MEDICAL POLICY

POLICY TITLE	CORNEAL TRANSPLANT, ENDOTHELIAL KERATOPLASTY AND KERATOPROSTHESES
POLICY NUMBER	MP-9.011

Effective Date:	9/1/2023

I. POLICY

Corneal Transplant

Corneal transplantation may be considered **medically necessary** for patients with the following conditions:

- Aphakic corneal edema
- Chemical injuries
- Complications of transplanted organ
- Congenital opacities
- Corneal degenerations
- Ectasias/thinnings
- Keratoconus
- Mechanical complication of corneal graft
- Mechanical trauma, non-surgical
- Microbial /post-microbial keratitis
- Non-infectious ulcerative keratitis or perforation
- Other causes of corneal opacification/distortion
- Primary corneal endotheliopathies
- Pseudophakic corneal edema
- Regraft related to allograft rejection
- Regraft unrelated to allograft rejection
- Stromal corneal dystrophies
- Viral/post-viral keratitis

Corneal transplantation for indications other than those listed in this policy (e.g., astigmatism, correction of refractive errors) is considered **not medically necessary**.

Keratoprostheses

The Boston (Dohlman-Doane) Keratoprosthesis (Boston KPro) may be considered **medically necessary** for the surgical treatment of severe corneal opacification under the following conditions:

- The cornea is severely opaque and vascularized; **AND**
- Best-corrected vision is ≤20/400 in the affected eye and ≤20/40 in the contralateral eye; **AND**
- No end-stage glaucoma or retinal detachment is present; **AND**
- The patient has one of the following indications:

- History of 1 or more corneal transplant graft failures
- Stevens-Johnson syndrome
- Ocular cicatricial pemphigoid
- Autoimmune conditions with rare ocular involvement
- Ocular chemical burns
- An ocular condition unlikely to respond favorably to primary corneal transplant surgery (e.g., limbal stem cell compromise or post herpetic anesthesia).

Note that patients should be expected to be able to be compliant with postoperative care.

Note: Implantation of a keratoprosthesis is considered a high-risk procedure associated with numerous complications and probable need for additional surgery. Therefore, the likelihood of regaining vision and the patient's visual acuity in the contralateral eye should be taken into account when considering the appropriateness of this procedure. Treatment should be restricted to centers experienced in treating this condition and staffed by surgeons adequately trained in techniques addressing implantation of this device.

A permanent keratoprosthesis for all other conditions Is considered **investigational**.

All other types of permanent keratoprostheses are considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures.

Endothelial Keratoplasty

Endothelial keratoplasty (Descemet stripping endothelial keratoplasty [DSEK] or Descemet stripping automated endothelial keratoplasty [DSAEK], Descemet 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 the following conditions:

- ruptures in Descemet membrane
- endothelial dystrophy
- aphakic and pseudophakic bullous keratopathy
- iridocorneal endothelial syndrome
- corneal edema attributed to endothelial failure
- 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**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

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

POLICY TITLE	CORNEAL TRANSPLANT, ENDOTHELIAL KERATOPLASTY AND KERATOPROSTHESES
POLICY NUMBER	MP-9.011

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 who are adequately trained and experienced in the specific techniques and devices used.

Cross-references:

MP 1.044 Corneal Surgery, Implantation of Intrastromal Corneal Ring Segment and Corneal Topography/Photokeratoscopy
MP 2.028 Eye Care
MP 6.031 Gas Permeable Scleral Contact Lens and Therapeutic Soft Contact Lens

II. PRODUCT VARIATIONS

TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

TOP

Corneal Transplant
Corneal transplants are also referred to as keratoplasty. This surgical procedure is usually performed under local anesthesia in an outpatient setting and involves implantation of a cornea from a donor eye. This is the most common organ transplant procedure in the United States. There are two major types of corneal transplants, lamellar keratoplasty and penetrating keratoplasty (PK).

Endothelial Keratoplasty
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.

POLICY TITLE	CORNEAL TRANSPLANT, ENDOTHELIAL KERATOPLASTY AND KERATOPROSTHESES
POLICY NUMBER	MP-9.011

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 1 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. Penetrating keratoplasty 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 the 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.

Endothelial keratoplasty 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 (eg, DSEK) or with the assistance of an automated microkeratome (eg, 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 4 to 8 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 35,555 in 2019. 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. Endothelial keratoplasty-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
Endothelial keratoplasty 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.

Keratoprostheses
A keratoprosthesis, consisting of a central optic held in a cylindrical frame, is an artificial cornea intended to restore vision to patients with severe bilateral corneal disease for whom a corneal transplant is not an option. The keratoprosthesis replaces the cornea that has been removed and is held in place by the surrounding tissue. Various biologic materials are being investigated to improve integration of the prosthetic into the eye.

Cornea
The cornea, a clear, dome-shaped membrane that covers the front of the eye, is a key refractive element of sight. 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.

Treatment
The established surgical treatment for corneal disease is penetrating keratoplasty, which involves making a large central opening through the cornea and then filling the opening with a full-thickness donor cornea. In certain conditions, such as Stevens-Johnson syndrome, ocular cicatricial pemphigoid, chemical injury, or prior failed corneal transplant, survival of transplanted

cornea is poor. The keratoprosthesis was developed to restore vision in patients for whom a corneal transplant is not an option.

Keratoprosthetic devices consist of a central optic held in a cylindrical frame. The keratoprosthesis replaces the section of the cornea that has been removed, and, along with being held in place by the surrounding tissue, may be covered by a membrane to further anchor the prosthesis. A variety of biologic materials are being investigated to improve the integration of prosthetic corneal implants into the stroma and other corneal layers.

