BlueCross BlueShield of Alabama

Name of Policy:
Endothelial Keratoplasty

Policy #: 382
Category: Other

Latest Review Date: September 2014
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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.

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 its entry, 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 a 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 EK techniques was termed deep lamellar endothelial keratoplasty (DLEK), which utilized 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 utilizes 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 is comprised of 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. In order 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 to 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 US increased from 1429 in 2005 to 23,409 in 2012. The EBAA report estimates that approximately ½ 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.

Policy:

Effective for dates of service on or after December 1, 2013:

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]) meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the treatment of endothelial dysfunction, including but not limited to:

- Ruptures in Descemet's membrane; **OR**
- Endothelial dystrophy; **OR**
- Aphakic, and pseudophakic bullous keratopathy; **OR**
- Iridocorneal endothelial (ICE) syndrome; **OR**
- 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) do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational**.

Effective for dates of service prior to December 1, 2013:
Endothelial keratoplasty (Descemet's stripping endothelial keratoplasty or Descemet's stripping automated endothelial keratoplasty) **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the treatment of endothelial dysfunction, including but not limited to Fuchs' endothelial dystrophy, aphakic and pseudophakic bullous keratopathy, and failure or rejection of a previous corneal transplant.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent update was performed with a literature search through September 2014.

Literature Review

Descemet's Stripping Endothelial Keratoplasty and Descemet's Stripping Automated Endothelial Keratoplasty (DSEK/DSAEK)
A 2009 review of the safety and efficacy of DSAEK, performed by the American Academy of Ophthalmology's (AAO) Ophthalmic Technology Assessment Committee, identified one Level I study (randomized controlled trial of precut vs. surgeon dissected) along with nine Level II (well-designed observational studies) and 21 Level III studies (mostly retrospective case series). Although greater than 2000 eyes treated with DSAEK were reported in different publications, most were reported by one research group with some overlap in patients. The main results from this evidence review are as follows:

- DSAEK induced hyperopia ranged from 0.9 diopters (D) to 1.5 D, with minimal induction of astigmatism (ranging from 0 D to 0.6 D).

- The reporting of visual acuity was not standardized in the studies reviewed. The average best-corrected visual acuity (BCVA) ranged from 20/33 to 20/66, and the percentage of patients seeing 20/40 or better ranged from 38% to 100%.

- The most common complication from DSAEK in the studies reviewed 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 figure may be skewed by multiple publications from one research group with low complication rates. Graft dislocation required additional surgical procedures (re-bubble procedures) but did not lead to sight threatening vision loss in the articles reviewed.

- Endothelial graft rejection occurred in an average 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 two months, occurred in 5% of patients (range 0 to 29%). Iatrogenic glaucoma occurred in an average 3% of patients (range 0 to 15%) due to a pupil block induced from the air bubble in the immediate post-operative period or delayed glaucoma from topical corticosteroid side-effects.

- Endothelial cell loss, which provides an estimate of long-term graft survival, was an average 37% at six months and 42% at 12 months. This was reported to be similar to the percentage of cell loss observed with PK.

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

It was noted that the specific techniques are still evolving; the authors identified the following future research needs:

> "*Future research should be directed at assessing better surgical techniques for increasing endothelial cell survival with endothelial procedures, whether this represents new surgical techniques and/or new instrumentation…. Both new surgical techniques such as Descemet's membrane endothelial keratoplasty and new insertion techniques must be validated by basic laboratory ex vivo studies and large, well-designed cohort or randomized controlled studies and/or long-term prospective studies demonstrating complication rates and long-term endothelial cell survival*."

A number of studies included in the AAO review were from Chen, Terry, and colleagues at the Devers Eye Institute. One of the publications reported six-month clinical outcomes from 100 of the first 150 consecutive eyes treated by DSAEK at this tertiary care center during 2005 and 2006. Fifty eyes were not available for six-month follow-up due to illness, death, or residence out of state. Preoperatively, every patient had a diagnosis of endothelial dysfunction with clinically evident stromal edema; BCVA averaged 20/86 and uncorrected visual acuity (UCVA) averaged 20/155. Cataract surgery (n = 51) was concurrently performed if the patient had visually significant cataract or mild cataract with expectation of progression and minimal remaining accommodative amplitude. At six-month follow-up all grafts were clear and there were no primary graft failures. There was an average gain of >4 Snellen lines with an average BCVA of 20/38. Eighty-five percent of eyes had better visual acuity than they had preoperatively, and 81% obtained vision of 20/40 or better. When patients were excluded due to other possible causes of visual loss such as macular or glaucomatous damage, BCVA improved from 20/60 to 20/30 (n=74), with an average gain of three Snellen lines. Eighty-eight percent of

eyes in this group had better visual acuity at six months than they had preoperatively, and 97% of eyes had obtained a vision of 20/40 or better. The reporting of results on visual acuity did not distinguish between patients who had received concurrent cataract surgery and those whose improvements could be attributed entirely to DSAEK.

There were several additional reports identified which were published after the AAO technology assessment. Several case reports were identified on complications (e.g., epithelial ingrowth and adverse effects of the bubbles) as well as a number of papers on DSEK/DSAEK technique. Chen and colleagues reported the effect of training on outcomes following DSAEK. Out of 327 consecutive cases performed at their tertiary care centers during 2005-2007, 235 were performed by the attending corneal surgeon and 92 were performed by the corneal fellows. Loss-to-follow up at six months (36% to 37%) was due to illness, death, or residence out of state. For the 208 patients who returned for the six-month assessment, 91% of those treated by the attending surgeon and 69% of those treated by fellows had also undergone concurrent phacoemulsification for visually significant cataract at the time of DSAEK. There were no graft failures in either group and all grafts were clear at the six-month assessment. Dislocations and endothelial cell loss were similar in the two groups of patients (2% vs. 1% dislocations and mean cell loss of 32% and 35%). Patients from both groups gained about four Snellen lines, with a six-month average best corrected visual acuity of 20/37 and 20/36. Vision of 20/40 or better was obtained by 78% of patients treated by attending surgeons and 90% of patients treated by fellows. Vision of 20/20 or better was obtained by 14% of patients treated by attending surgeons and 3% treated by fellows.

In 2012, Anshu reported on the following study:
Longer-term graft survival has been reported in a retrospective analysis from the Cornea Research Foundation of American and Price Vision Group. A total of 453 cases were identified (out of 835 performed) that had received DSEK by a single surgeon between 2003 and 2007 and had at least one-year follow-up. Most cases (n=342) had no preexisting glaucoma, while 65 had medically managed glaucoma and 46 had undergone prior glaucoma surgery with either a shunt or trabeculectomy. With graft failure defined as persistent corneal edema resulting in irreversible loss of optical clarity, one-year graft survival was similar (96% to 100%) in the three groups. Kaplan-Meier analysis showed five-year graft survival to be 96% in eyes with no prior glaucoma, 90% in eyes with medically managed preexisting glaucoma, and 48% in eyes with prior glaucoma surgery ($p<0.001$). In a multivariate model, prior glaucoma surgery and a prior rejection episode were significant risk factors for corneal endothelial failure.

Three-year outcomes after DSAEK were reported from the Devers Eye Institute in 2012. 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 was found to improve over the three years of the study. For example, the percentage of patients who reached a visual acuity of 20/20 or greater was 0.9% at baseline, 11.1% at six months, 13.9% at one year, 34.3% at two years, and 47.2% at three years. Ninety-eight percent of patients reached a visual acuity of 20/40 or greater by three years.

Descemet's Membrane Endothelial Keratoplasty (DMEK) and Descemet's Membrane Automated Endothelial Keratoplasty (DMAEK)

Reviews suggest that by eliminating the stroma on the donor tissue, DMEK/DMAEK may reduce stromal interface haze and provide better visual acuity outcomes than DSEK/DSAEK. Current literature is limited to large case series and retrospective comparisons. Tourtas et al reported a retrospective comparison of 38 consecutive patients/eyes that underwent DMEK versus 35 consecutive patients/eyes that had undergone DSAEK. Only patients with Fuchs' endothelial dystrophy or pseudophakic bullous keratopathy were included in the study. After DMEK, 82% of eyes required re-bubbling. After DSAEK, 20% of eyes required re-bubbling. BCVA in the two groups was comparable at baseline (DMEK, 0.70 logMAR and DSAEK, 0.75 logMAR). At six-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 six 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 two procedures (41% after DMEK and 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 (64%) evaluated for visual outcome at six 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 six months were available in 251 eyes, with an average cell density of 1,674 cells/mm^2; a decrease of 34.6% from preoperative donor cell density. The major postoperative complication in this series was graft detachment requiring re-bubbling or re-graft, which occurred in 10.3% of eyes. Allograft rejection occurred in three eyes (1%). Twenty eyes (6.7%) had an elevation of intraocular pressure. Except for three early cases that may have been prematurely regrafted, all but one eye with an attached graft cleared in one to twelve weeks.

A review of the first 50 consecutive cases from another group in Europe suggests that a greater number of patients achieve 20/25 vision or better with DMEK. Of the 50 consecutive eyes, ten (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, and the ultimate success of DMEK will depend on the reliability of graft adherence and demonstrated improvement in visual acuity outcomes in comparison with DSAEK. In 2011, this group reported on the learning curve of DMEK, with their first 135 consecutive cases retrospectively divided into three 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 found to be similar in the three groups, with an average endothelial cell density of 1,747 cells and 73% of cases achieving a BCVA of 20/25 or better at six months.

