Protocol

Endothelial Keratoplasty

(90322)

Medical Benefit		**Effective Date**: 04/01/14	**Next Review Date**: 11/20
Preauthorization	No	**Review Dates**: 01/14, 11/14, 11/15, 11/16, 11/17, 11/18, 11/19	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

Populations	Interventions	Comparators	Outcomes
Individuals: • With endothelial disease of the cornea	Interventions of interest are: • Descemet stripping endothelial keratoplasty or Descemet stripping automated endothelial keratoplasty	Comparators of interest are: • Penetrating keratoplasty	Relevant outcomes include: • Change in disease status • Morbid events • Functional outcomes
Individuals: • With endothelial disease of the cornea	Interventions of interest are: • Descemet membrane endothelial keratoplasty or Descemet membrane automated endothelial keratoplasty	Comparators of interest are: • Penetrating keratoplasty	Relevant outcomes include: • Change in disease status • Morbid events • Functional outcomes
Individuals: • With endothelial disease of the cornea	Interventions of interest are: • Femtosecond laser-assisted endothelial keratoplasty or femtosecond/excimer laser-assisted endothelial keratoplasty	Comparators of interest are: • Penetrating keratoplasty	Relevant outcomes include: • Change in disease status • Morbid events • Functional outcomes

DESCRIPTION

Endothelial keratoplasty, 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). Endothelial keratoplasty, and particularly DSEK, DSAEK, DMEK, and DMAEK, are becoming standard procedures. Femtosecond laser-assisted endothelial keratoplasty (FLEK) and femtosecond and excimer laser-assisted endothelial keratoplasty have also been reported as alternatives to prepare the donor endothelium.

SUMMARY OF EVIDENCE

For individuals who have endothelial disease of the cornea who receive DSEK or DSAEK, the evidence includes a number of cohort studies and a systematic review. Relevant outcomes are change in disease status, morbid events, and functional outcomes. The available literature has indicated that these procedures improve visual outcomes and reduce serious complications associated with penetrating keratoplasty (PK). Specifically, visual

recovery occurs much earlier. Because endothelial keratoplasty maintains an intact globe without a sutured donor cornea, astigmatism or 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 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 one 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 femtosecond and excimer laser-assisted endothelial keratoplasty, the evidence includes a multicenter randomized trial that compared FLEK with PK. Relevant outcomes are change in disease status, morbid events, and functional outcomes. Mean best-corrected visual acuity was worse after 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, whereas complications in the PK group were related to sutures and elevated intraocular pressure. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

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

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

Femtosecond laser-assisted endothelial keratoplasty or femtosecond and excimer laser-assisted endothelial keratoplasty are considered **investigational**.

Endothelial keratoplasty is **not medically necessary** when endothelial dysfunction is not the primary cause of decreased corneal clarity.

POLICY GUIDELINES

Endothelial keratoplasty should not be used in place of penetrating keratoplasty 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 has 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. Endothelial keratoplasty should be performed by surgeons adequately trained and experienced in the specific techniques and devices used.

BACKGROUND

CORNEAL DISEASE

The cornea, a clear, dome-shaped membrane that covers the front of the eye, is a key refractive element for vision. Layers of the cornea consist of the epithelium (outermost layer); Bowman layer; the stroma, which comprises approximately 90% of the cornea; Descemet membrane; and the endothelium. The endothelium removes fluid from and limits fluid into the stroma, 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.

Treatment

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 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 the 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, 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 stripping endothelial keratoplasty, which uses hand-dissected donor tissue, and Descemet stripping automated endothelial keratoplasty, which uses an automated microkeratome to assist in donor tissue dissection. These techniques include donor stroma along with the endothelium and Descemet membrane, which results in a thickened stromal layer after transplantation. If the donor tissue comprises 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 a potential improvement over Descemet stripping endothelial keratoplasty and Descemet stripping automated endothelial keratoplasty. A variation of DMEK is Descemet membrane automated endothelial keratoplasty. Descemet membrane automated endothelial keratoplasty contains a stromal rim of tissue at the periphery of the DMEK graft to improve adherence and improve handling of the donor tissue. A laser may also be used for stripping in a procedure called femtosecond laser-assisted endothelial keratoplasty and femtosecond and excimer laser-assisted endothelial keratoplasty.

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 the corneoscleral tissue after removing the anterior donor corneal stroma by hand (e.g., DSEK) or with the assistance of an automated microkeratome (e.g., Descemet stripping automated endothelial keratoplasty) or laser (femtosecond laser-assisted endothelial keratoplasty or femtosecond and excimer laser-assisted endothelial keratoplasty). 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. For minimal 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 the 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 immune-suppressants may be provided topically or orally to reduce the potential for graft rejection. Visual recovery following EK is typically four to eight weeks.

Eye Bank Association of America statistics have shown the number of EK cases in the United States increased from 30,710 in 2015 to 32,221 in 2016.[1] The Eye Bank Association of America estimated that, as of 2016, nearly 40% of corneal transplants performed in the United States were endothelial grafts. As with any new surgical technique, questions have been posed about long-term efficacy and 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.

REGULATORY STATUS

EK is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration. Several microkeratomes have been cleared for marketing by Food and Drug Administration through the 510(k) process.

RELATED PROTOCOLS

Keratoprosthesis

Optical Coherence Tomography of the Anterior Eye Segment

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

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