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| <b>Policy Name</b>                   | Clinical Policy – Keratoplasty and Keratectomy (Corneal Transplantation) |
| <b>Policy Number</b>                 | 1315.00                                                                  |
| <b>Department</b>                    | Clinical Product & Strategy                                              |
| <b>Subcategory</b>                   | Medical Management                                                       |
| <b>Original Approval Date</b>        | 03/21/2018                                                               |
| <b>Current MPC/CCO Approval Date</b> | 01/03/2024                                                               |
| <b>Current Effective Date</b>        | 05/01/2024                                                               |

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| <b>Company Entities Supported (Select All that Apply)</b><br><input checked="" type="checkbox"/> Superior Vision Benefit Management<br><input checked="" type="checkbox"/> Superior Vision Services<br><input checked="" type="checkbox"/> Superior Vision of New Jersey, Inc.<br><input checked="" type="checkbox"/> Block Vision of Texas, Inc. d/b/a Superior Vision of Texas<br><input checked="" type="checkbox"/> Davis Vision<br>(Collectively referred to as 'Versant Health' or 'the Company') |
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| <b>ACRONYMS</b> |                                                           |
|-----------------|-----------------------------------------------------------|
| ALK             | Anterior lamellar keratoplasty                            |
| DALK            | Deep anterior lamellar keratoplasty                       |
| DLEK            | Deep lamellar endothelial keratoplasty                    |
| DMEK            | Descemet's membrane endothelial keratoplasty              |
| DSEK            | Descemet's stripping endothelial keratoplasty             |
| DSO             | Descemet's stripping only                                 |
| ED              | Epithelial debridement                                    |
| EK              | Endothelial keratoplasty                                  |
| FALK            | Femtosecond laser assisted anterior lamellar keratoplasty |
| FLAK            | Femtosecond laser assisted keratoplasty                   |
| PK              | Penetrating keratoplasty                                  |
| PTK             | Excimer laser phototherapeutic keratectomy                |
| SK              | Superficial keratectomy                                   |
| KPro            | Keratoprosthesis                                          |

## PURPOSE

To provide the medical necessity criteria to support the indication(s) for keratoplasty and keratectomy for medical necessity determinations. Applicable procedure codes are also defined.

## POLICY

### A. Background

Variations of corneal transplants include keratoplasty and keratectomies for removing the cornea's surface portion. These procedures are used to treat scarring from infections, corneal dystrophy, corneal degeneration, chemical burns, edema of the cornea, and corneal complications following other intraocular surgery. When corneal transplants fail, additional surgery may be necessary.

The type of corneal procedure performed depends upon the portion of the cornea involved in the disease or injury. Treatments include epithelial debridement (ED), superficial keratectomy (SK), phototherapeutic keratectomy (PTK), anterior lamellar keratoplasty (ALK), deep anterior lamellar keratoplasty (DALK) endothelial keratoplasty (EK), Descemet's stripping automated endothelial keratoplasty (DSEK), Descemet's membrane endothelial keratoplasty (DMEK), penetrating keratoplasty (PK), and keratoprosthesis (e.g., KPro).

### B. Medically Necessary

When a medically necessary keratoplasty is performed, processing, preserving and transporting corneal tissue (V2785) is managed and reported by the facility (i.e., hospital outpatient department or ambulatory surgery center) that provides the donor cornea, not the surgeon.

1. ED may be medically necessary in patients with redundant irregular epithelium, such as epithelial basement membrane dystrophy and eyes with recurrent erosions.
2. SK or PTK may be medically necessary for the treatment of epithelial basement membrane dystrophy, Salzmann's nodular corneal degeneration, band keratopathy, Reis-Bucklers corneal dystrophy, Thiel-Behnke corneal dystrophy, lattice corneal dystrophy, granular corneal dystrophy and rarely Schnyder's corneal dystrophy and macular corneal dystrophy. PTK may be used for removal of superficial corneal scarring and recurrent corneal dystrophies after keratoplasty.
3. SK or PTK may be medically necessary for treating all types of recurrent corneal erosions resulting from trauma or underlying disease.
4. ALK or DALK may be medically necessary for treatment of Reis-Bucklers corneal dystrophy, Thiel-Behnke corneal dystrophy, lattice corneal dystrophy, granular corneal dystrophy, Schnyder's corneal dystrophy, macular corneal dystrophy, keratoconus, and mid to posterior corneal stromal scarring.

