MEDICAL POLICY DETAILS

<table>
<thead>
<tr>
<th>Medical Policy Title</th>
<th>PHOTOTHERAPEUTIC KERATOPLASTY</th>
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</thead>
<tbody>
<tr>
<td>Policy Number</td>
<td>9.01.01</td>
</tr>
<tr>
<td>Category</td>
<td>Technology Assessment</td>
</tr>
<tr>
<td>Effective Date</td>
<td>03/03/00</td>
</tr>
<tr>
<td>Revised Date</td>
<td>10/18/01, 08/15/02, 06/19/03, 01/15/04, 11/18/04, 09/15/05, 08/17/06, 07/19/07</td>
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<td>07/17/08</td>
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<td>Edited Date</td>
<td>07/16/09, 07/15/10, 06/16/11, 06/21/12, 06/20/13, 06/19/14, 06/18/15, 06/16/16, 06/15/17, 09/20/18, 09/19/19</td>
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Product Disclaimer

- If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.
- If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY STATEMENT

Based on our criteria and assessment of the peer-reviewed literature, phototherapeutic keratectomy/keratoplasty (PTK) is considered medically appropriate in the treatment of the following conditions, when the goals of treatment are to improve vision, induce ocular healing and to avoid more risky or invasive surgery (e.g., penetrating or lamellar keratoplasty):

I. Traumatic recurrent erosions not responding to medical treatment and causing the patient pain, visual loss, or ocular morbidity.

II. Recurrent erosion associated with corneal epithelial or stromal dystrophies not responding to medical treatment, and causing the patient pain, visual loss, or other ocular morbidity including certain non-healing corneal ulcers (e.g., vernal shield ulcers) recalcitrant to medical treatment.

III. Anterior central corneal opacities and scars associated with visual loss (post-trauma, post-infection, other pathologic conditions).

IV. Irregular corneal surfaces associated with visual loss, patient discomfort, or contact lens intolerance when excimer PTK is considered more effective or associated with less morbidity than conventional medical or surgical therapies. Irregular corneal surfaces include, but are not limited to:
   A. Salzmann’s nodular dystrophy;
   B. Spheroid degeneration;
   C. Post-surgical scars;
   D. Keratoconus nodules;
   E. Recalcitrant calcific band keratopathy; or
   F. Other causes of anterior corneal irregularity or scarring.

V. Corneal dystrophies associated with visual loss where the pathology causing the visual loss is mostly or entirely confined to the anterior 1/5 of the cornea. Corneal dystrophies include, but are not limited to:
   A. Anterior Basement Membrane Dystrophy;
   B. Reis Bucklers Dystrophy with visual loss;
   C. Lattice Dystrophy with visual loss; or
   D. Granular Dystrophy with visual loss.

VI. Anisometropia/anisokonia associated with surgically induced myopic shift of refraction (such as can occur after penetrating keratoplasty). Parameters should be 3 diopters of spherical anisometropia and/or 3 diopters of astigmatic
anisometropia. There must be associated patient symptoms due to the anisometropia.

VII. Bullous keratopathy.

Refer to Corporate Medical Policy #9.01.08 regarding Refractive Procedures.

POLICY GUIDELINES

Medical therapies must have failed and patients must have documented morbidity. Note: a peripheral corneal scar may be completely asymptomatic and thus treatment of it is considered not medically necessary.

DESCRIPTION

Phototherapeutic keratoplasty/keratectomy (PTK) involves the use of suture or excimer laser to treat medical conditions of the anterior cornea. PTK functions by sequentially ablating uniformly thin layers of corneal tissue, thereby creating a new, healthy surface. PTK may be performed in an office setting under topical anesthesia.

Phototherapeutic keratoplasty/keratectomy needs to be distinguished from photorefractive keratoplasty, which involves the use of the excimer laser to correct refractive errors.

RATIONALE

The U.S. Food and Drug Administration (FDA) regulates the sale of medical devices such as the lasers used for phototherapeutic keratoplasty. The FDA has approved several laser devices for use in PTK. For those patients suffering from corneal diseases causing visual loss, pain, or other corneal morbidity, phototherapeutic keratoplasty provides an alternative method of treatment from more invasive surgery such as penetrating keratoplasty or corneal transplant that allows improvement in vision and induces ocular healing. The role of excimer laser in post corneal transplant patients has been shown to be beneficial, but the optical techniques have yet to be worked out. The use of the excimer laser in post-surgery patients should be limited to cases when using the laser is less invasive, safer, or more effective than intraocular or incisional surgery.

CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.
- CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>65400</td>
<td>Excision lesion, cornea</td>
</tr>
<tr>
<td>65435</td>
<td>Removal of corneal epithelium; with or without chemocauterization</td>
</tr>
<tr>
<td>65436</td>
<td>Removal of corneal epithelium; with application of chelating agent</td>
</tr>
<tr>
<td>65710</td>
<td>Keratoplasty (corneal transplant); anterior lamellar</td>
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HCPCS Codes

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>S0812</td>
<td>Phototherapeutic Keratectomy (PTK)</td>
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ICD10 Codes

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>A18.59</td>
<td>Other tuberculosis of eye</td>
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Medical Policy: PHOTOTHERAPEUTIC KERATOPLASTY
Policy Number: 9.01.01
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*Key Article

KEY WORDS
Phototherapeutic keratectomy, PTK

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, there is no specific local or national coverage determination for phototherapeutic keratoplasty. Though no formal coverage determination exists, Medicare may provide coverage without a formal coverage determination. The national coverage determination, Refractive Keratoplasty (NCD # 80.7) contains the following statement: “Keratoplasty that treats specific lesions of the cornea, such as phototherapeutic keratectomy that removes scar tissue from the visual field, deals with an abnormality of the eye and is not cosmetic surgery. Such cases may be covered under §1862(a)(1)(A) of the Act.” This NCD is located at: