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Phototherapeutic Keratectomy

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Phototherapeutic keratectomy (PTK) **may be considered medically necessary** for ANY of the following indications:

1. Superficial corneal dystrophy (including granular, lattice and Reis-Bückler's dystrophy); OR
2. Epithelial membrane dystrophy; OR
3. Irregular corneal surfaces due to Salzmann's nodular degeneration or keratoconus nodule; OR
4. Corneal scars and opacities, including post-traumatic, post-infectious, postsurgical and secondary to pathology; OR
5. Recurrent corneal erosions when more conservative measures (e.g., lubricants, hypertonic saline, patching, bandage contact lenses, gentle debridement of severely aberrant epithelium) have failed to halt the erosions.

PTK **is considered experimental, investigational, and/or unproven** for all other indications.

NOTE: Phototherapeutic keratectomy (PTK) should not be confused with photorefractive keratectomy (PRK). Although technically the same procedure, PTK is used for the correction of particular corneal diseases, whereas PRK involves use of the excimer laser for correction of refractive errors (e.g., myopia, hyperopia, astigmatism, and presbyopia) in persons with otherwise non-diseased corneas.

CONTRACT: Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.

Policy Guidelines

None.

Description

Phototherapeutic keratectomy (PTK) involves the use of the excimer laser to treat visual impairment or irritative symptoms relating to diseases of the anterior cornea by sequentially ablating uniformly thin layers of corneal tissue. PTK may be performed in the office setting with the use of local anesthetic eye drops prior to the removal of the corneal epithelium. A laser is then used to uniformly ablate thin layers of corneal tissue. Essentially, PTK functions by removing anterior stromal opacities or eliminating elevated corneal lesions while maintaining a smooth corneal surface. The objective of PTK is to create a smooth stromal surface to improve postoperative corneal clarity, decrease existing scarring and to facilitate epithelial adhesion. (1) Potential complications of PTK include refractive errors, most commonly hyperopia, corneal scarring, glare and halos. PTK must be distinguished from photorefractive keratectomy (PRK), which involves the use of the excimer laser to correct refractive errors of the eye (i.e., myopia, astigmatism, hyperopia, and presbyopia). (2)

When PTK is used to remove only the epithelial surface of the cornea, the alternative technology is mechanical superficial keratectomy (i.e., corneal scraping). When PTK is used to remove deeper layers of the cornea, (i.e., extending into Bowman’s layer), competing technologies include lamellar keratoplasty. In addition, candidates for PTK should have exhausted medical approaches. Recurrent corneal erosions can be treated conservatively with lubricants, patching, bandage contact lenses, or anterior stromal punctures, while keratoconus can be treated with rigid contact lenses to correct the astigmatism.

Regulatory Status

The United States (U.S.) Food and Drug Administration (FDA) approval for the excimer laser identifies the following ophthalmologic therapeutic indications (3):

- 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 (i.e., post-traumatic, post-infectious, and secondary to pathology).

Rationale

This policy was created in 2002 and has been updated regularly with scientific literature reviews, most recently through May 13, 2024. The following is a summary of the key literature.

Although not included in the initial Food and Drug Administration (FDA) labeling, phototherapeutic keratectomy (PTK) is utilized as a treatment option for recurrent corneal erosions in patients who have not responded to conservative therapy with patching, cycloplegia, topical antibiotics, and lubricants.

The 1995 FDA approval is based on data from uncontrolled trials of patients with a variety of corneal pathologies. For example, Summit Technology presented data on 398 eyes, including 103 eyes with dystrophy (25.9%), 64 eyes with recurrent erosion (16.1%), and 231 eyes with scars, opacities, or other irregular surfaces (58%). (3) Outcomes included best-corrected visual acuity and/or decrease in irritative symptoms, such as pain and discomfort. Among cases undergoing PTK to increase comfort, 88.5% were considered successes at one year. Among those with visual impairment, 63.4% were considered successes. The most common adverse effect was corneal scarring and glare, occurring in 13.7% and 12.2% of cases, respectively.

