Corneal remodeling, Corneal Keratectomy, Keratoplasties and Keratoprosthesis

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Coverage Policy	Surgical 55
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All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses Corneal remodeling, Corneal Keratectomy, Keratoplasties and Keratoprosthesis.

Description & Definitions:

Anterior Lamellar Keratoplasty (ALK) corneal transplant that replaces a partial-thickness of the cornea without removing the endothelium layer.

Corneal Remodeling is a surgical procedure to correct refractive errors such as Photorefractive Keratectomy (PRK) is a laser treatment to reshape the cornea for refractory errors and vision that cause myopia (nearsightedness), hyperopia (farsightedness) and astigmatism.

Endothelial keratoplasty (EK) also known as Partial corneal transplant is a surgery to replace this layer of the cornea called "endothelium" with healthy tissue. Two types DSEK (or DSAEK) — Descemet's Stripping (Automated) Endothelial Keratoplasty and DMEK — Descemet's Membrane Endothelial Keratoplasty.

Keratoprosthesis procedure is an artificial cornea implant (the clear tissue that covers the eyeball) to correct refractive errors of vision such as near- and farsightedness and difficulty focusing. The physician creates a new anterior chamber with a plastic optical implant that replaces a severely damaged cornea that cannot be repaired. Sometimes the corneal prosthesis is sutured to the sclera; other times, extensive damage to the eye requires the implant be sutured to the closed and incised eyelid**.**

Penetrating keratoplasty (PK) corneal transplant that replaces the full thickness of the cornea.

Phototherapeutic keratectomy (PTK) is a laser treatment to ablate corneal tissue to reshape the corneal surface using a less invasive technique.

Criteria:

Corneal remodeling, Corneal Keratectomy, Keratoplasties and Keratoprosthesis are considered medically necessary for indications of **1 or more of the following:**

- **Phototherapeutic keratectomy** (PTK) for individuals with **1 or more of the following:**
  - Superficial corneal dystrophy (including granular, lattice, and Reis-Buckler's dystrophy)
  - Epithelial membrane dystrophy
  - Irregular corneal surfaces due to Salzmann's nodular degeneration or kertonconus nodules
  - Corneal scars and opacities (including post-traumatic, post-infectious, post-surgical, and secondary to pathology)
  - Recurrent corneal erosions when more conservative measures have failed to halt the erosions (including but not limited to lubricants, hypertonic saline, patching, bandage contact lenses, gentle debridement of the epithelium)

- **Endothelial keratoplasty** for individuals with **ALL of the following:**
  - Endothelial failure with **1 or more of the following:**
    - Descemet's stripping endothelial keratoplasty (DSEK)
    - Descemet's stripping automated endothelial keratoplasty (DSAEK)
    - Descemet's membrane endothelial keratoplasty (DMEK)
    - Descemet's membrane automated endothelial keratoplasty (DMAEK)
  - Diagnoses including **1 or more of the following:**
    - Corneal edema
    - Bullous keratopathy
    - Rupture of Descemet's membrane
    - Endothelial corneal dystrophy and other posterior corneal dystrophies
    - Mechanical complications due to corneal graft or ocular lens prostheses

- **Corneal remodeling** correction of surgically induced astigmatism for individuals with **ALL of the following:**
  - Corneal relaxing incision or corneal wedge resection with **1 or more of the following:**
    - Individual has had previous penetrating keratoplasty within past 60 months
    - Individual has had cataract surgery within the past 36 months
  - Degree of astigmatism must be 3.00 diopters or greater
  - Individual is intolerant of glasses or contact lenses

- **Penetrating keratoplasty** and **anterior lamellar keratoplasty** are considered medically necessary for individuals with indications of **1 or more of the following:**
  - Procedure is to improve poor visual acuity caused by an opaque cornea or keratopathy
  - Procedure is to treat or remove active corneal disease for, including but not limited to:
    - Bullous/dystrophic keratopathy
    - Chemical injuries
    - Corneal degeneration
    - Corneal dystrophies
    - Corneal edema
    - Corneal scar with opacity
    - Corneal transplant rejection
    - Corneal tumors, such as pterygium
    - Ectasias
    - Fuch's dystrophy
    - Herpes simplex keratitis
    - Keratoconus
    - Mechanical trauma
    - Microbial keratitis including fungal and bacterial keratitis

        - Noninfectious ulcerative keratitis
        - Regraft related to allograft rejection
        - Regraft unrelated to allograft rejection
        - Scarring after infectious keratitis
        - Viral keratitis
    - Failure of a previous keratoplasty
    - Intralase-Enabled Keratoplasty (IEK) also known as laser assisted corneal transplant as an additional method of penetrating keratoplasty instead of the traditional trephine (a specialized circular blade) to remove piece of cornea a laser is used.)

