



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject **Corneal Transplant**

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## Hyperlink to Related Coverage Policies

Computer-Assisted Corneal Topography  
Corneal Pachymetry  
Corneal Remodeling

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2011 CIGNA

## Coverage Policy

**CIGNA covers penetrating keratoplasty (PK) for visual impairment as medically necessary for ANY of the following indications:**

- bullous keratopathy
- chemical burns of the eye
- failure or rejection of a previous corneal transplant
- corneal dystrophy (e.g., Fuch's dystrophy, lattice dystrophy)
- keratoconus
- corneal ulcers
- traumatic corneal injuries
- corneal edema or scarring

**CIGNA covers lamellar keratoplasty/non-penetrating keratoplasty, including deep anterior lamellar keratoplasty (DALK), as medically necessary for ANY of the following indications:**

- corneal ectasia
- corneal edema, scarring, or thinning
- corneal ulcers
- infectious keratitis
- keratoconus

- pellucid marginal degeneration
- stromal dystrophies (e.g., lattice, macular, granular)

**CIGNA covers endothelial keratoplasty (e.g., Descemet's stripping endothelial keratoplasty [DSEK], Descemet's stripping automated endothelial keratoplasty [DSAEK], deep lamellar endothelial keratoplasty [DLEK]) for ANY of the following indications:**

- bullous keratopathy
- failure or rejection of a previous corneal transplant
- Fuch's dystrophy
- corneal edema or scarring

**CIGNA covers a keratoprosthesis as medically necessary for the treatment of corneal blindness when BOTH of the following criteria are met:**

- severe corneal opacity
- failure of at least two (2) corneal transplant procedures

**CIGNA does not cover deep lamellar keratoplasty (DLKP) because it is considered experimental, investigational or unproven.**

## General Background

The cornea, a clear, dome-shaped membrane that covers the front of the eye, is a key refractive element of the eye. Corneal tissue is arranged in a number of layers: the epithelium or outermost layer; the Bowman's layer, a tough layer of basement membrane right under the epithelium; the stroma, which comprises approximately 90% of the cornea; and the endothelium, whose primary task it is to pump excess water out of the stroma. The Descemet membrane, or basement layer, lies between the stroma and endothelial layer of the cornea. For optimal vision, all layers of the cornea must be of normal shape and curvature and free of any cloudy or opaque areas. While many corneal disorders can be managed medically, more than 45,000 corneal transplants are performed annually. Indications for corneal transplant include corneal dystrophies and degenerations (e.g., keratoconus, Fuch's dystrophy, lattice dystrophy), bullous keratopathy, and failure of a prior corneal transplant. Scarring from infection or trauma may also cause corneal changes that may require surgical intervention (American Academy of Ophthalmology [AAO], 2001). While some corneal damage can be treated by performing corrective surgery on the surface of the cornea, more often vision can be restored only with a corneal transplant.

Corneal transplant or keratoplasty is the surgical replacement of a diseased or scarred cornea. Corneal tissue used for transplant surgery is typically donated through a certified eye bank and undergoes extensive testing prior to use for transplantation. Since the cornea normally contains no blood vessels, this type of transplant is associated with a low rejection rate. Generally, blood and tissue typing are not needed in corneal transplants.

### Penetrating Keratoplasty (PK)

PK involves the replacement of the full thickness of the cornea with donor cornea, while retaining the peripheral cornea. Most PKs are performed to improve poor visual acuity caused by an opaque cornea. PK is also used to restore altered corneal structure; to prevent loss of the globe that has been punctured; and to remove active corneal disease, such as persistent severe bacterial, fungal, or amoebic inflammation of the cornea (keratitis) after appropriate antibiotic therapy. PK is highly successful, with over 90% of procedures done in the United States achieving restoration of vision. Complications that can occur include infection, bleeding, suture-induced astigmatism and graft rejection. Rejection reactions are typically treated with steroids. Patients remain at risk for graft rejection throughout life, although the risk of rejection diminishes markedly after three years (AAO, 2000). When full rejection of a graft occurs, repeated surgery is sometimes needed to achieve a successful transplant.