A North American group reported three-month outcomes from a prospective consecutive series of 60 cases of DMEK in 2009, and in 2011, they reported one-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 grafts (8.8%) had failed. For the 108 grafts that were examined and found to be clear at one year, 98% achieved BCVA of 20/30 or better. Endothelial cell loss was 31% at three months and 36% at one 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 found to be more challenging. A 2012 cohort study by this group found reduced transplant rejection with DMEK. One patient (0.7% of 141) in the DMEK group had a documented episode of rejection compared with 54 (9% of 598) in the DSEK group and five (17% of 30) in the PK group.

The same group of investigators 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 ten eyes (25%) to promote graft attachment; two grafts (5%) failed to clear and were successfully regrafted. Compared with a median BCVA of 20/40 at baseline (range, 20/25-20/400), median BCVA at one month was 20/30 (range, 20/15 -20/50). At six months, 48% of eyes had 20/20 vision or greater and 100% were 20/40 or greater. Mean endothelial cell loss at six months relative to baseline donor cell density was 31%.

Femtosecond Laser-assisted Corneal Endothelial Keratoplasty (FLEK)
In 2009, Cheng et al reported a multicenter randomized trial from Europe that compared FLEK with PD. Eight patients with Fuchs' endothelial dystrophy, pseudophakic bullous keratopathy or posterior polymorphous dystrophy, and best spectacle-corrected visual acuity lower than 20/50, were included in the study. In the FLEK group, four of the 40 eyes did not receive the treatment due to significant preoperative events and were excluded from the analysis. Eight eyes failed (22% of 36) and two patients were lost to follow-up due to death in the FLEK group. Only one patient was lost to follow-up in the PD group due to health issues. At 12 months postoperatively, refractive astigmatism was lower in the FLEK group than the PD group, but there was greater hyperopic shift. Mean best corrected visual acuity was better following PK than FLEK at three-, six-, and 12-months follow-up. There was greater endothelial cell loss in the FLEK group (65%) than the PK group (23%). With the exception of dislocation and need for repositioning of the FLEK grafts in 28% of eyes, the percentage of complications were similar in the two groups. Complications in the FLEK group were due to pupillary block, graft failure, epithelia ingrowth and elevated intraocular pressure, whereas complications in the PK group were related to the sutures and elevated intraocular pressure.

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). (17) There was also greater surface irregularity with the laser-assisted EK.

Summary
Endothelial keratoplasty, and particularly DSEK, DSAEK, DMEK, and DMAEK are relatively new procedures. FLEK had been reported as another way 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 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 towards 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 vision 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.

FLEK and FELEK have not been shown to have improved outcomes compared to existing techniques.

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.

Technology Assessments, Guidelines and Position Statements
In 2009, the Health Policy Committee of the American Academy of Ophthalmology (AAO) published a position paper on endothelial keratoplasty, 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 Descemet's stripping automated endothelial keratoplasty (DSAEK) by the American Academy of Ophthalmology's Ophthalmic Technology Assessment Committee. The Technology Assessment 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 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.*"

The United Kingdom's National Institute for Health and Clinical Excellence released guidance on corneal endothelial transplantation in 2009. The studies reviewed utilized DLEK, DSEK, and DSAEK. Additional data reviewed from the UK Transplant Register showed lower graft survival rates after EK than after PK, 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 Committee noted that the techniques for this procedure continue to evolve, and thorough data collection should continue to allow future review of outcomes.

Key Words:

Deep lamellar endothelial keratoplasty (DLEK), Descemet's membrane endothelial keratoplasty (DMEK), Descemet's stripping endothelial keratoplasty (DSEK), Descemet's stripping automated endothelial keratoplasty (DSAEK), Endothelial keratoplasty (EK), Penetrating keratoplasty (PK), FLEK, FELEK, femtosecond laser-assisted corneal endothelial keratoplasty, femtosecond and excimer lasers-assisted endothelial keratoplasty

Approved by Governing Bodies:

Not applicable

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home policy provisions apply.
FEP contracts: Special benefit consideration may apply Wal-Mart: Special benefit consideration may apply. Refer to member's benefit plan.
Pre-certification requirements: Not applicable.

Current Coding:

CPT Codes:

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

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Policy History:

Medical Policy Group, August 2009 **(2)**
Medical Policy Administration Committee, September 2009
Available for comment September 4-October 19, 2009
Medical Policy Panel, August 2010
Medical Policy Group, September 2010 **(2)**
Medical Policy Group, September 2012 **(2)**: Update to Description, Key Points and References
Medical Policy Panel, September 2013
Medical Policy Group, October 2013 **(2)**: Policy updated with literature search. DMEK [Descemet's membrane endothelial keratoplasty] and DMAEK [Descemet's membrane automated endothelial keratoplasty] added as covered indications. FLEK and FELEK added as investigational. Description, Key Points, Key Words, References updated to support new policy statements and literature findings.
Medical Policy Administration Committee, October 2013
Available for comments October 16 through November 30, 2013
Medical Policy Panel, September 2014
Medical Policy Group, September 2014 **(1):** updated policy with current literature review; no change to policy statement