In 1995, Maloney and colleagues (4) conducted a prospective multicenter trial of excimer laser PTK for corneal vision loss. Two hundred thirty-two eyes of 211 patients with corneal vision loss were evaluated with a mean follow-up of 10 ± 8 months. All had corneal pathology in the anterior 100 µm of the stroma. The primary outcome was change in best spectacle-corrected visual acuity. At postoperative month 12, best spectacle-corrected visual acuity improved in 46 (45%) of 103 eyes and worsened in nine (9%) of 103 eyes by 2 or more Snellen lines. Best spectacle-corrected visual acuity improved by a mean of 1.6 ± 2.8 Snellen lines (95% confidence interval, 1.1 to 2.1 lines). Each postoperative visit confirmed statistically significant improvement of mean best spectacle-corrected acuity. At month 12, treated eyes had a mean hyperopic shift in refraction of 0.87 diopter and a mean reduction in astigmatism of 0.36 diopter. Treatment was most effective in eyes with hereditary corneal dystrophies, Salzmann's nodular degeneration, and corneal scars and least effective in eyes with calcific band keratopathy. Complications included recurrence of underlying pathology, corneal graft rejection, and bacterial keratitis. The authors confirmed that argon fluoride excimer laser PTK is

effective, with minimal complications for treating vision loss from corneal opacification or irregularity however, efficacy was dependent on the underlying diagnoses.

In 2006, Baryla et al. (5) assessed the long-term sequelae and time-to-first recurrence of PTK for the treatment of recurrent corneal erosion syndrome (RCES). A retrospective case series was performed. Thirty-nine eyes in 33 patients with RCES required PTK and were treated using the VISX STAR Excimer Laser System. The data were analyzed with the Kaplan-Meier survival estimate. Patients were characterized by the cause of their RCES. More than 50% had epithelial corneal dystrophies, 31% were posttraumatic, and 15% were idiopathic. Overall, 25% of eyes had a recurrence by 3 months, and 36% had a recurrence by 9 months. The mean follow-up time was 17.4 months (range, 0.4-67.6 months). Of those who had a primary recurrence, 38% had a second and 15% had a third. Visual acuity was slightly decreased within 2 weeks after surgery, and 10% of patients developed transient haze. No serious adverse effects were reported. In conclusion, PTK is an important treatment of RCES refractory to other therapies. Long-term data suggest that most patients treated with PTK do not develop recurrences, and side effects from PTK are minimal.

In 2006, Pogorelov et al. (6) studied the long-term results of PTK for corneal dystrophy. Patients with corneal dystrophy suffer typically from recurrent corneal erosion, disturbed vision, or both. The purpose of this study was to assess the morphologic and functional long-term results of subepithelial PTK for corneal map-dot-fingerprint dystrophy. A total of 390 PTKs performed between October 1994 and January 2004 were evaluated including 15 PTKs on 15 eyes of 11 patients in this single-center study. All patients had symptoms of recurrent corneal erosion; in 12 eyes, reduced visual acuity was observed. The median duration of complaints was 18 months. Using 193-nm excimer laser, a manually guided spot profile was applied in 7 cases (pulse energy, 12 mJ; repetition rate, 2/s or 3/s; 189-425 pulses). In 8 cases, a scanning slit mode was chosen (intended ablation, 1 microm/scan; repetition rate, 20/s; 150-483 pulses). In each case, a broad de-epithelialization of the Bowman layer was followed by application of defocused overlapping laser pulses. Complete epithelial closure was achieved after an average of 3.5 +/- 0.6 days (median, 3 days). The mean follow-up was 4.8 +/- 3.0 years, with a maximum of 9.3 years. Best corrected visual acuity increased from 0.7 +/- 0.26 preoperatively to 0.9 +/- 0.16 postoperatively. The keratometric central power remained constant (preoperatively, 43.0 +/- 1.6 D; postoperatively, 42.6 +/- 1.0 D). The average keratometric astigmatism remained constant (1.3 +/- 0.9 D, preoperatively; 1.0 +/- 0.5 D, postoperatively). In the early postoperative stage, subtle superficial corneal opacities ("haze") were observed in 6 eyes (40%), being completely reversible during the follow-up in 5 cases. No recurrence of corneal erosion was observed during the follow-up. Asymptomatic dystrophic signs in the midperiphery became visible in 2 eyes 3 and 5 years after PTK. For corneal map-dot-fingerprint dystrophy, PTK using an excimer laser with low pulse energy and low number of pulses can be considered an effective and minimal invasive treatment modality to achieve a fast and durable epithelial closure, to prevent recurrent corneal erosions, and to increase visual acuity in most patients.