### Lamellar (Non-Penetrating) Keratoplasty

Lamellar or non-penetrating keratoplasty is a corneal transplant procedure in which a partial thickness of the cornea is removed. The diseased tissue is replaced with a partial-thickness donor cornea. Lamellar keratoplasty had largely been replaced by PK. However recent improvements in surgical instruments and the introduction of

new techniques of corneal dissection have resulted in the re-introduction of lamellar keratoplasty as an acceptable alternative to conventional PK (Karimian and Feizi, 2010). Lamellar keratoplasty may be indicated for a number of corneal diseases, including scarring, edema, thinning, distortion, dystrophies, degenerations and keratoconus. Less invasive techniques that do not require suturing are thought to result in a faster recovery and better postoperative vision compared with PK. In cases where the recipient's endothelium is preserved, the risk of graft rejection is decreased. Lamellar keratoplasty is considered investigational and not medically necessary when performed solely to correct astigmatism and other refractive errors.

Deep anterior lamellar keratoplasty (DALK) is used when the pathology is confined to front layers of the cornea. In this procedure, most of the anterior layers of the cornea (i.e., epithelium, Bowman's membrane, stroma) are removed. The most common indication for DALK is likely keratoconus because these patients benefit the most from preserving their own endothelium. Generally, DALK can be considered for all corneal pathologies other than those affecting the endothelium (e.g., aphakic and pseudophakic bullous keratopathy, Fuchs' endothelial dystrophy, iridocorneal endothelial syndrome and posterior polymorphous dystrophy) (Karimian and Feizi, 2010).

**DALK Literature Review:** Studies investigating the safety and effectiveness of DALK have primarily been in the form of case series with patient populations of 21–234, and follow up of 12–50 months (Kubaloglu, et al., 2010; Feizi, et al., 2010; Bahar, et al., 2008b; Ardjomand, et al., 2007; Noble, et al., 2007; Van Dooren, et al., 2004). Earlier studies reported increased levels of higher order aberrations and Descemet membrane perforation after DALK compared to PK. However mean best spectacle-corrected visual acuity (BSCVA) after DALK has been found to be equal to levels attained post-PK in comparative series, with lower levels of long-term endothelial cell loss (Javadi, et al., 2010; Cohen, et al., 2010; Han, et al., 2009; Bahar, et al., 2008b; Ardjomand, et al., 2007; Noble, et al., 2007; Van Dooren, et al., 2004).

In a technology assessment by the AAO, Reinhart et al. (2011) compared the results of DALK and PK procedures in a single randomized controlled trial and 10 comparative trials. Studies included data on 481 eyes that had DALK and 501 eyes that had PK. Patient in a total of seven studies had keratoconus. The most common operative complication was DM perforation (11.7%). There was no significant difference found in the postoperative BSCVA between the DALK and PK groups in six of the comparative studies. Overall, there was no significant difference in spherical refractive error or astigmatism between the two groups. Consistently higher ECD in the DALK group was reported at intervals of 12–60 months in six of 11 studies. The findings of this report were summarized as follows:

- DALK is equivalent to PK for the outcome measure of BSCVA.
- There is no advantage to DALK for refractive error outcomes.
- Postoperative data indicate that DALK is superior to PK for preservation of ECD.
- DALK has important theoretical safety advantages because it is an extraocular procedure.
- DALK is a good option for visual rehabilitation of corneal disease in patients whose endothelium is not compromised.

There is sufficient evidence in the published peer-reviewed medical literature to support the use of DALK as an alternative to PK for the corneal diseases that do not affect the endothelium.

**Endothelial Keratoplasty:** Posterior lamellar keratoplasty techniques have been developed in which the main objective is to replace diseased corneal endothelium while keeping the anterior corneal surface intact, thus reducing refractive error and irregular astigmatism (Price and Price, 2008). Deep lamellar keratoplasty (DLKP) is a surgical method that completely removes pathological corneal stromal tissue down to the Descemet's membrane, followed by transplantation of donor tissue. The technique was modified with redesigned instrumentation, and renamed deep lamellar endothelial keratoplasty (DLEK). Subsequent modification of this procedure led to the development of Descemet's stripping endothelial keratoplasty (DSEK).

