Title

Endothelial Keratoplasty

Related Policy:
Surgical Vision Services and Vision Training, #241

Description

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 endothelial keratoplasty (EK) techniques was termed deep lamellar endothelial keratoplasty (DLEK), 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's stripping endothelial keratoplasty (DSEK), which uses hand-dissected donor tissue, and Descemet's 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's membrane, which results in a thickened stromal layer after transplantation. If the donor tissue comprises 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 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 United States increased from 1,398 in 2005 to 14,159 in 2007. (1) 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.

When services are covered for commercial products and for Medicare HMO Blue and Medicare PPO Blue products[1]

We cover **endothelial keratoplasty** (Descemet's stripping endothelial keratoplasty or Descemet's stripping automated endothelial keratoplasty) 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.

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

Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

For services already billed	Prior to performance of service
Blue Cross Blue Shield of Massachusetts Provider Appeals PO Box 986065 Boston, MA 02298	Blue Cross Blue Shield of Massachusetts Case Creation/Medical Policy One Enterprise Drive Quincy, MA 02171 Tel: 1-800-327-6716 Fax: 1-888-282-0780

Authorization Information

For Managed Care members:

- No authorization is required for this service; *see* ***Managed Care Guidelines*** *for additional requirements.*

For Indemnity and PPO members:

- No authorization is required for this service; *see* ***Indemnity and PPO Guidelines*** *for additional requirements.*

Managed Care Guidelines

All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan description; however,

For Medicare HMO Blue members:

- The service must meet the criteria for coverage noted in this policy, be medically necessary, prescribed by a plan physician and provided by a network provider.
- Referrals are required for all visits to a specialist.

For all other Managed Care plans:

- Any specialist visit requires a referral, except for visits performed by OB/GYN specialists.
- Authorization is required for an inpatient admission.

Indemnity and PPO Guidelines

All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan description, however;

- Authorization is required for an inpatient admission.
- Authorizations are not required for most outpatient services as determined by the individual's subscriber certificate.
- Referrals to a specialist are not required.

Other information

For our Medical Technology Assessment Guidelines, see document #350.

Coding information

Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

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) 3/15: Should this code be added? The Clinical Team had determined that backbench codes would not be added to the medical policies since they are not direct patient procedures.

- **0289T:** Corneal incisions in the donor cornea created using a laser, in preparation for penetrating or lamellar keratoplasty (List separately in addition to code for primary procedure)
- **0290T:** Corneal incisions in the recipient cornea created using a laser, in preparation for penetrating or lamellar keratoplasty (List separately in addition to code for primary procedure)

Policy update history

New policy effective 5/1/2010. Updated 12/10, adding references. Reviewed 2/2011 MPG – Psychiatry and Ophthalmology, no changes in coverage were made. Updated to add new CPT codes 0289T and 0290T. Reviewed 2/2012 MPG Psychiatry and Ophthalmology, no changes in coverage were made. Updated 4/2012 with additional references based on BCBSA national policy, reviewed 8/2011.

References

References for footnote 1:

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3. Chen ES, Terry MA, Shamie N et al. Descemet-stripping automated endothelial keratoplasty: six-month results in a prospective study of 100 eyes. Cornea 2008; 27(5):514-20.
4. Chen ES, Terry MA, Shamie N et al. Endothelial keratoplasty: vision, endothelial survival, and complications in a comparative case series of fellows vs attending surgeons. Am J Ophthalmol 2009; 148(1):26-31.e2.
5. Cheng YY, Schouten JS, Tahzib NG et al. Efficacy and safety of femtosecond laser-assisted corneal endothelial keratoplasty: a randomized multicenter clinical trial. Transplantation 2009; 88(11):1294-302.
6. Dapena I, Ham L, Melles GR. Endothelial keratoplasty: DSEK/DSAEK or DMEK--the thinner the better? Curr Opin Ophthalmol 2009; 20(4):299-307.
7. Rose L, Kelliher C, Jun AS. Endothelial keratoplasty: historical perspectives, current techniques, future directions. Can J Ophthalmol 2009; 44(4):401-5.
8. 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 (Lond) 2009; 23(10):1990-8.
9. Price MO, Giebel AW, Fairchild KM et al. Descemet's membrane endothelial keratoplasty: prospective multicenter study of visual and refractive outcomes and endothelial survival. Ophthalmology 2009; 116(12):2361-8.
10. McCauley MB, Price MO, Fairchild KM et al. Prospective study of visual outcomes and endothelial survival with Descemet membrane automated endothelial keratoplasty. Cornea 2011; 30(3):315-9.
11. American Academy of Ophthalmology Health Policy Committee Position Paper on Endothelial Keratoplasty, January 29, 2009.
12. National Institute for Health and Clinical Excellence. Corneal endothelial transplantation. Available online at: http://www.nice.org.uk/nicemedia/pdf/IPG304Guidance.pdf . Last accessed June 2011.

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Footnotes

[1] Based on BCBSA national policy 9.03.22, Endothelial Keratoplasty, reviewed 8/2011.