In 2019, Hieda et al. (7) evaluated 714 eyes in 477 consecutive patients (mean age: 66.0 ± 15.2 years; range: 6-101 years) who underwent initial PTK for anterior corneal disease. Each cornea

was treated with PTK, followed up by slit-lamp examination and corrected distance visual acuity (CDVA) testing. The study included 376 granular corneal dystrophy (GCD) eyes, 238 band keratopathy (BK) eyes, 23 epithelium attachment disorder eyes, 16 gelatinous drop-like corneal dystrophy (GDLD) eyes, 13 lattice corneal dystrophy (LCD) eyes, and 48 eyes with other corneal diseases. Main outcome measures comprised of slit-lamp results, CDVA testing, and evaluation of patient complaints. The mean follow-up period was 44.0 ± 38.8 months (range: 1-156 months). The CDVA significantly improved from LogMAR (Logarithm of the Minimum Angle of Resolution) of 0.65 ± 0.61 pre-PTK to a LogMAR of 0.26 ± 0.39 post-PTK. An improvement of 2 or more lines of CDVA was noted in the GCD eyes (67.8%), BK eyes (49.2%), epithelium attachment disorder eyes (57.1%), GDLD eyes (87.5%), LCD eyes (76.9%), and other corneal disease eyes (60.4%). The recurrence of BK was rare and GCD recurred slowly. Epithelium attachment disorder eyes remitted simultaneously and recurred comparatively faster. This study proved that PTK is a successful therapy for use in all 6 corneal disease categories and disease recurrence post-PTK differed among the disease type.

In 2023, Chen et al. (8) noted that PTK is being used to treat severe recurrent corneal erosion syndrome (RCES) in individuals who are unresponsive to other treatment. However, the efficacy and complication of available studies are currently uncertain due to varying rates therefore Chen sought to investigate the safety and efficacy of PTK for recurrent corneal erosions (RCE). A systematic literature review was performed in the Cochrane database, Embase, PubMed, Scopus, and the Web of Science through December 20, 2022. The extracted data including recurrence rate and the adverse event rate were used for meta-analysis. The recurrence rate was 18% (95% CI, 13%–24%) (129/700 eyes). Subgroup analysis showed that the RCE recurrence was 17% (95% CI, 9%–24%) after trauma and 22% (95% CI, 11%–32%) in the corneal dystrophy group. Treatment-related adverse events included subepithelial haze, hyperopic shift, and decrease of the best spectacle-corrected visual acuity. Overall, the incidence of these events was 13% (95% CI, 6%–21%), 20% (95% CI, 11%–28%), and 11% (95% CI, 5%–16%), respectively. PTK represented a valuable treatment option for patients with recurrent corneal erosions, especially those with traumatic injuries.

Pr**ofessional Guidelines and Position Statements**

National Institute for Health and Clinical Excellence (NICE)

In 2010, NICE issued guidance related to the use of laser PTK for corneal surface irregularities. (1) NICE states that symptomatic corneal surface irregularities may result from a range of pathologies including band keratopathy, corneal scarring, nodular degeneration, epithelial basement membrane dystrophy or other dystrophies. Standard treatment includes lubrication of the ocular surface, bandage contact lens placement or topical medication. Surgical procedures may include anterior stromal puncture, mechanical debridement, lamellar keratoplasty or resurfacing keratectomy using a diamond burr. Corneal transplantation may be considered in eyes refractory to treatment.