DSEK involves the scraping of the Descemet's membrane and endothelium from the recipient cornea instead of the lamellar dissection and excision procedures performed in DLKP and DLEK. DSEK is also less technically challenging than DLEK. A variant of DSEK is Descemet's stripping automated endothelial keratoplasty (DSAEK), in which the preparation of the donor epithelium is done with an automated microkeratome instead of manually. DSEK may be used to treat corneal dysfunction associated with Fuchs' endothelial dystrophy, bullous

keratopathy, iridocorneal endothelial syndrome or a failed penetrating graft. The incidence of graft rejection is reported to be 7.5% compared to 13% for standard PK. (Price and Price, 2007b). The primary complications of endothelial replacement procedures are disc dislocation and endothelial cell loss.

**DLKP Literature Review:** Prospective and retrospective studies have examined the use of DLKP. An RCT (n=26) by Shimazaki et al. (2002) compared outcomes for patients undergoing PK and DLKP. No significant differences were found between the two groups in visual acuity and corneal topography. Other studies include case series and comparative trials (n=22-45) with follow-up period of 12-24 months (Kawashima, et al., 2006; Funnell, et al., 2005; Watson, et al., 2004). It is difficult to draw conclusions about the safety and effectiveness of this procedure based on based on the small numbers of patients in the available studies.

**DLEK Literature Review:** The safety and effectiveness of DLEK have also been evaluated in comparative and non-comparative case series with sample sizes ranging from 23–88, as well as one RCT. Patel et al. (2008) conducted a randomized clinical trial to compare vision, intraocular forward light scatter and corneal backscatter between DLEK and PK for endothelial dysfunction. No differences were detected in high-contrast BSCVA between eyes randomized to DLEK (n=13) or PK (n=15) through 12 months after surgery (Patel, et al., 2008).

In general, study results have indicated that there is comparable improvement in BSCVA, and fewer occurrences of regular and irregular astigmatism (Mashor, et al., 2010; Fillmore, et al., 2010; Yi, et al., 2010; Heidemann, et al., 2008; Terry, 2007; Hyams, et al., 2007; Yepes, et al., 2007; Terry and Ousley, 2006). Reported concerns include the technical difficulty of the procedure and the significant levels of endothelial cell loss at one- and two-year follow-up. The long-term endothelial cell survival compared to PK is unknown. The DLEK technique has largely been supplanted by DSAEK, but may still be indicated in selected cases such as endothelial failure combined with posterior stromal opacification (Dalton, 2011).

**DSEK/DSAEK Literature Review:** A technology assessment on DSEK done by the AAO examined 34 studies including large case series, observational studies and one RCT. DSEK was used to refer to Descemet's stripping keratoplasty regardless of the method of donor tissue preparation and reports on either or both approaches (i.e., DSEK, DSAEK) were included in the analysis. The report summarized that the evidence reviewed was found to be supportive of DSEK being a safe and effective treatment for endothelial diseases of the cornea. DSEK appears similar to penetrating keratoplasty (PK) in terms of surgical risks, complication rates, graft survival (clarity), visual acuity, and endothelial cell loss. It seems to be superior to PK in terms of earlier visual recovery, refractive stability, postoperative refractive outcomes, wound and suture-related complications, and intraoperative and late suprachoroidal hemorrhage risk. The most common complications of DSEK (e.g., posterior graft dislocations, endothelial graft rejection, primary graft failure, and iatrogenic glaucoma) do not appear to be detrimental to the ultimate vision recovery in most cases (Lee, et al., 2009).

A 2009 National Institute for Health and Clinical Excellence (NICE) guidance states that the current evidence on the safety and efficacy of corneal endothelial transplantation (also known as endothelial keratoplasty [EK]) is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance and consent (NICE, 2009).

A number of nonrandomized comparative studies (Hjortdal and Ehlers, 2009; Bahar, et al., 2008a; Allan, et al., 2007; Price and Price, 2006b), large case series (Price and Price, 2008; Terry, et al., 2008; Suh, et al., 2008; Mearza, et al., 2007), and one RCT (Price, et al., 2008) have examined the safety and effectiveness of DSEK and DSAEK. There is sufficient evidence in the published peer-reviewed literature to support the use of DSEK and DSAEK for the treatment of corneal endothelial disorders.

