PHOTOTHERAPEUTIC KERATECTOMY (PTK)
SUR713.023

COVERAGE:

Phototherapeutic Keratectomy (PTK) may be eligible for coverage when used as (1.) an alternative to a lamellar keratoplasty OR as (2.) a subsequent therapy for patients who have failed conservative measures in the treatment of:

- Recurrent corneal erosions;
- Visual impairments or irritative symptoms related to;
  - corneal scars,
  - opacities, or
  - dystrophies beyond the epithelial layer, such as stromal corneal dystrophy; or
- Superficial corneal dystrophy, such as;
  - Juvenile epithelial corneal dystrophy,
  - Anterior corneal dystrophy,
  - Granular corneal dystrophy,
  - Epithelial basement membrane dystrophy, or
  - Lattice corneal dystrophy.
- PTK is not eligible for coverage, as it is considered not medically necessary when used as an alternative to a superficial mechanical keratectomy in treating patients with irregular corneal surfaces due to Salzmann's nodular degeneration (nodular degeneration of cornea) or keratoconus nodules.

PTK is not eligible for coverage as it is considered investigational for the following applications, including but not limited to infectious keratitis. Infectious keratitis may include:

- Tuberculosis of the eye,
- Herpes zoster keratoconjunctivitis,
- Ophthalmologic herpes simplex,
- Measles keratoconjunctivitis,
- Epidemic keratoconjunctivitis,
- Syphilitic interstitial keratitis, and
- Keratitis or keratoconjunctivitis in exanthema.

NOTE: PTK must be distinguished from photoREFRACTIVE keratectomy (PRK). For more details on the PRK procedure and benefits, refer to the separate PRK medical policy, SUR713.001.

NOTE: For those Contracts without refractive benefits, PTK may be allowed to correct refractive errors which are a result of corneal disease and non-surgical measures that have not corrected the refractive errors. Those non-surgical measures may include,
but are not limited to, lubricants, patching, or bandage contact lenses.

DESCRIPTION:

Phototherapeutic Keratectomy (PTK) involves using an excimer laser to treat visual impairment or irritative symptoms relating to disease of the anterior cornea by sequentially ablating uniform thin layers of corneal tissue. PTK must be distinguished from photorefractive keratectomy (PRK), which involves the use of the excimer laser to correct refractive errors of the eye, such as:

- Myopia (nearsightedness),
- Astigmatism (unequal curvature of the eye creating difficulty in focusing),
- Hyperopia (longsightedness), and
- Presbyopia (slowed eye accommodation for distances).

PRK is addressed within a separate policy, SUR713.001.

In March 1995, the FDA approved the excimer laser for PTK as an alternative to corneal transplantation in select indications:

- Superficial corneal dystrophies (including granular, lattice, and Reis-Buckler's dystrophies);
- Epithelial basement membrane dystrophy, irregular corneal surfaces (secondary to Salzmann's degeneration, keratoconus nodules or other irregular surfaces);
- Corneal scars and opacities (such as post-traumatic, post-surgical, post-infectious, and secondary to pathology).

Although, not included in the FDA labeling for PTK, there has been interest in PTK as a treatment of recurrent corneal erosions in patients who have not responded to conservative therapy with patching, cycloplegia, topical antibiotics, and lubricants. Candidates for PTK should have exhausted medical approaches. This procedure involves the use of the same excimer laser, which was approved for PRK.

The excimer laser emits pulses of ultraviolet light, combining two gases using photons of energy, which ablates corneal tissue with extreme precision. Each high-energy pulse of the computer controlled application of the laser energy removes 0.25 microns of tissue. The excimer laser does not cut tissue like a scalpel; rather, the greatest advantage of the excimer laser is its ability to precisely remove or vaporize tissue with little or no effect on surrounding tissue. This laser has been shown to be effective in the treatment of anterior corneal opacities or irregularities, achieving the desired refractive correction. The procedure removes superficial stroma in a way that leaves an optically smooth surface, while at the same time reforming adherent basement membrane complexes. The resulting surface is smoother than what can be obtained with a scalpel or a diamond burr. The procedure is performed under local anesthesia, in an outpatient or clinic setting, and currently takes about 30 to 60 minutes to perform. Pre-treatment work-up may utilize corneal topography to assess the surface structure of the cornea and optical pachymetry to determine the thickness of the entire cornea and depth of the scar. Optical pachymetry may be repeated during the PTK procedure.
Unlike the excimer laser for PRK or LASIK technique for correction of refractive errors, such as myopia where close objects are seen clearly and distant objects appear blurred, PTK treatments will vary with different corneal disorders. The clinical goals of PTK may, likewise, vary depending upon the patient's symptoms and is not considered to be cosmetic surgery.

**NOTE:** PTK must be distinguished from photoREFRACTIVE keratectomy (PRK). For more details on the PRK procedure and benefits, refer to the separate PRK medical policy, SUR713.001.

**RATIONALE:**

There has been no controlled clinical study that has directly compared PTK with other forms of treatment, including:

- Superficial keratectomy (used to treat superficial lesions) or
- Lamellar keratoplasty (used to treat deeper lesions) or
- Anterior stromal puncture (used to treat recurrent corneal erosions).

The FDA approval of the laser was based on data from uncontrolled trials of patients with a variety of corneal pathologies.

Superficial mechanical keratectomy is regarded as a minimally invasive, safe, and effective procedure to remove the superficial layer of the cornea. While PTK offers a more precise and elegant method of epithelial removal, there have been no controlled studies that have demonstrated that this technological superiority results in an improved patient health benefit. The precision of PTK may be most significant when deeper corneal lesions involving Bowman's layer are present. In this situation, PTK presents a minimally invasive alternative to lamellar keratoplasty.

There is inadequate data regarding the effectiveness of PTK in treating infectious keratitis.

**DISCLAIMER:**

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.

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