The Dohlman-Doane keratoprosthesis, most commonly referred to as the Boston Keratoprosthesis (KPro), is manufactured under the auspices of the Harvard Medical School affiliated Massachusetts Eye and Ear Infirmary. The Boston type 1 Kpro uses a donor cornea between a central stem and a back plate. The Boston type 2 prosthesis is a modification of the type 1 prosthesis and is designed with an anterior extension to allow implantation through surgically closed eyelids. The AlphaCor, previously known as the Chirila keratoprosthesis (Chirila Kpro), consists of a polymethylmethacrylate (PMMA) device with a central optic region fused to a surrounding sponge skirt; the device is inserted in a 2-stage surgical procedure.

Autologous keratoprostheses use a central PMMA optic supported by a skirt of either tibia bone or the root of a tooth with its surrounding alveolar bone. The most common is the osteo-odonto-keratoprosthesis, which uses osteodental lamina derived from an extracted tooth root and attached alveolar bone that has been removed from the patient's jaw. Insertion of the osteo-odonto-keratoprosthesis device requires a complex staged procedure, in which the cornea is first covered with buccal mucosa. The prosthesis itself consists of a PMMA optical cylinder, which replaces the cornea, and is held in place by biologic support made from a canine tooth extracted from the recipient. A hole is drilled through the dental root and alveolar bone, and the PMMA prosthesis is placed within. This entire unit is placed into a subcutaneous ocular pocket and is then retrieved 6 to 12 months later for final insertion.

Hydroxyapatite, with a similar mineral composition to both bone and teeth (phosphate and calcium), may also be used as a bone substitute and as a bioactive prosthesis with the orbit. Collagen coating and scaffolds have also been investigated to improve growth and biocompatibility with the corneal epithelial cells, which form the protective layer of the eye. Many of these materials and devices are currently being tested in vitro or animal models.

Regulatory Status

In 1992, the Boston KPro (Dohlman-Doane keratoprosthesis; Massachusetts Eye and Ear Infirmary) was approved by the U.S. Food and Drug Administration through the premarket approval process for use in patients with severe corneal opacity. The device is used when standard corneal transplant has failed or would be unlikely to succeed. There are 2 types of Boston Kpro. Type 1 is used in eyes when eyelids, blink mechanism, and tear film are intact. Type 2 is used with severe dry eye and in eyes with mucosal keratinization and obliteration of normal conjunctival fornices.

In August 2002, the AlphaCor® (Chirila Keratoprosthesis) was cleared for marketing by the Food and Drug Association through the 510(k) process. The Food and Drug Administration determined that this device was substantially equivalent to the Dolman-Doane keratoprosthesis. The AlphaCor® device is indicated as a keratoprosthesis in adults with corneal opacity when standard penetrating keratoplasty with donor tissue is not suitable, when patients have declined standard penetrating keratoplasty, or when adjunctive procedures to prevent graft rejection are contraindicated.

FDA product code: HQM

IV. RATIONALE

TOP

Endothelial Keratoplasty

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, randomized controlled trial (RCTs), and systematic reviews. 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. 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 Descemet Endothelial Thickness Comparison Trial (DETECT) RCT reported improved visual acuity outcomes with Descemet membrane endothelial keratoplasty compared to ultra-thin Descemet stripping automated endothelial keratoplasty. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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 an improvement in the net health outcome.

For individuals who have endothelial disease of the cornea who receive femtosecond laser-assisted endothelial keratoplasty and femtosecond and excimer laser-assisted endothelial keratoplasty, the evidence includes a multicenter RCT and a systematic review comparing femtosecond laser-assisted endothelial keratoplasty with penetrating keratoplasty, and an RCT comparing femtosecond-prepared Descemet stripping automated endothelial keratoplasty to microkeratome-prepared Descemet membrane automated endothelial keratoplasty. Relevant outcomes are change in disease status, morbid events, and functional outcomes. There were conflicting results in the evidence regarding mean best-corrected visual acuity and endothelial

cell loss after femtosecond laser-assisted endothelial keratoplasty versus penetrating keratoplasty. Mean best-corrected visual acuity was worse after femtosecond laser-assisted endothelial keratoplasty than after penetrating keratoplasty, and endothelial cell loss was higher with femtosecond laser-assisted endothelial keratoplasty. With the exception of dislocation and need for repositioning of the femtosecond laser-assisted endothelial keratoplasty, the percentage of complications was similar between groups. Complications in the femtosecond laser-assisted endothelial keratoplasty group were due to pupillary block, graft failure, epithelial ingrowth, and elevated intraocular pressure, whereas complications in the penetrating keratoplasty group were related to sutures and elevated intraocular pressure. Worsened visual acuity and a 100% graft dislocation rate were reported for femtosecond-prepared Descemet stripping automated endothelial keratoplasty compared to 0% in manually prepared Descemet stripping automated endothelial keratoplasty. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Keratoprostheses

Summary of Evidence
For individuals who have corneal blindness and have failed or are not candidates for corneal transplantation who receive a Boston Keratoprosthesis (Boston KPro), the evidence includes case series and systematic reviews. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Numerous case series have been published. Together, studies have assessed thousands of eyes. A 2015 systematic review of Boston KPro efficacy included 22 series with a total of 2176 eyes. Systematic reviews and case series with longer follow-up (i.e., at least 2 years) have shown improvement in visual outcomes in a substantial percentage of patients with Boston KPro. This procedure is high-risk and associated with numerous complications (e.g., the growth of retro prosthetic membranes) and a probable need for additional surgery, thus careful patient selection is important. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have corneal blindness and have failed or are not candidates for corneal transplantation who receive a keratoprosthesis using the AlphaCor device, the evidence includes case series. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Only a few published case series have evaluated the AlphaCor device. There are insufficient data on improvement in vision outcomes using the AlphaCor device. Moreover, the device has been associated with complications, including thinning, or melting of the anterior corneal surface and corneal necrosis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have corneal blindness and have failed or are not candidates for corneal transplantation who receive an osteo-odonto-keratoprosthesis, the evidence includes case series and a systematic review. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. A 2012 systematic review of case series, all conducted outside of the United States, found high anatomic survival rates at 5 and 20 years, but vision outcomes were not well-described. Osteo-odonto-keratoprosthesis is a complex

surgical procedure and has been associated with a number of complications, including extrusion of the keratoprosthesis, retinal detachment, and vitreoretinal complications. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

TOP

APHAKIA is a condition in which part, or all of the crystalline lens of the eye is absent, due to a congenital defect or because it has been surgically removed, as in the treatment of cataracts.