### **Keratoprosthesis**

Keratoprosthesis have been proposed for a small subset of patients with corneal blindness for whom corneal transplants have not been successful. Keratoprosthesis devices are designed to be implanted in patients with severe bilateral corneal conditions, such as Stevens-Johnson syndrome and chemical burns. In general, keratoprosthesis consist of a transparent cylinder-shaped optical portion and a haptical portion. The optical cylinder is inserted into a central circular opening of the opacified cornea, focusing images on a functioning retina. The haptical section is fixed to and buried under neighboring tissue. The different designs of keratoprosthesis vary primarily in the haptical portion of the devices. For example, the osteo-odonto-keratoprosthesis (OOKP) is a method of corneal substitution which uses a prosthesis composed of an acrylic optical cylinder mounted in a section of one of the patient's own teeth. This type of implant is proposed for use in

patients who are at high risk of graft rejection, as autologous tissue is utilized for the procedure. The biocolonisable microporous fluorocarbon haptic keratoprosthesis (BIOKOP) procedure utilizes a synthetic hydrogel core surrounded by a porous skirt that allows biointegration and prevents epithelial downgrowth.

**U.S. Food and Drug Administration (FDA):** While several keratoprosthetic devices and techniques are under investigation, only two devices have been approved by the FDA: the AlphaCor™ (CooperVision Surgical Inc, Lake Forest, CA) and the Dohlman Doane (Massachusetts Eye & Ear Infirmary, Boston, MA). The AlphaCor is a hydrogel keratoprosthesis. According to the FDA, the AlphaCor is intended to be used for “adult patients with corneal opacity that is unsuitable for standard PK with donor tissues, or where donor tissue has been declined or where adjunctive measures required to prevent graft rejection are medically contraindicated” (FDA, 2002). The AlphaCor was granted marketing approval by the FDA via the 510(k) process on August 29, 2002, because it is considered to be substantially equivalent to another device already on the market, the Dohlman Doane Type I keratoprosthesis.

**Literature Review:** Studies evaluating the safety and effectiveness of keratoprostheses have primarily been in the form of case series (n=11–136) with a follow-up range of 10–60 months. Selection criteria for studies have included patients with corneal opacification, chemical eye injuries and repeat corneal transplant failures. Outcomes of visual acuity, integration within the eye, durability and adverse events have been measured. Post operative visual acuity of 20/200 or better has been reported in 70%–80% of eyes. Overall retention rates 83%–85% of patients receiving various types of keratoprosthetic devices including the AlphaCor, Boston (Dohlman Doane) Type 1 and BIOKOP keratoprostheses (Aldave, et al., 2009; Bradley, et al., 2009; Aquavella, et al., 2007; Zerbe, et al., 2006; Aquavella, et al., 2005; Falcinelli, et al., 2005; Alio, et al., 2004; Hicks, et al., 2003).

The National Institute for Clinical Excellence (NICE) guidance on the insertion of hydrogel keratoprosthesis states that the current evidence on the safety and efficacy does not appear adequate to support the use of this procedure. According to NICE, stromal melting was found to be a frequent complication for all keratoprostheses. In addition, the literature seemed to suggest that certain patients such as smokers and those with herpetic eye disease were at increased risk for complications (NICE, 2004).

There is some evidence in the published peer-reviewed medical literature to support the use of keratoprostheses for patients who have had multiple graft failure or who were otherwise determined to be poor candidates for conventional keratoplasty.

### **Professional Societies/Organizations**

The AAO has no current official policy statements concerning corneal transplant procedures.

### **Summary**

Penetrating keratoplasty (PK) is considered a standard surgical intervention for corneal conditions such as keratoconus, bullous keratopathy, Fuchs' endothelial dystrophy, and graft failure. Lamellar keratoplasty has been an established procedure for a number of corneal disorders such as keratoconus. More specifically deep anterior lamellar keratoplasty (DALK) has been proven to be as effective as PK for a subset of patients without endothelial dysfunction.

Evidence in the published peer-reviewed medical literature supports the safety and effectiveness of endothelial keratoplasty procedures such as Descemet's stripping endothelial keratoplasty (DSEK)/Descemet's stripping automated endothelial keratoplasty (DSAEK) and deep lamellar endothelial keratoplasty (DLEK) for the treatment of corneal endothelial disease.

The available evidence in the published peer-reviewed medical literature supporting the use of keratoprostheses is not robust. However, the overall body of literature does suggest that a keratoprosthesis is considered a salvage procedure for those with severe corneal opacities, who have failed previous penetrating keratoplasties.

