

## Corporate Medical Policy

### Endothelial Keratoplasty

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<b>Origination:</b>	9/2009
<b>Last CAP Review:</b>	6/2011
<b>Next CAP Review:</b>	6/2012
<b>Last Review:</b>	6/2011

#### 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'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 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. 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.

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

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automated microkeratome (e.g., DSAEK). 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 1,398 in 2005 to 14,159 in 2007. About 1/3 of corneal transplants performed in the United States were EK procedures, and EK was performed for over 85% of patients with endothelial disease. 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 curve on the risk of complications.

***\*\*\*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's stripping endothelial keratoplasty or Descemet's stripping automated endothelial keratoplasty) 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.

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## When Endothelial Keratoplasty is covered

Endothelial keratoplasty (Descemet's stripping endothelial keratoplasty or Descemet's stripping automated endothelial keratoplasty) may be considered medically necessary for the treatment of endothelial dysfunction, including but not limited to the following:

- Fuchs' endothelial dystrophy,
- aphakic and pseudophakic bullous keratopathy (corneal edema following cataract extraction),
- failure or rejection of a previous corneal transplant.

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## When Endothelial Keratoplasty is not covered

Endothelial keratoplasty (Descemet's stripping endothelial keratoplasty or Descemet's stripping automated endothelial keratoplasty) is not covered for indications other than those listed above.

Endothelial keratoplasty (Descemet's stripping endothelial keratoplasty or Descemet's stripping automated endothelial keratoplasty) should not be used in place of PK for conditions with concurrent endothelial disease and anterior corneal disease. These situations would include the following:

- concurrent anterior corneal dystrophies,
- anterior corneal scars from trauma or prior infection,
- ectatic conditions of the cornea such as keratoconus, pellucid marginal degeneration and ectasia after previous laser vision correction surgery.

EK should be performed by surgeons who are adequately trained and experienced in the specific techniques and devices used.

*\*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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Corneal endothelial failure may result in impairment or loss of vision. Corneal transplantation is the most common type of transplant done in the United States. Penetrating keratoplasty (PK) has been the standard surgical intervention to treat diseased or damaged corneal endothelial tissue and stroma. Surgical treatment of corneal disorders is evolving with attempts to replace only the diseased portion of the cornea. Various techniques have emerged, which have advantages over PK, such as less suturing and faster visual rehabilitation.

Endothelial keratoplasty, and particularly DSEK and DSAEK, are relatively new procedures. 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 toward intervention at an earlier stage of endothelial disease.

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

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.

## 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, 0289T, 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.

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## Scientific Background and Reference Sources

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Specialty Matched Consultant Review Panel -6/2011

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## 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)

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- 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)

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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.