CORNEA is the transparent anterior portion of the sclera (the fibrous outer layer of the eyeball); it 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.

MYOPIA is an error in refraction in which light rays are focused in front of the retina, enabling the person to see distinctly for only a short distance.

STROMA refers to the supporting tissue or the matrix of an organ.

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

TOP

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when Medically Necessary for Corneal Transplant:

Procedure Codes								
65710	65730	65750	65755					

Medically Necessary Diagnosis for Corneal Transplant:

ICD-10-CM Diagnosis Codes	Description
A18.52	Tuberculous keratitis
A18.59	Other tuberculosis of eye
A54.33	Gonococcal keratitis
B00.52	Herpesviral keratitis
B02.33	Zoster keratitis
B05.81	Measles keratitis and keratoconjunctivitis
B30.0	Keratoconjunctivitis due to adenovirus
B60.13	Keratoconjunctivitis due to Acanthamoeba
H16.011	Central corneal ulcer, right eye
H16.012	Central corneal ulcer, left eye
H16.013	Central corneal ulcer, bilateral
H16.021	Ring corneal ulcer, right eye
H16.022	Ring corneal ulcer, left eye
H16.023	Ring corneal ulcer, bilateral
H16.031	Corneal ulcer with hypopyon, right eye
H16.032	Corneal ulcer with hypopyon, left eye
H16.033	Corneal ulcer with hypopyon, bilateral
H16.041	Marginal corneal ulcer, right eye
H16.042	Marginal corneal ulcer, left eye
H16.043	Marginal corneal ulcer, bilateral
H16.051	Mooren's corneal ulcer, right eye
H16.052	Mooren's corneal ulcer, left eye
H16.053	Mooren's corneal ulcer, bilateral
H16.061	Mycotic corneal ulcer, right eye
H16.062	Mycotic corneal ulcer, left eye
H16.063	Mycotic corneal ulcer, bilateral

POLICY TITLE	CORNEAL TRANSPLANT, ENDOTHELIAL KERATOPLASTY AND KERATOPROSTHESES
POLICY NUMBER	MP-9.011

ICD-10-CM Diagnosis Codes	Description
H16.071	Perforated corneal ulcer, right eye
H16.072	Perforated corneal ulcer, left eye
H16.073	Perforated corneal ulcer, bilateral
H17.11	Central corneal opacity, right eye
H17.12	Central corneal opacity, left eye
H17.13	Central corneal opacity, bilateral
H17.811	Minor opacity of cornea, right eye
H17.812	Minor opacity of cornea, left eye
H17.813	Minor opacity of cornea, bilateral
H17.821	Peripheral opacity of cornea, right eye
H17.822	Peripheral opacity of cornea, left eye
H17.823	Peripheral opacity of cornea, bilateral
H17.89	Other corneal scars and opacities
H18.061	Stromal corneal pigmentations, right eye
H18.062	Stromal corneal pigmentations, left eye
H18.063	Stromal corneal pigmentations, bilateral
H18.211	Corneal edema secondary to contact lens, right eye
H18.212	Corneal edema secondary to contact lens, left eye
H18.213	Corneal edema secondary to contact lens, bilateral
H18.221	Idiopathic corneal edema, right eye
H18.222	Idiopathic corneal edema, left eye
H18.223	Idiopathic corneal edema, bilateral
H18.231	Secondary corneal edema, right eye
H18.232	Secondary corneal edema, left eye
H18.233	Secondary corneal edema, bilateral
H18.43	Other calcerous corneal degeneration
H18.451	Nodular corneal degeneration, right eye
H18.452	Nodular corneal degeneration, left eye
H18.453	Nodular corneal degeneration, bilateral
H18.461	Peripheral corneal degeneration, right eye
H18.462	Peripheral corneal degeneration, left eye
H18.463	Peripheral corneal degeneration, bilateral
H18.49	Other corneal degeneration
H18.501	Unspecified hereditary corneal dystrophies, right eye
H18.502	Unspecified hereditary corneal dystrophies, left eye
H18.503	Unspecified hereditary corneal dystrophies, bilateral

POLICY TITLE	CORNEAL TRANSPLANT, ENDOTHELIAL KERATOPLASTY AND KERATOPROSTHESES
POLICY NUMBER	MP-9.011

ICD-10-CM Diagnosis Codes	Description
H18.509	Unspecified hereditary corneal dystrophies, unspecified
H18.511	Endothelial Corneal Dystrophy, right eye
H18.512	Endothelial Corneal Dystrophy, left eye
H18.513	Endothelial Corneal Dystrophy, bilateral
H18.519	Endothelial Corneal Dystrophy, unspecified eye
H18.521	Epithelial (juvenile) corneal dystrophy, right eye
H18.522	Epithelial (juvenile) corneal dystrophy, left eye
H18.523	Epithelial (juvenile) corneal dystrophy, bilateral
H18.529	Epithelial (juvenile) corneal dystrophy, unspecified eye
H18.531	Granular corneal dystrophy, right eye
H18.532	Granular corneal dystrophy, left eye
H18.533	Granular corneal dystrophy, bilateral
H18.539	Granular corneal dystrophy, unspecified eye
H18.541	Lattice corneal dystrophy, right eye
H18.542	Lattice corneal dystrophy, left eye
H18.543	Lattice corneal dystrophy, bilateral
H18.549	Lattice corneal dystrophy, unspecified eye
H18.551	Macular corneal dystrophy, right eye
H18.552	Macular corneal dystrophy, left eye
H18.553	Macular corneal dystrophy, bilateral
H18.559	Macular corneal dystrophy, unspecified eye
H18.591	Other hereditary corneal dystrophies, right eye
H18.592	Other hereditary corneal dystrophies, left eye
H18.593	Other hereditary corneal dystrophies, bilateral
H18.599	Other hereditary corneal dystrophies, unspecified eye
H18.611	Keratoconus, stable, right eye
H18.612	Keratoconus, stable, left eye
H18.613	Keratoconus, stable, bilateral
H18.621	Keratoconus, unstable, right eye
H18.622	Keratoconus, unstable, left eye
H18.623	Keratoconus, unstable, bilateral
H18.711	Corneal ectasia, right eye
H18.712	Corneal ectasia, left eye
H18.713	Corneal ectasia, bilateral
Q13.3	Congenital corneal opacity
Q13.4	Other congenital corneal malformations