5. EK, DSEK, DMEK, may be medically necessary for treatment of diseases of the endothelial layer, such as Fuchs' dystrophy, posterior polymorphous dystrophy, and secondary corneal edema.
6. Descemet stripping only (DSO) may be medically necessary for treatment of Fuchs' dystrophy. <sup>[1]</sup>
7. Full thickness PK may be medically necessary for the same indications as the partial thickness transplants. The use of femtosecond laser to assist PK is an incidental part of the surgery and is not reviewed as a standalone procedure. The indications for the laser-assisted PK are the same as any other PK.
8. Artificial corneal transplants, such as the Boston KPro, are reserved for patients who have had two prior unsuccessful corneal transplants, or where corneal transplantation is not an option such as patients with Stevens-Johnson Syndrome and severe chemical injuries.

### **C. Not Medically Necessary**

Procedures performed to reduce or eliminate the patient's dependence on eyeglasses, e.g., keratoplasty to treat refractive defects

### **D. Documentation**

Keratoplasty and Keratectomy services must be supported by adequate and complete documentation in the beneficiary's medical record that describes the procedure and the medical rationale for it. At a minimum, all the following items are required. If a subsequent medical review audit is necessary, these items are expected to sustain previous payments. For any retrospective review, a full operative report and medical plan of care is needed.

Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, date(s) of service) with an electronic or written signature. Stamped signatures are not accepted.

1. Eye exam with description of medical justification for surgery on the cornea.
2. Allied diagnostic testing with physician's order, medical rationale, findings, interpretation and report.
3. Detailed procedure/operative report that incorporates:
  - a. Indications
  - b. Procedure description
  - c. Post operative report

### **E. Procedural Detail**

CPT instructs corneal transplant includes use of fresh or preserved grafts. The preparation of donor material is included for penetrating or anterior lamellar keratoplasty but reported separately for endothelial keratoplasty.

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<sup>1</sup> Hakim, 2023

| <b>CPT/HCPCS Codes</b> |                                                                                                                                                                                   |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 65400                  | Excision of lesion, cornea (keratectomy, lamellar, partial), except pterygium (PTK) (SK)                                                                                          |
| 65435                  | Removal of corneal epithelium; with or without chemocauterization (abrasion, curettage) (ED)                                                                                      |
| 65436                  | Removal of corneal epithelium; with application of chelating agent (e.g., EDTA)                                                                                                   |
| 65710                  | Keratoplasty (corneal transplant); anterior lamellar                                                                                                                              |
| 65730                  | Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia) (PK)                                                                                           |
| 65750                  | Keratoplasty (corneal transplant); penetrating (in aphakia) (PK)                                                                                                                  |
| 65755                  | Keratoplasty (corneal transplant); penetrating (in pseudophakia) (PK)                                                                                                             |
| 65756                  | Keratoplasty (corneal transplant); endothelial (DLEK, DSEK, EK, PLK, DMEK)                                                                                                        |
| 65757                  | Backbench preparation of corneal endothelial allograft prior to transplantation (List separately in addition to code for primary procedure) (Use 65757 in conjunction with 65756) |
| 65767                  | Backbench preparation of corneal endothelial allograft prior to transplantation (List separately in addition to code for primary procedure)                                       |
| 65770                  | Keratoprosthesis                                                                                                                                                                  |
| 66999                  | Unspecified anterior segment procedure (use for Descemet Stripping Only)                                                                                                          |
| S0812                  | Phototherapeutic keratectomy (PTK)                                                                                                                                                |
| V2785                  | Processing, preserving and transporting corneal tissue                                                                                                                            |

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| <b>DOCUMENT HISTORY</b> |                                                                                                                                            |                       |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| <b>Approval Date</b>    | <b>Revisions</b>                                                                                                                           | <b>Effective Date</b> |
| 03/21/2018              | Initial policy                                                                                                                             | 03/21/2018            |
| 10/18/2019              | Annual review; no criteria changes.                                                                                                        | 11/01/2019            |
| 08/19/2020              | Annual review; no criteria changes.                                                                                                        | 01/01/2021            |
| 01/06/2021              | Annual review; revised with consideration of CMS newly released ICD-10 codes; no criteria changes.                                         | 04/01/2021            |
| 01/05/2022              | Annual review; no criteria changes.                                                                                                        | 04/01/2022            |
| 01/04/2023              | Annual review; removal of CPT code 0290T; delete requirement to submit surgical clearance; added indication of corneal erosion for SK/PTK: | 07/01/2023            |
| 09/20/2023              | Administrative review for CMS 2024 final rule Medicare Part C equity: no changes.                                                          | n/a                   |
| 01/03/2024              | Add DSO procedure for indication of Fuchs' dystrophy; added unlisted procedure code 66999 for DSO.                                         | 05/01/2024            |

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