing PK. Postoperative visual improvement was faster after EK than after PK. For example, among patients with Fuchs endothelial dystrophy, 50% of patients achieved a BCVA of Snellen 6/12 or more 18 months after DSAEK vs more than 24 months after PK. Endothelial cell loss was similar after EK or PK in the early postoperative period. However, after an early decrease, endothelial cell loss stabilized in patients who received EK whereas the decrease continued in those who had PK. Among patients with Fuchs endothelial dystrophy, there was a slightly increased risk of late endothelial failure in the first two years with EK than with PK. Graft failure was lower after bullous keratopathy than after Fuchs endothelial dystrophy (numbers not reported).

Longer term outcomes were reported in several studies. Five-year outcomes from a prospective study conducted at the Mayo Clinic were published in 2016 by Wacker et al. The study included 45 participants (52 eyes) with Fuchs endothelial corneal dystrophy who underwent Descemet stripping endothelial keratoplasty (DSEK). Five-year follow-up was available for 34 (65%) eyes. Mean high-contrast BCVA was 20/56 Snellen equivalent presurgery, and decreased to 20/25 Snellen equivalent at 60 months. The difference in high-contrast BCVA at 5 years vs presurgery was statistically significant (p<0.001). Similarly, the proportion of those with BCVA of 20/25 Snellen equivalent or better increased from 26% at 1 year postsurgery to 56% at 5 years (p<0.001). There were six graft failures during the study period (four failed to clear after surgery, two failed during follow-up). All patients with graft failures were regrafted.
Previously, in 2012, 3-year outcomes after DSAEK were reported by the Devers Eye Institute. This retrospective analysis included 108 patients who underwent DSAEK for Fuchs endothelial dystrophy or pseudophakic bullous keratopathy and had no other ocular comorbidities. BCVA was measured at six months and one, two, and three years. BCVA after DSAEK improved over the three years of the study. For example, the percentage of patients who reached a BCVA of 20/20 or greater was 0.9% at baseline, 11.1% at 6 months, 13.9% at 1 year, 34.3% at 2 years, and 47.2% at 3 years. Ninety-eight percent of patients reached a BCVA of 20/40 or greater by 3 years.

**DESCEMET MEMBRANE ENDOTHELIAL KERATOPLASTY AND DESCEMET MEMBRANE AUTOMATED ENDOTHELIAL KERATOPLASTY**

It has been suggested that by eliminating the stroma on the donor tissue, Descemet membrane endothelial keratoplasty (DMEK) and Descemet membrane automated endothelial keratoplasty (DMAEK) may reduce stromal interface haze and provide better visual acuity outcomes than DSEK or DSAEK. Tourtas et al reported a retrospective comparison of 38 consecutive patients/eyes that underwent DMEK vs 35 consecutive patients (35 eyes) who had undergone DSAEK. Only patients with Fuchs endothelial dystrophy or pseudophakic bullous keratopathy were included. After DMEK, 82% of eyes required rebubbling. After DSAEK, 20% of eyes required rebubbling. BCVA in the 2 groups was comparable at baseline (DMEK=0.70 logMAR; DSAEK=0.75 logMAR). At 6-month follow-up, mean visual acuity improved to 0.17 logMAR after DMEK and 0.36 logMAR after DSAEK. This difference was statistically significant. At 6 months following surgery, 95% of DMEK-treated eyes reached a visual acuity of 20/40 or better, and 43% of DSAEK-treated eyes reached a visual acuity of 20/40 or better. Endothelial cell density decreased by a similar amount after the 2 procedures (41% after DMEK, 39% after DSAEK).

In 2013, van Dijk et al reported outcomes of their first 300 consecutive eyes treated with DMEK. Indications for DMEK were Fuchs dystrophy, pseudophakic bullous keratopathy, failed PK, or failed EK. Of the 142 eyes evaluated for visual outcome at 6 months, 79% reached a BCVA of 20/25 or more, and 46% reached a BCVA of 20/20 or more. Endothelial cell density measurements at 6 months were available in 251 eyes. An average cell density was 1674 cells/mm², representing a decrease of 34.6% from preoperative donor cell density. The major postoperative complication in this series was graft detachment requiring rebubbling or regraft, which occurred in 10.3% of eyes. Allograft rejection occurred in 3 eyes (1%), and intraocular pressure (IOP) was increased in 20 (6.7%) eyes. Except for 3 early cases that may have been prematurely regrafted, all but 1 eye with an attached graft cleared in 1 to 12 weeks.

A 2009 review of cases from another group in Europe suggested that a greater number of patients achieve 20/25 vision or better with DMEK. Of the first 50 consecutive eyes, 10 (20%) required a secondary DSEK for failed DMEK. For the remaining 40 eyes, 95% had a BCVA of 20/40 or better, and 75% had a BCVA of 20/25 or better. Donor detachments and primary graft failure with DMEK were
problematic. In 2011, this group reported on the surgical learning curve for DMEK, with their first 135 consecutive cases retrospectively divided into 3 subgroups of 45 eyes. Graft detachment was the most common complication, and decreased with experience. In their first 45 cases, a complete or partial graft detachment occurred in 20% of cases, compared with 13.3% in the second group and 4.4% in the third group. Clinical outcomes in eyes with normal visual potential and a functional graft (n=110) were similar across the 3 groups, with an average endothelial cell density of 1747 cells and 73% of cases achieving a BCVA of 20/25 or better at 6 months.

A North American group reported 3-month outcomes from a prospective consecutive series of 60 cases of DMEK in 2009, and in 2011, they reported 1-year outcomes from these 60 cases plus an additional 76 cases of DMEK. Preoperative BCVA averaged 20/65 (range of 20/20 to counting fingers). Sixteen eyes were lost to follow-up, and 12 (8.8%) grafts had failed. For the 108 grafts examined and found to be clear at 1 year, 98% achieved BCVA of 20/30 or better. Endothelial cell loss was 31% at 3 months and 36% at 1 year. Although visual acuity outcomes appeared to be improved over a DSAEK series from the same investigators, preparation of the donor tissue and attachment of the endothelial graft were more challenging. A 2012 cohort study by this group found reduced transplant rejection with DMEK. One (0.7%) of 141 patients in the DMEK group had a documented episode of rejection compared with 54 (9%) of 598 in the DSEK group and 5 (17%) of 30 in the PK group.

The same group also reported a prospective consecutive series of their initial 40 cases (36 patients) of DMAEK (microkeratome dissection and a stromal ring) in 2011. Indications for EK were Fuchs endothelial dystrophy (87.5%), pseudophakic bullous keratopathy (7.5%), and failed EK (5%). Air was reinjected in 10 (25%) eyes to promote graft attachment; 2 (5%) grafts failed to clear and were successfully regrafted. Compared with a median BCVA of 20/40 at baseline (range, 20/25 to 20/400), median BCVA at 1 month was 20/30 (range, 20/15 to 20/50). At 6 months, 48% of eyes had 20/20 vision or better, and 100% were 20/40 or better. Mean endothelial cell loss at 6 months relative to baseline donor cell density was 31%.

**FEMTOSECOND LASER-ASSISTED ENDOTHELIAL KERATOPLASTY**

In 2009, Cheng et al reported a multicenter randomized trial from Europe that compared femtosecond laser-assisted endothelial keratoplasty (FLEK) with PK. Eighty patients with Fuchs endothelial dystrophy, pseudophakic bullous keratopathy, or posterior polymorphous dystrophy, and a BCVA less than 20/50 were included in the study. In the FLEK group, 4 of the 40 eyes did not receive treatment due to significant preoperative events and were excluded from the analysis. Eight (22%) of 36 eyes failed, and 2 patients were lost to follow-up due to death in the FLEK group. One patient was lost to follow-up in the PK group due to health issues. At 12 months postoperatively, refractive astigmatism was lower in the FLEK group than in the PK group (86% vs 51%, respectively, with astigmatism of □3 oculus dexter), but there was greater hyperopic shift. Mean BCVA was better following PK than FLEK at 3-, 6-, and 12-month follow-ups. There
was greater endothelial cell loss in the FLEK group (65%) than in the PK group (23%). With the exception of dislocation and need to reposition the FLEK grafts in 28% of eyes, the percentage of complications was similar between groups. Complications in the FLEK group were due to pupillary block, graft failure, epithelial ingrowth, and elevated IOP, whereas complications in the PK group were related to the sutures and elevated IOP.

A small retrospective cohort study from 2013 found a reduction in visual acuity when the endothelial transplant was prepared with laser (FLEK=0.48 logMAR; n=8) compared with microtome (DSAEK=0.33 logMAR; n=14).(16) There was also greater surface irregularity with FLEK.