POLICY TITLE	CORNEAL TRANSPLANT, ENDOTHELIAL KERATOPLASTY AND KERATOPROSTHESES
POLICY NUMBER	MP-9.011

ICD-10-CM Diagnosis Codes	Description
T26.11XA	Burn of cornea and conjunctival sac, right eye, initial encounter
T26.11XD	Burn of cornea and conjunctival sac, right eye, subsequent encounter
T26.12XA	Burn of cornea and conjunctival sac, left eye, initial encounter
T26.12XD	Burn of cornea and conjunctival sac, left eye, subsequent encounter
T85.318A	Breakdown (mechanical) of other ocular prosthetic devices, implants and grafts, initial encounter
T85.318D	Breakdown (mechanical) of other ocular prosthetic devices, implants and grafts, subsequent encounter
T85.398A	Other mechanical complication of other ocular prosthetic devices, implants and grafts, initial encounter
T85.398D	Other mechanical complication of other ocular prosthetic devices, implants and grafts, subsequent encounter
T85.79XA	Infection and inflammatory reaction due to other internal prosthetic devices, implants, and grafts, initial
T85.79XD	Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts, subsequent encounter
T86.8401	Corneal Transplant Rejection, Right Eye
T86.8402	Corneal Transplant Rejection, Left Eye
T86.8403	Corneal Transplant Rejection, Bilateral
T86.8409	Corneal Transplant Rejection, Unspecified Eye
T86.8411	Corneal Transplant Failure, Right Eye
T86.8412	Corneal Transplant Failure, Left Eye
T86.8413	Corneal Transplant Failure, Bilateral
T86.8419	Corneal Transplant Failure, Unspecified Eye
T86.8421	Corneal transplant infection, Right Eye
T86.8422	Corneal transplant infection, Left Eye
T86.8423	Corneal transplant infection, Bilateral
T86.8429	Corneal transplant infection, Unspecified Eye
T86.8481	Other Complications of Corneal Transplant, Right Eye
T86.8482	Other Complications of Corneal Transplant, Left Eye
T86.8483	Other Complications of Corneal Transplant, Bilateral
T86.8489	Other Complications of Corneal Transplant, Unspecified Eye
T86.8491	Unspecified Complication of Corneal Transplant, Right Eye
T86.8492	Unspecified Complication of Corneal Transplant, Left Eye
T86.8493	Unspecified Complication of Corneal Transplant, Bilateral
T86.8499	Unspecified Complication of Corneal Transplant, Unspecified Eye
Z94.7	Corneal transplant status

POLICY TITLE	CORNEAL TRANSPLANT, ENDOTHELIAL KERATOPLASTY AND KERATOPROSTHESES
POLICY NUMBER	MP-9.011

Covered when Medically Necessary for Endothelial Keratoplasty:

Procedure Codes								
65756	65757							

Medically Necessary for Diagnosis for Endothelial Keratoplasty:

ICD-10-CM Diagnosis Codes	Description
H18.11	Bullous keratopathy, right eye
H18.12	Bullous keratopathy, left eye
H18.13	Bullous keratopathy, bilateral
H18.331	Rupture in Descemet's membrane, right eye
H18.332	Rupture in Descemet's membrane, left eye
H18.333	Rupture in Descemet's membrane, bilateral
H18.51	Endothelial corneal dystrophy
H18.52	Epithelial (juvenile) corneal dystrophy
H18.53	Granular corneal dystrophy
H18.54	Lattice corneal dystrophy
H18.55	Macular corneal dystrophy
H18.59	Other hereditary corneal dystrophies
H18.891	Other specified disorders of cornea, right eye
H18.892	Other specified disorders of cornea, left eye
H18.893	Other specified disorders of cornea, bilateral
H59.011	Keratopathy (bullous aphakic) following cataract surgery, right eye
H59.012	Keratopathy (bullous aphakic) following cataract surgery, left eye
H59.013	Keratopathy (bullous aphakic) following cataract surgery, bilateral
T85.398A	Other mechanical complication of other ocular prosthetic devices, implants and grafts, initial encounter
T85.398D	Other mechanical complication of other ocular prosthetic devices, implants and grafts, subsequent encounter
T86.840	Corneal transplant rejection
T86.8401	Corneal Transplant Rejection, Right Eye
T86.8402	Corneal Transplant Rejection, Left Eye
T86.8403	Corneal Transplant Rejection, Bilateral
T86.8409	Corneal Transplant Rejection, Unspecified Eye
T86.841	Corneal transplant failure
T86.8411	Corneal Transplant Failure, Right Eye
T86.8412	Corneal Transplant Failure, Left Eye
T86.8413	Corneal Transplant Failure, Bilateral

