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*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

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.

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'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 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 one 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. 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 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. 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. 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 four to eight 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 1,429 in 2005 to 23,409 in 2012. The EBAA report estimates that approximately 1/2 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.

Related Protocol

Keratoprosthesis

Policy (Formerly Corporate Medical Guideline)

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]) may be considered **medically necessary** for the treatment of endothelial dysfunction, including but not limited to:

- ruptures in Descemet's 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.

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.

Policy Guideline

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.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Lee WB, Jacobs DS, Musch DC et al. Descemet's stripping endothelial keratoplasty: safety and outcomes: a report by the American Academy of Ophthalmology. *Ophthalmology* 2009; 116(9):1818-30.
2. 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.
3. 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.
4. Anshu A, Price MO, Price FW. Descemet's Stripping Endothelial Keratoplasty: Long-term Graft Survival and Risk Factors for Failure in Eyes with Preexisting Glaucoma. *Ophthalmology* 2012; 119(10):1982-7.
5. Li JY, Terry MA, Goshe J et al. Three-year visual acuity outcomes after Descemet's stripping automated endothelial keratoplasty. *Ophthalmology* 2012; 119(6):1126-9.
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. Tourtas T, Laaser K, Bachmann BO et al. Descemet membrane endothelial keratoplasty versus descemet stripping automated endothelial keratoplasty. *Am J Ophthalmol* 2012; 153(6):1082-90 e2.

9. van Dijk K, Ham L, Tse WH et al. Near complete visual recovery and refractive stability in modern corneal transplantation: Descemet membrane endothelial keratoplasty (DMEK). *Cont Lens Anterior Eye* 2013; 36(1):13-21.
10. 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.
11. Dapena I, Ham L, Droutsas K et al. Learning Curve in Descemet's Membrane Endothelial Keratoplasty: First Series of 135 Consecutive Cases. *Ophthalmology* 2011; 118(11):2147-54.
12. 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.
13. Guerra FP, Anshu A, Price MO et al. Descemet's membrane endothelial keratoplasty: prospective study of 1-year visual outcomes, graft survival, and endothelial cell loss. *Ophthalmology* 2011; 118(12):2368-73.
14. Anshu A, Price MO, Price FW, Jr. Risk of corneal transplant rejection significantly reduced with Descemet's membrane endothelial keratoplasty. *Ophthalmology* 2012; 119(3):536-40.
15. 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.
16. 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.
17. Vetter JM, Butsch C, Faust M et al. Irregularity of the posterior corneal surface after curved interface femtosecond laser-assisted versus microkeratome-assisted descemet stripping automated endothelial keratoplasty. *Cornea* 2013; 32(2):118-24.
18. American Academy of Ophthalmology Health Policy Committee Position Paper on Endothelial Keratoplasty, January 29, 2009.
19. National Institute for Health and Clinical Excellence. Corneal endothelial transplantation. 2009. Available online at: <http://www.nice.org.uk/nicemedia/pdf/IPG304Guidance.pdf>. Last accessed July, 2012.