- **Keratoprosthesis** (i.e KPro) device is considered medically necessary for **1 or more of the following**:
    - Corneal blindness
    - Severely opaque and vascularized cornea; and
    - Two or more failed corneal transplant procedures.

Lamellar keratoplasty and penetrating keratoplasty is considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- Acute conjunctivitis
- Advanced ocular surface disease
- Anterior staphyloma
- Blepharitis
- Episcleritis
- Meibomian gland disease
- Retinal detachment
- Severe dry eye
- Steven Johnson syndrome
- Toxic epidermal necrolysis

Lamellar keratoplasty (non-penetrating keratoplasty) is considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- For pterygium or
- when performed improvement in visual acuity to solely to correct astigmatism or
- other refractive errors.

Penetrating keratoplasty is considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- when performed solely to correct astigmatism or
- other refractive errors

Keratoprosthesis is considered **not medically necessary** for any use other than those indicated in clinical criteria.

Coding:

Medically necessary with criteria:

Coding	Description

65756	Keratoplasty (corneal transplant); endothelial
65757	Backbench preparation of corneal endothelial allograft prior to transplantation (List separately in addition to code for primary procedure)
65772	Corneal relaxing incision for correction of surgically induced astigmatism
65775	Corneal wedge resection for correction of surgically induced astigmatism
S0810	Photorefractive keratectomy (PRK)
S0812	Phototherapeutic keratectomy (PTK)
65710	Keratoplasty (corneal transplant); anterior lamellar
65730	Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia)
65750	Keratoplasty (corneal transplant); penetrating (in aphakia)
65755	Keratoplasty (corneal transplant); penetrating (in pseudophakia)
66999	Unlisted procedure, anterior segment of eye
58353	Endometrial ablation, thermal, without hysteroscopic guidance
65770	Keratoprosthesis
L8609	Artificial cornea

Considered Not Medically Necessary:

Coding	Description
S0810	Photorefractive keratectomy (PRK)

U.S. Food and Drug Administration (FDA) - approved only products only.

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- 2010: April

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References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

(2023). Retrieved July 11, 2023, from MCG 26th Edition: https://careweb.careguidelines.com/ed26/index.html

Descemet Membrane Endothelial Keratoplasty. (2023, Feb 6). Retrieved July 11, 2023, from American Academy of Ophthalmology (AAO): https://eyewiki.aao.org/Descemet_Membrane_Endothelial_Keratoplasty

Descemet Stripping With Manual Or Automated Endothelial Keratoplasty For Corneal Endothelial Degeneration - ARCHIVED Mar 9, 2012. (n.d.). Retrieved July 11, 2023, from Hayes: https://evidence.hayesinc.com/report/htb.descemets

Keratoconus. (2023, June). Retrieved July 11, 2023, from UpToDate: https://www.uptodate.com/contents/keratoconus?search=Refractive%20Keratoplasty%20&source=search_result&selectedTitle=3~98&usage_type=default&display_rank=3#

Laser refractive surgery. (2023). Retrieved July 11, 2023, from UpToDate 2: https://www.uptodate.com/contents/laser-refractive-surgery?search=Photorefractive%20keratectomy&source=search_result&selectedTitle=1~6&usage_type=default&display_rank=1

National Coverage Determination (NCD) Refractive Keratoplasty (80.7). (1997). Retrieved July 11, 2023, from Centers for Medicare & Medicaid Services NCD: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=72&ncdver=1&keyword=keratectomy&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

Photorefractive Keratectomy. (2023, July 8). Retrieved July 11, 2023, from American Academy of Ophthalmology: https://eyewiki.aao.org/Photorefractive_Keratectomy#Procedure