POLICY TITLE	CORNEAL TRANSPLANT, ENDOTHELIAL KERATOPLASTY AND KERATOPROSTHESES
POLICY NUMBER	MP-9.011

ICD-10-CM Diagnosis Codes	Description
T86.8419	Corneal Transplant Failure, Unspecified Eye
T86.842	Corneal transplant infection
T86.8421	Corneal transplant infection, Right Eye
T86.8422	Corneal transplant infection, Left Eye
T86.8423	Corneal transplant infection, Bilateral
T86.8429	Corneal transplant infection, Unspecified Eye
T86.848	Other complications of corneal transplant
T86.8481	Other Complications of Corneal Transplant, Right Eye
T86.8482	Other Complications of Corneal Transplant, Left Eye
T86.8483	Other Complications of Corneal Transplant, Bilateral
T86.8489	Other Complications of Corneal Transplant, Unspecified Eye
T86.849	Unspecified complication of corneal transplant
T86.8491	Unspecified Complication of Corneal Transplant, Right Eye
T86.8492	Unspecified Complication of Corneal Transplant, Left Eye
T86.8493	Unspecified Complication of Corneal Transplant, Bilateral
T86.8499	Unspecified Complication of Corneal Transplant, Unspecified Eye
Z94.7	Corneal transplant status

Covered when Medically Necessary for Keratoprostheses:

Procedure Codes								
C1818	L8609	65770						

Medically Necessary for Diagnosis for Keratoprostheses:

ICD-10-CM Diagnosis Codes	Description
H16.441	Deep vascularization of cornea, right eye
H16.442	Deep vascularization of cornea, left eye
H16.443	Deep vascularization of cornea, bilateral
H16.449	Deep vascularization of cornea, unspecified eye
H17.10	Central corneal opacity, unspecified eye
H17.11	Central corneal opacity, right eye
H17.12	Central corneal opacity, left eye
H17.13	Central corneal opacity, bilateral
H17.89	Other corneal scars and opacities
L12.1	Cicatricial pemphigoid

POLICY TITLE	CORNEAL TRANSPLANT, ENDOTHELIAL KERATOPLASTY AND KERATOPROSTHESES
POLICY NUMBER	MP-9.011

ICD-10-CM Diagnosis Codes	Description
L51.1	Stevens-Johnson syndrome
T26.10XA	Burn of cornea and conjunctival sac, unspecified eye, initial encounter
T26.10XD	Burn of cornea and conjunctival sac, unspecified eye, subsequent encounter
T26.11XA	Burn of cornea and conjunctival sac, right eye, initial encounter
T26.11XD	Burn of cornea and conjunctival sac, right eye, subsequent encounter
T26.12XA	Burn of cornea and conjunctival sac, left eye, initial encounter
T26.12XD	Burn of cornea and conjunctival sac, left eye, subsequent encounter
T86.8401	Corneal Transplant Rejection, Right Eye
T86.8402	Corneal Transplant Rejection, Left Eye
T86.8403	Corneal Transplant Rejection, Bilateral
T86.8409	Corneal Transplant Rejection, Unspecified Eye
T86.841	Corneal transplant failure
T86.8411	Corneal Transplant Failure, Right Eye
T86.8412	Corneal Transplant Failure, Left Eye
T86.8413	Corneal Transplant Failure, Bilateral
T86.8419	Corneal Transplant Failure, Unspecified Eye
T86.842	Corneal transplant infection
T86.8421	Corneal transplant infection, Right Eye
T86.8422	Corneal transplant infection, Left Eye
T86.8423	Corneal transplant infection, Bilateral
T86.8429	Corneal transplant infection, Unspecified Eye
T86.848	Other complications of corneal transplant
T86.8481	Other Complications of Corneal Transplant, Right Eye
T86.8482	Other Complications of Corneal Transplant, Left Eye
T86.8483	Other Complications of Corneal Transplant, Bilateral
T86.8489	Other Complications of Corneal Transplant, Unspecified Eye
T86.849	Unspecified complication of corneal transplant
T86.8491	Unspecified Complication of Corneal Transplant, Right Eye
T86.8492	Unspecified Complication of Corneal Transplant, Left Eye
T86.8493	Unspecified Complication of Corneal Transplant, Bilateral
T86.8499	Unspecified Complication of Corneal Transplant, Unspecified Eye
Z94.7	Corneal transplant status