**SUMMARY OF EVIDENCE**

For individuals who have endothelial disease of the cornea who receive DSEK, DSAEK, DMEK, or DMAEK, the evidence includes a number of cohort studies and a systematic review. Relevant outcomes are a 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, and 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.

For individuals who have endothelial disease of the cornea who receive FLEK and FELEK, the evidence includes a multicenter randomized trial that compared FLEK with PK. Relevant outcomes are a change in disease status, morbid events, and functional outcomes. Mean best-corrected visual acuity was worse after FLEK than after PK, although endothelial cell loss was higher. 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.

Clinical input when this evidence review was created supported DSEK and DSAEK as the standard of care for endothelial failure, based on improved outcomes compared with PK. Subsequently, clinical input was obtained on evolving techniques for endothelial keratoplasty, which uniformly considered DMEK and DMAEK to be medically necessary procedures, while most input considered FLEK and FELEK to be investigational. Input was mixed on the exclusion of patients with anterior corneal disease. Additional indications suggested by the reviewers were added as medically necessary.
SUPPLEMENTAL INFORMATION

CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2013 Vetting
In response to requests, input was received through 3 physician specialty societies (2 reviewers) and 3 academic medical centers while this policy was under review in 2013. Input uniformly considered Descemet membrane endothelial keratoplasty and Descemet membrane automated endothelial keratoplasty to be medically necessary procedures, while most input considered Femtosecond laser-assisted endothelial keratoplasty and femtosecond and excimer lasers-assisted endothelial keratoplasty to be investigational. Input was mixed on the exclusion of patients with anterior corneal disease. Additional indications suggested by the reviewers were added as medically necessary.

2009 Vetting
In response to requests, input was received through physician specialty societies (3 reviewers representing 3 associated organizations) and 2 academic medical centers while this policy was under review in 2009. Input supported Descemet stripping endothelial keratoplasty and Descemet stripping automated endothelial keratoplasty (DSAEK) as the standard of care for endothelial failure, due to improved outcomes compared with penetrating keratoplasty.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Academy of Ophthalmology
In 2009, the Health Policy Committee of the American Academy of Ophthalmology (AAO) published a position paper on endothelial keratoplasty (EK), stating that the optical advantages, speed of visual rehabilitation, and lower risk of catastrophic wound failure have driven the adoption of EK as the standard of care for patients with endothelial failure and otherwise healthy corneas. The AAO position paper was based in large part on a comprehensive review of the literature on DSAEK by AAO’s Ophthalmic Technology Assessment Committee.(1) This committee concluded that “the evidence reviewed suggests DSAEK appears safe and efficacious for the treatment of endothelial diseases of the cornea. Evidence from retrospective and prospective DSAEK reports described a variety of complications from the procedure, but these complications do not appear to be permanently sight-threatening or detrimental to the ultimate vision recovery in the majority of cases. Long-term data on endothelial cell survival and the risk of late endothelial rejection cannot be determined with this review.” “DSAEK should not be used in lieu of PK [penetrating keratoplasty] for conditions with concurrent endothelial disease and anterior corneal disease. These situations would include concurrent
anterior corneal dystrophies, anterior corneal scars from trauma or prior infection, and ectasia after previous laser vision correction surgery.”

**National Institute for Health and Care Excellence**
The U.K.’s National Institute for Health and Care Excellence released guidance on corneal endothelial transplantation in 2009.(17) Additional data reviewed from the U.K. Transplant Register showed lower graft survival rates after EK than after penetrating keratoplasty; however, the difference in graft survival between the two procedures was noted to be narrowing with increased experience in EK use. The guidance concluded that “current evidence on the safety and efficacy of corneal endothelial transplantation (also known as endothelial keratoplasty [EK]) is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance and consent.” The guideline committee noted that techniques for this procedure continue to evolve, and thorough data collection should continue to allow future review of outcomes.

**U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS**
Not applicable.

**MEDICARE NATIONAL COVERAGE**
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**ONGOING AND UNPUBLISHED CLINICAL TRIALS**
Currently unpublished trials that might influence this review are listed in Table 1.

### Table 1. Summary of Key Trials

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NCT: national clinical trial.

**References**


**Billing Coding/Physician Documentation Information**

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**ICD-10 Codes**

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<td>Complications of corneal transplant, code range</td>
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Additional Policy Key Words
N/A

Policy Implementation/Update Information
11/1/15  New Policy. Considered medically necessary.
11/1/16  No policy statement changes.
11/1/17  No policy statement changes.

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