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## **Coding/Billing Information**

**Note:** This list of codes may not be all-inclusive.

## **Penetrating Keratoplasty (PK)**

Covered when medically necessary:

<b>CPT®*</b> <b>Codes</b>	<b>Description</b>
65730	Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia)
65750	Keratoplasty (corneal transplant); penetrating (in aphakia)
65755	Keratoplasty (corneal transplant); penetrating (in pseudophakia)
<b>ICD-9-CM</b> <b>Diagnosis</b> <b>Codes</b>	<b>Description</b>
264.9	Vitamin A deficiency with xerophthalmic scars of cornea
371.00 – 371.05	Corneal scars and opacities
371.20 – 371.24	Corneal edema
371.50	Hereditary corneal dystrophy unspecified
371.57	Endothelial corneal dystrophy
371.60 – 371.62	Keratoconus
871.0 – 871.9	Open wound of the eyeball
940.2	Alkaline chemical burn of cornea and conjunctival sac
996.51	Mechanical complication due to corneal graft
V42.5	Cornea replaced by transplant

## **Lamellar Keratoplasty/Non-penetrating Keratoplasty/Deep Anterior Lamellar Keratoplasty (DALK)**

Covered when medically necessary:

<b>CPT®*</b> <b>Codes</b>	<b>Description</b>
65710	Keratoplasty (corneal transplant); anterior lamellar
<b>ICD-9-CM</b> <b>Diagnosis</b> <b>Codes</b>	<b>Description</b>
264.9	Vitamin A deficiency with xerophthalmic scars of cornea
370.00 – 370.07	Keratitis
371.00 – 371.05	Corneal scars and opacities
371.20 – 371.24	Corneal edema
371.40	Unspecified corneal degeneration
371.50	Hereditary corneal dystrophy unspecified
371.51	Juvenile epithelial corneal dystrophy
371.52	Other anterior corneal dystrophies
371.53	Granular corneal dystrophy
371.54	Lattice corneal dystrophy
371.55	Macular corneal dystrophy
371.56	Other stromal corneal dystrophies
371.60 – 371.62	Keratoconus

**Endothelial Keratoplasty (e.g., Descemet’s stripping endothelial keratoplasty [DSEK], Descemet’s stripping automated endothelial keratoplasty [DSAEK], deep lamellar endothelial keratoplasty [DLEK])**

**Covered when medically necessary:**

<b>CPT®* Codes</b>	<b>Description</b>
65756	Keratoplasty (corneal transplant); endothelial
65757	Backbench preparation of corneal endothelial allograft prior to transplantation (List separately in addition to code for primary procedure)
<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
264.9	Vitamin A deficiency with xerophthalmic scars of cornea
371.00 – 371.05	Corneal scars and opacities
371.20 – 371.24	Corneal edema
371.50	Hereditary corneal dystrophy unspecified
371.57	Endothelial corneal dystrophy
371.60 – 371.62	Keratoconus
996.51	Mechanical complication due to corneal graft
V42.5	Cornea replaced by transplant

**Keratoprosthesis**

**Covered when medically necessary:**

<b>CPT®* Codes</b>	<b>Description</b>
65770	Keratoprosthesis
<b>HCPCS Codes</b>	<b>Description</b>
C1818	Integrated keratoprosthesis
V2785	Processing, preserving and transporting corneal tissue

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
371.00 – 371.05	Corneal scars and opacities
695.13	Stevens-Johnson syndrome
940.2	Alkaline chemical burn of cornea and conjunctival sac
996.51	Mechanical complication due to corneal graft
V42.5	Cornea replaced by transplant

**Deep Lamellar Keratoplasty (DLKP)**

**Experimental, Investigational or Unproven/Not Covered when used to report deep lamellar keratoplasty:**

<b>CPT* Codes</b>	<b>Description</b>
69999	Unlisted procedure, anterior segment of eye

ICD-9-CM Diagnosis Codes	Description
264.9	Vitamin A deficiency with xerophthalmic scars of cornea
370.00-370.9	Keratitis
371.00-371.9	Corneal opacity and other disorders of cornea
871.0 – 871.9	Open wound of the eyeball
940.2	Alkaline chemical burn of cornea and conjunctival sac
996.51	Mechanical complication due to corneal graft
V42.5	Cornea replaced by transplant

**\*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

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## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	9/15/2008	0390	Corneal Transplant

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