IX. REFERENCES

TOP

Endothelial Keratoplasty

1. Eye Bank Association of America. 2019 Eye Banking Statistical Report. 2019
2. Woo JH, Ang M, Htoon HM, et al. Descemet Membrane Endothelial Keratoplasty Versus Descemet Stripping Automated Endothelial Keratoplasty and Penetrating Keratoplasty. Am J Ophthalmol. Nov 2019; 207: 288-303. PMID 31228467
3. 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. Sep 2009; 116(9): 1818-30. PMID 19643492
4. Stuart AJ, Romano V, Virgili G, et al. Descemet's membrane endothelial keratoplasty (DMEK) versus Descemet's stripping automated endothelial keratoplasty (DSAEK) for corneal endothelial failure. Cochrane Database Syst Rev. Jun 25 2018; 6(6): CD012097. PMID 29940078
5. Marques RE, Guerra PS, Sousa DC, et al. DMEK versus DSAEK for Fuchs' endothelial dystrophy: A meta-analysis. Eur J Ophthalmol. Jan 2019; 29(1): 15-22. PMID 29661044
6. Chamberlain W, Lin CC, Austin A, et al. Descemet Endothelial Thickness Comparison Trial: A Randomized Trial Comparing Ultrathin Descemet Stripping Automated Endothelial Keratoplasty with Descemet Membrane Endothelial Keratoplasty. Ophthalmology. Jan 2019; 126(1): 19-26. PMID 29945801
7. Duggan MJ, Rose-Nussbaumer J, Lin CC, et al. Corneal Higher-Order Aberrations in Descemet Membrane Endothelial Keratoplasty versus Ultrathin DSAEK in the Descemet Endothelial Thickness Comparison Trial: A Randomized Clinical Trial. Ophthalmology. Jul 2019; 126(7): 946-957. PMID 30776384
8. Hirabayashi KE, Chamberlain W, Rose-Nussbaumer J, et al. Corneal Light Scatter After Ultrathin Descemet Stripping Automated Endothelial Keratoplasty Versus Descemet Membrane Endothelial Keratoplasty in Descemet Endothelial Thickness Comparison Trial: A Randomized Controlled Trial. Cornea. Jun 2020; 39(6): 691-696. PMID 31939923
9. Dunker SL, Dickman MM, Wisse RPL, et al. Descemet Membrane Endothelial Keratoplasty versus Ultrathin Descemet Stripping Automated Endothelial Keratoplasty: A Multicenter Randomized Controlled Clinical Trial. Ophthalmology. Sep 2020; 127(9): 1152-1159. PMID 32386811
10. Fuest M, Ang M, Htoon HM, et al. Long-term Visual Outcomes Comparing Descemet Stripping Automated Endothelial Keratoplasty and Penetrating Keratoplasty. Am J Ophthalmol. Oct 2017; 182: 62-71. PMID 28739420
11. Heinzelmann S, Böhringer D, Eberwein P, et al. Outcomes of Descemet membrane endothelial keratoplasty, Descemet stripping automated endothelial keratoplasty and penetrating keratoplasty from a single centre study. Graefes Arch Clin Exp Ophthalmol. Mar 2016; 254(3): 515-22. PMID 26743748
12. Wacker K, Baratz KH, Maguire LJ, et al. Descemet Stripping Endothelial Keratoplasty for Fuchs' Endothelial Corneal Dystrophy: Five-Year Results of a Prospective Study. Ophthalmology. Jan 2016; 123(1): 154-60. PMID 26481820
13. Li JY, Terry MA, Goshe J, et al. Three-year visual acuity outcomes after Descemet's stripping automated endothelial keratoplasty. Ophthalmology. Jun 2012; 119(6): 1126-9. PMID 22364863
14. Dapena I, Ham L, Melles GR. Endothelial keratoplasty: DSEK/DSAEK or DMEK--the thinner the better?. Curr Opin Ophthalmol. Jul 2009; 20(4): 299-307. PMID 19417653

15. Rose L, Kelliher C, Jun AS. Endothelial keratoplasty: historical perspectives, current techniques, future directions. Can J Ophthalmol. Aug 2009; 44(4): 401-5. PMID 19606160
16. Deng SX, Lee WB, Hammersmith KM, et al. Descemet Membrane Endothelial Keratoplasty: Safety and Outcomes: A Report by the American Academy of Ophthalmology. Ophthalmology. Feb 2018; 125(2): 295-310. PMID 28923499
17. Singh A, Zarei-Ghanavati M, Avadhanam V, et al. Systematic Review and Meta-Analysis of Clinical Outcomes of Descemet Membrane Endothelial Keratoplasty Versus Descemet Stripping Endothelial Keratoplasty/Descemet Stripping Automated Endothelial Keratoplasty. Cornea. Nov 2017; 36(11): 1437-1443. PMID 28834814
18. Pavlovic I, Shajari M, Herrmann E, et al. Meta-Analysis of Postoperative Outcome Parameters Comparing Descemet Membrane Endothelial Keratoplasty Versus Descemet Stripping Automated Endothelial Keratoplasty. Cornea. Dec 2017; 36(12): 1445-1451. PMID 28957976
19. Li S, Liu L, Wang W, et al. Efficacy and safety of Descemet's membrane endothelial keratoplasty versus Descemet's stripping endothelial keratoplasty: A systematic review and meta-analysis. PLoS One. 2017; 12(12): e0182275. PMID 29252983
20. Wu J, Wu T, Li J, et al. DSAEK or DMEK for failed penetrating keratoplasty: a systematic review and single-arm meta-analysis. Int Ophthalmol. Jul 2021; 41(7): 2315-2328. PMID 34117964
21. Maier AB, Milek J, Joussen AM, et al. Systematic Review and Meta-analysis: Outcomes After Descemet Membrane Endothelial Keratoplasty Versus Ultrathin Descemet Stripping Automated Endothelial Keratoplasty. Am J Ophthalmol. Jan 2023; 245: 222-232. PMID 36220351
22. Oellerich S, Baydoun L, Peraza-Nieves J, et al. Multicenter Study of 6-Month Clinical Outcomes After Descemet Membrane Endothelial Keratoplasty. Cornea. Dec 2017; 36(12): 1467-1476. PMID 28957979
23. Tourtas T, Laaser K, Bachmann BO, et al. Descemet membrane endothelial keratoplasty versus descemet stripping automated endothelial keratoplasty. Am J Ophthalmol. Jun 2012; 153(6): 1082-90.e2. PMID 22397955
24. 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. Feb 2013; 36(1): 13-21. PMID 23108011
25. 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). Oct 2009; 23(10): 1990-8. PMID 19182768
26. Dapena I, Ham L, Droutsas K, et al. Learning Curve in Descemet's Membrane Endothelial Keratoplasty: First Series of 135 Consecutive Cases. Ophthalmology. Nov 2011; 118(11): 2147-54. PMID 21777980
27. 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. Dec 2009; 116(12): 2361-8. PMID 19875170
28. 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. Dec 2011; 118(12): 2368-73. PMID 21872938

