

## Corporate Medical Policy

### Endothelial Keratoplasty

<b>File Name:</b>	endothelial_keratoplasty
<b>Origination:</b>	9/2009
<b>Last CAP Review:</b>	6/2018
<b>Next CAP Review:</b>	6/2019
<b>Last Review:</b>	6/2018

#### Description of Procedure or Service

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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). 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 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 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 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 stripping endothelial keratoplasty (DSEK) which uses hand-dissected donor tissue, and Descemet 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 membrane, which results in a thickened stromal layer after

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transplantation. If the donor tissue is comprised of 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'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 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 US increased from 1,429 in 2005 to 23,409 in 2012. The EBAA report estimates that approximately one-half 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. Also of interest is the impact of the surgeon's learning. Long-term complications include increased intraocular pressure, graft rejection, and late endothelial failure.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

## Policy

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**BCBSNC will provide coverage for 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]) when it is determined to be medically necessary and when medical criteria and guidelines shown below are met.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

**Endothelial keratoplasty may require prior review.**

Complications requiring additional procedures after previous laser vision correction surgery are excluded benefits under most member benefit plans.

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## When Endothelial Keratoplasty is covered

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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:

- endothelial dystrophy,
- aphakic and pseudophakic bullous keratopathy,
- iridocorneal endothelial (ICE) syndrome,
- corneal edema attributed to endothelial failure,
- failure or rejection of a previous corneal transplant,
- ruptures in Descemet membrane

## When Endothelial Keratoplasty is not covered

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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]) is considered not medically necessary for indications other than those listed above.

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

*\*Note: Treatment of side effects or complications as a result of a prior non-covered procedure (such as laser vision correction surgery) is a benefit exclusion under most benefit plans.*

## Policy Guidelines

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For individuals who have endothelial disease of the cornea who receive DSEK or DSAEK, the evidence 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. 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.

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 FELEK, the evidence includes a multicenter randomized trial that compared FLEK with PK. Relevant outcomes

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include change in disease status, morbid events, and functional outcomes. Mean best-corrected visual acuity was worse following 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 (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.

Input obtained in 2013 considered FLEK and FELEK 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..

## **Billing/Coding/Physician Documentation Information**

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 65756, 65757, 0290T*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## **Scientific Background and Reference Sources**

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Eye Bank Association of America. 2007 Eye banking statistical report. Retrieved on September 2, 2009 from <http://restoresight.org/newsroom/2007StatisticalReport.pdf>

Lee WB, Jacobs DS, Musch DC, Kaufman SC, Reinhart WJ, Shtein RM. American Academy of Ophthalmology. Descemet's Stripping Endothelial Keratoplasty: Safety and Outcomes A Report by the American Academy of Ophthalmology. Ophthalmology, 2009, in press.

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Ham L, Dapena I, van Luijk C et al. Descemet membrane endothelial keratoplasty (DMEK) for Fuchs endothelial dystrophy: review of the first 50 consecutive cases. Eye. 2009 Jan 30. [Epub ahead of print]

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BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.22, 8/13/09.  
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.22, 8/12/10.  
Specialty Matched Consultant Review Panel -6/2011  
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.22, 8/9/12  
Specialty Matched Consultant Review Panel- 10/2012  
Specialty Matched Consultant Review Panel review- 6/2013  
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.22, 9/12/13  
Specialty Matched Consultant Advisory Panel review- 6/2014  
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BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.22, 3/10/16  
Specialty Matched Consultant Advisory Panel review- 6/2016  
Specialty Matched Consultant Advisory Panel review- 6/2017  
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.22, 9/14/17  
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.22, 3/8/18  
Specialty Matched Consultant Advisory Panel review- 6/2018

## Policy Implementation/Update Information

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9/28/09 New policy issued. (pmo)  
11/9/09 Reference source added. (pmo)  
6/22/10 Policy Number(s) removed (amw)  
8/3/10 Added statement under “When Endothelial Keratoplasty is not covered” section: Note: Treatment of side effects or complications as a result of a prior non-covered procedure (laser vision correction surgery) is a benefit exclusion under most benefit plans”. Reviewed by Senior Medical Director. (lpr)  
7/19/11 Specialty Matched Consultant review panel meeting 6/29/2011. No change in policy statement. Reference added. (lpr)  
11/22/11 Added CPT codes 0289T, 0290T and HCPCS code C9732 to Billing/Coding section effective 1/1/2012. (lpr)  
12/20/11 Removed HCPCS code C9732 from Billing/Coding section (only 1U allowed for implantation in one eye only.) (lpr)  
10/30/12 Updated Description section and reference added. Specialty Matched Consultant review panel meeting 10/17/2012. No change to policy statement. (lpr)  
7/16/13 Updated Policy Guidelines section. Specialty Matched consultant review panel 6/19/2013. No change to policy statement. (lpr)  
11/12/13 Revised Description and Policy Guidelines sections. Under “When Covered” section added the following statements as medically necessary: “Descemet’s membrane endothelial keratoplasty (DMEK) and Descemet’s membrane automated endothelial keratoplasty (DMAEK); ruptures in Descemet’s membrane, endothelial dystrophy, iridocorneal endothelial (ICE) syndrome and corneal edema attributed to endothelial failure.” Under

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- “When Not Covered” section added the following statement: Femtosecond laser-assisted corneal endothelial keratoplasty (FLEK) or femtosecond and excimer lasers-assisted endothelial keratoplasty (FELEK) are considered investigational.” Reference added. (lpr)
- 7/15/14 Specialty matched consultant advisory panel review meeting 6/24/2014. No change to policy statement. (lpr)
- 10/28/14 Reference added. No change to policy statement. (lpr)
- 7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. No change to policy statement. (lpr)
- 10/30/15 Updated Description and Policy Guidelines sections. Removed the letter “s” from all Descemet references. Reference added. No change to policy statement. (lpr)
- 4/29/16 Reference added. No change to policy statement. (lpr)
- 7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. No change to policy statement. (lpr)
- 12/30/16 Deleted CPT code 0289T from Billing/Coding section for effective date 1/1/2017. (lpr)
- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/28/2017. No change to policy statement. (lpr)
- 10/13/17 Reference added. (lpr)
- 8/10/18 Updated Policy Guidelines section. Reference added. Specialty Matched Consultant Advisory Panel review 6/2018. No change to policy statement. (lpr)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.