American Academy of Ophthalmology (AAO)

In 2013, the AAO (2) published a paper on the use and principles of the excimer laser in PTK which states “surface irregularities can severely disrupt the optical performance of the anterior

cornea. Patients may complain of diminished visual acuity and optical aberrations such as monocular diplopia, glare, or halos. Common causes of surface irregularities include:

- Anterior corneal dystrophies, including basement membrane dystrophy, Reis-Bucklers' dystrophy, Schnyder crystalline corneal dystrophy, and anterior granular and lattice stromal dystrophies;
- Elevated corneal scars, including apical scars associated with keratoconus; and
- Degenerations, such as Salzmann nodule formation and band keratopathy. Irregular astigmatism also can occur after refractive surgery.

Many sources of surface irregularity are also associated with corneal opacities. Smoothing the optical surface alone sometimes significantly improves the patient's visual function without the hyperopic shift and potential scarring that can be associated with the deeper ablations often necessary for removal of opacities".

In 2023, the AAO (9) updated their summary benchmarks related to external disease of the cornea. Overall, the therapeutic goal is to determine and manage the cause for the opacity and enhance the individual's quality of life by improving visual acuity and comfort. In most cases treatment starts with medical management. When medical management is insufficient then surgery may be considered and is dependent on the tissue layer(s) involved. The AAO offers the following surgical management guidance:

- Lamellar keratoplasty may be indicated for removal of deeper deposits;
- Penetrating keratoplasty may be indicated for removal of even deeper multilevel opacities;
- Ethylenediaminetetraacetic acid (EDTA) may be used to remove calcific band keratopathy.

Summary of Evidence

Published literature includes case series, small non-randomized and randomized comparative trials, and review articles related to phototherapeutic keratectomy (PTK). The current coverage is supported by the FDA approval that is based on data from uncontrolled trials with a variety of corneal pathologies. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome when the above criteria are met.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	65400, 65435, 65436, 66999
HCPCS Codes	S0812

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
06/15/2024	Document updated with literature review. Coverage unchanged. Added reference 8; others updated.
07/15/2023	Reviewed. No changes.
12/01/2022	Document updated with literature review. Coverage unchanged. Updated reference 8.
05/15/2021	Reviewed. No changes.
04/15/2020	Document updated with literature review. Coverage unchanged. Added references 7, 8.
07/15/2018	Reviewed. No changes.
09/15/2017	Document updated with literature review. Coverage unchanged.
09/15/2016	Reviewed. No changes.
03/01/2015	Policy updated with literature review. The following indications were added to the coverage section as may be considered medically necessary: 1) Superficial corneal dystrophy (including granular, lattice and Reis-Bückler's dystrophy) 2) Corneal scars and opacities, including post-traumatic, postinfectious, postsurgical and secondary to pathology; 3.) Recurrent corneal erosions when more conservative measures (e.g., lubricants, hypertonic saline, patching, bandage contact lenses, gentle debridement of severely aberrant epithelium) have failed to halt the erosions. The following note was added to coverage: PTK should not be confused with PRK. Although technically the same procedure, PTK is used for the correction of particular corneal diseases, whereas PRK involves use of the excimer laser for correction of refractive errors (e.g., myopia, hyperopia, astigmatism, and presbyopia) in persons with otherwise non-diseased corneas. All sections of this policy significantly revised.
09/15/2011	Policy updated with literature review. Coverage unchanged. This policy is no longer scheduled for routine literature review and update.
08/15/2009	Policy reviewed with literature search, no change in coverage. This policy is no longer scheduled for routine literature review and update.
09/01/2005	Revised/Updated Entire Document.
02/01/2002	New medical document