29. Anshu A, Price MO, Price FW. Risk of corneal transplant rejection significantly reduced with Descemet's membrane endothelial keratoplasty. Ophthalmology. Mar 2012; 119(3): 536-40. PMID 22218143
30. McCauley MB, Price MO, Fairchild KM, et al. Prospective study of visual outcomes and endothelial survival with Descemet membrane automated endothelial keratoplasty. Cornea. Mar 2011; 30(3): 315-9. PMID 21099412
31. Liu Y, Li X, Li W, et al. Systematic review and meta-analysis of femtosecond laser-enabled keratoplasty versus conventional penetrating keratoplasty. Eur J Ophthalmol. May 2021; 31(3): 976-987. PMID 32223431
32. Ivarsen A, Hjortdal J. Clinical outcome of Descemet's stripping endothelial keratoplasty with femtosecond laser-prepared grafts. Acta Ophthalmol. Aug 2018; 96(5): e655-e656. PMID 29372934
33. Cheng YY, Schouten JS, Tahzib NG, et al. Efficacy and safety of femtosecond laser-assisted corneal endothelial keratoplasty: a randomized multicenter clinical trial. Transplantation. Dec 15 2009; 88(11): 1294-302. PMID 19996929
34. Sorkin N, Mednick Z, Einan-Lifshitz A, et al. Three-Year Outcome Comparison Between Femtosecond Laser-Assisted and Manual Descemet Membrane Endothelial Keratoplasty. Cornea. Jul 2019; 38(7): 812-816. PMID 30973405
35. Singhal D, Maharana PK. RE: "Three-Year Outcome Comparison Between Femtosecond Laser-Assisted and Manual Descemet Membrane Endothelial Keratoplasty". Cornea. Nov 2019; 38(11): e51. PMID 31414998
36. Hosny MH, Marrie A, Karim Sidky M, et al. Results of Femtosecond Laser-Assisted Descemet Stripping Automated Endothelial Keratoplasty. J Ophthalmol. 2017; 2017: 8984367. PMID 28695004
37. 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. Feb 2013; 32(2): 118-24. PMID 23132446
38. Trinh L, Saubaméa B, Auclin F, et al. A new technique of endothelial graft: the femtosecond and excimer lasers-assisted endothelial keratoplasty (FELEK). Acta Ophthalmol. Sep 2013; 91(6): e497-9. PMID 23607667
39. National Institute for Health and Care Excellence (NICE). Corneal endothelial transplantation [IPG304]. 2009
40. Blue Cross Blue Shield Association Medical Policy Reference Manual. 9.03.22, Endothelial Keratoplasty. April 2023

Keratoprosthesis

1. Lee WB, Shtein RM, Kaufman SC, et al. Boston Keratoprosthesis: Outcomes and Complications: A Report by the American Academy of Ophthalmology. Ophthalmology. Jul 2015; 122(7): 1504-11. PMID 25934510
2. Ahmad S, Mathews PM, Lindsley K, et al. Boston Type 1 Keratoprosthesis versus Repeat Donor Keratoplasty for Corneal Graft Failure: A Systematic Review and Meta-analysis. Ophthalmology. Jan 2016; 123(1): 165-77. PMID 26545318
3. Ciolino JB, Belin MW, Todani A, et al. Retention of the Boston keratoprosthesis type 1: multicenter study results. Ophthalmology. Jun 2013; 120(6): 1195-200. PMID 23499061

4. Rudnisky CJ, Belin MW, Guo R, et al. Visual Acuity Outcomes of the Boston Keratoprosthesis Type 1: Multicenter Study Results. Am J Ophthalmol. Feb 2016; 162: 89-98.e1. PMID 26550696
5. Srikumaran D, Munoz B, Aldave AJ, et al. Long-term outcomes of boston type 1 keratoprosthesis implantation: a retrospective multicenter cohort. Ophthalmology. Nov 2014; 121(11): 2159-64. PMID 25017414
6. Rudnisky CJ, Belin MW, Todani A, et al. Risk factors for the development of retroprosthetic membranes with Boston keratoprosthesis type 1: multicenter study results. Ophthalmology. May 2012; 119(5): 951-5. PMID 22361316
7. Dunlap K, Chak G, Aquavella JV, et al. Short-term visual outcomes of Boston type 1 keratoprosthesis implantation. Ophthalmology. Apr 2010; 117(4): 687-92. PMID 20096462
8. Odorcic S, Haas W, Gilmore MS, et al. Fungal Infections After Boston Type 1 Keratoprosthesis Implantation: Literature Review and In Vitro Antifungal Activity of Hypochlorous Acid. Cornea. Dec 2015; 34(12): 1599-605. PMID 26488624
9. Chan CC, LoVerde L, Qiang J, et al. Incidence, Risk Factors, and Surgical Management of Boston Type 1 Keratoprothesis Corneal Melts, Leaks, and Extrusions. Cornea. Aug 2016; 35(8): 1049-56. PMID 27391092
10. Goldman DR, Hubschman JP, Aldave AJ, et al. Postoperative posterior segment complications in eyes treated with the Boston type I keratoprosthesis. Retina. Mar 2013; 33(3): 532-41. PMID 23073339
11. Hicks CR, Crawford GJ, Lou X, et al. Corneal replacement using a synthetic hydrogel cornea, AlphaCor: device, preliminary outcomes and complications. Eye (Lond). Apr 2003; 17(3): 385-92. PMID 12724702
12. Crawford GJ, Hicks CR, Lou X, et al. The Chirila Keratoprosthesis: phase I human clinical trial. Ophthalmology. May 2002; 109(5): 883-9. PMID 11986092
13. Hoffart L, Carles G, Matonti F. Lamellar corneal lenticule graft to treat keratolysis after AlphaCor keratoprosthesis implantation. Eur J Ophthalmol. 2015; 25(1): 1-7. PMID 25198171
14. Tan A, Tan DT, Tan XW, et al. Osteo-odonto keratoprosthesis: systematic review of surgical outcomes and complication rates. Ocul Surf. Jan 2012; 10(1): 15-25. PMID 22330056
15. Falcinelli G, Falsini B, Taloni M, et al. Modified osteo-odonto-keratoprosthesis for treatment of corneal blindness: long-term anatomical and functional outcomes in 181 cases. Arch Ophthalmol. Oct 2005; 123(10): 1319-29. PMID 16219722
16. Michael R, Charoenrook V, de la Paz MF, et al. Long-term functional and anatomical results of osteo- and osteoodonto-keratoprosthesis. Graefes Arch Clin Exp Ophthalmol. Aug 2008; 246(8): 1133-7. PMID 18491123
17. De La Paz MF, De Toledo JÁ, Charoenrook V, et al. Impact of clinical factors on the long-term functional and anatomic outcomes of osteo-odonto-keratoprosthesis and tibial bone keratoprosthesis. Am J Ophthalmol. May 2011; 151(5): 829-839.e1. PMID 21310387
18. Hughes EH, Mokete B, Ainsworth G, et al. Vitreoretinal complications of osteoodontokeratoprosthesis surgery. Retina. Oct 2008; 28(8): 1138-45. PMID 18779721
19. Liu C, Okera S, Tandon R, et al. Visual rehabilitation in end-stage inflammatory ocular surface disease with the osteo-odonto-keratoprosthesis: results from the UK. Br J Ophthalmol. Sep 2008; 92(9): 1211-7. PMID 18511541
20. Farid M, Rhee MK, Akpek EK, et al. Corneal Edema and Opacification Preferred Practice Pattern®. Ophthalmology. Jan 2019; 126(1): P216-P285. PMID 30366795