Procedure Fee Files & CPT Codes. (2023). Retrieved July 11, 2023, from Department of Medical Assistance Services: https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-files-cpt-codes/ & https://www.dmas.virginia.gov/for-providers/cardinal-care-transition/

(2023). Retrieved July 19, 2023, from Hayes: https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522Penetrating%2520keratoplasty%2522,

%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2522s

(2023). Retrieved July 19, 2023, from MCG 26th Edition: https://careweb.careguidelines.com/ed26/index.html

DMAS Manual - Hospital. (2023). Retrieved July 19, 2023, from DMAS DME: https://vamedicaid.dmas.virginia.gov/sites/default/files/2023-07/Hospital%20Manual%20App%20D%20%28updated%2012.8.21%29_Final.pdf

National Coverage Determination (NCD) Refractive Keratoplasty 80.7. (1999). Retrieved July 13, 2023, from Centers for Medicare & Medicaid Services NCD: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=72&ncdver=1&keyword=Refractive%20Keratoplasty&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

Penetrating Keratoplasty. (2023, May 20). Retrieved July 18, 2023, from National Library of Medicine - StatPearls: https://www.ncbi.nlm.nih.gov/books/NBK592388/

Penetrating Keratoplasty. (2023, April 16). Retrieved July 19, 2023, from American Academy of Ophthalmology (AAO): https://eyewiki.aao.org/Penetrating_Keratoplasty

(2023). Retrieved July 18, 2023, from MCG 26th Edition: https://careweb.careguidelines.com/ed26/index.html

AlphaCor™ Artificial Cornea (Addition Technology Inc.) - ARCHIVED Apr 20, 2011. (n.d.). Retrieved July 18, 2023, from Hayes: https://evidence.hayesinc.com/report/htb.alphacor

Artificial Cornea Transplantation. (2023, April 20). Retrieved July 18, 2023, from National Library of Medicine: https://www.ncbi.nlm.nih.gov/books/NBK568692/

Boston Keratoprosthesis. (2021, July 8). Retrieved July 18, 2023, from American Academy of Ophthalmology (AAO): https://www.aao.org/education/ophthalmic-technology-assessment/boston-keratoprosthesis-outcomes-complications-ota

Code of Federal Regulations Title 21 CFR 886.3400 Keratoprosthesis. (2023, June 7). Retrieved July 18, 2023, from FDA: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=886.3400

Cornea transplant. (2023). Retrieved July 18, 2023, from Mayo Clinic: https://www.mayoclinic.org/tests-procedures/cornea-transplant/about/pac-20385285

Intacs For The Treatment Of Keratoconus - ARCHIVED Apr 7, 2023. (n.d.). Retrieved July 18, 2023, from Hayes: https://evidence.hayesinc.com/report/dir.intacs851

National Coverage Determination (NCD) Refractive Keratoplasty 80.7. (1999). Retrieved July 13, 2023, from Centers for Medicare & Medicaid Services NCD: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=72&ncdver=1&keyword=Refractive%20Keratoplasty&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

Procedure Fee Files & CPT Codes. (2023). Retrieved July 18, 2023, from Department of Medical Assistance Services: https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-files-cpt-codes/ & https://www.dmas.virginia.gov/for-providers/cardinal-care-transition/

Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

Keywords:

Phototherapeutic Keratectomy, Endothelial Keratoplasty, Corneal Remodeling, Corneal Surgery, SHP Surgical 55, PTK, Superficial corneal dystrophy, granular, latice, Reis-Buckler's dystrophy, Epithelial membrane dystrophy, Salzmann's nodular degeneration, kertonconus nodules, Corneal scars, corneal opacities, corneal transplant, astigmatism, Descemet's stripping endothelial keratoplasty, DSEK, Descemet's stripping automated endothelial keratoplasty, DSAEK, Descemet's membrane endothelial keratoplasty, DLEK, Descemet's membrane, Bullous keratopathy, Corneal edema, Endothelial corneal dystrophy, corneal graft, ocular lens prostheses, excimer laser–based surgical procedure, corneal wedge resection, Descemet membrane endothelial keratoplasty, DMEK