21. American Academy of Ophthalmology Cornea/External Disease Panel. Preferred Practice Parameter: Corneal Edema and Opacification. San Francisco, CA: American Academy Ophthalmology; 2018
22. Blue Cross Blue Shield Association Medical Policy Reference Manual. 9.03.01 Endothelial Keratoprosthetics. April 2023

X. POLICY HISTORY

TOP

MP 9.011	**CAC 5/25/04**
	CAC 11/30/04
	CAC 6/28/05
	CAC 8/30/05
	CAC 7/25/06
	CAC 6/26/07
	CAC 11/27/07
	CAC 9/29/09 Policy retitled. Endothelial keratoplasty added to policy as medically necessary for treatment of endothelial dysfunction.
	CAC 5/25/10 Policy retitled. Policy criteria for keratoprostheses revised from investigational to medically necessary.
	CAC 4/26/11 Consensus
	CAC 6/26/12 Consensus review; no changes, references updated. **7/9/12** FEP variation revised to refer to the FEP medical policy manual.
	CAC 9/24/13 Consensus review. References updated but no changes to the policy statements. FEP variation revised to refer to FEP Keratoprosthesis medical policy. No coding changes.
	CAC 7/22/14 Minor. BCBSA adopted for endothelial prosthesis and keratoprosthesis. For endothelial keratoplasty DMEK [Descemet's membrane endothelial keratoplasty] and DMAEK [Descemet's membrane automated endothelial keratoplasty] added to the MN policy statement. Added the following as medically necessary; • ruptures in Descemet's membrane • iridocorneal endothelia (ICE) syndrome • corneal edema attributed to endothelial failure Investigational statement added for Femtosecond laser-assisted corneal endothelial keratoplasty (FLEK), femtosecond, and excimer lasers-assisted endothelial keratoplasty (FELEK). No change to policy statements related to keratoprosthesis or corneal transplant. References updated. Rationale section added.
	CAC 7/21/15 Minor revision. For keratoprosthesis**,** conditions that are likely to have poor outcomes with a corneal transplant were added to the medically necessary policy statement. No changes to the policy statements for endothelial keratoplasty or corneal transplant. Reference and rationale update**.** Coding reviewed.
	Admin update 11/23/16: Variation section reformatted.

POLICY TITLE	CORNEAL TRANSPLANT, ENDOTHELIAL KERATOPLASTY AND KERATOPROSTHESES
POLICY NUMBER	MP-9.011

	Admin Update 1/1/17: New diagnosis codes added effective 10/1/16. Removed end dated code 0289T; effective 1/1/17.
	CAC 7/26/16 Minor For keratoprosthesis. In the medically necessary policy statement. “Multiple graft failure” changed to “history of 1 or more” graft failures. Other wording changes did not alter intent of the policy. Background/Description, rationale and references updated. Coding reviewed.
	CAC 7/25/17 Consensus. No change to policy statements References and rationale updated with reorganization of codes by policy section. Added Medicare variation to reference LCD L35094.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	3/22/18 Consensus review. Description/Background, Rationale and Reference sections updated.
	2/15/19 Consensus review. No changes to the policy statements. References reviewed. Rationale revised.
	10/1/19 Admin Update. Diagnosis codes updated for 65770 and C1818.
	02/26/2020 Consensus review. No changes to the policy statements. References reviewed.
	9/2/20 Admin update. ICD 10 codes added, H18.501, H18.502, H18.503, H18.509, H18.511, H18.512, H18.513, H18.519, H18.521, H18.522, H18.523, H18.529, H18.531, H18.532, H18.533, H18.529, H18.541, H18.542, H18.543, H18.549, H18.551, H18.552, H19.553, H18.559, H18.591, H18.592, H18.593, H18.599
	4/23/2021 Consensus review. No change to policy statement. Background, Rationale and References updated.
	12/02/2021 Administrative update. Code 0290T deleted.
	7/21/2022 Consensus review. No changes to policy statement. Formatting changes to statement and guidelines. Updated FEP, rationale, references. Coding reviewed, no changes.
	10/10/2022 Corrected duplicate H18.502 and added code H18.503.
	04/27/2023 Consensus review. No change to policy statement. Rationale and References updated. Removed outdated ICD10 codes H18.51, H18.52, H18.53, H18.54, H18.55, H18.59, T86.840, T86.841, T86.842, T86.848 and T86.849.

Top

Health care benefit programs issued or administered by Capital Blue Cross and/or its subsidiaries, Capital Advantage Insurance Company®, Capital Advantage Assurance Company® and Keystone Health Plan® Central. Independent licensees of the Blue Cross BlueShield Association. Communications issued by Capital Blue Cross in its capacity as administrator of programs and provider relations for all companies.