Priority Health

MEDICAL POLICY
No. 91529-R4

REFRACTIVE KERATOPLASTY / LASIK

Effective Date: August 27, 2019	**Review Dates: 7/07, 6/08, 6/09, 6/10, 8/10, 8/11, 8/12, 8/13, 8/14, 8/15, 8/16, 8/17, 8/18, 8/19, 8/20, 8/21, 8/22, 8/23, 8/24**
Date Of Origin: July 2007	**Status: Current**

I. POLICY/CRITERIA

Keratoplasty that treats specific lesions of the cornea such as **phototherapeutic keratectomy (PTK)** that removes scar tissue from the visual field and deals with an abnormality of the eye may be considered medically necessary.

Post-Cataract Post-Transplant Corneal Surgery

Correction of surgically induced astigmatism with a corneal relaxing incision or corneal wedge resection is considered medically necessary if the member had previous penetrating keratoplasty (corneal transplant) within the past 60 months or cataract surgery within the last 36 months and both of the following criteria are met:

1. The degree of astigmatism must be 3.00 diopters or greater; *and*
2. The member must be intolerant of glasses or contact lenses.

Correction of surgically induced astigmatism with a corneal relaxing incision or corneal wedge resection is covered when medical necessity criteria are met, even if the member's plan excludes refractive surgery.

Intrastromal corneal ring segments (INTACS) are considered medically necessary for reduction or elimination of myopia or astigmatism in persons with keratoconus or pellucid marginal degeneration who are no longer able to achieve adequate vision using contact lenses or spectacles and for whom corneal transplant is the only remaining option.

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 the use of the excimer laser for correction of refractive errors (e.g. myopia, hyperopia, astigmatism, and presbyopia) in persons with otherwise non-diseased corneas.

PTK may be medically necessary for members with any of the following:

1. Superficial corneal dystrophy, including granular, lattice and Reis-Buckler's dystrophy

2. Epithelial membrane dystrophy
3. Irregular corneal surfaces due to Salzmann's nodular degeneration or keratoconus nodules
4. Corneal scars and opacities including post-traumatic, post infectious, post-surgical and secondary to pathology
5. Recurrent corneal erosions when more conservative measures such as lubricants, hypertonic saline, patching, bandage contact lenses, gentle debridement of severely aberrant epithelium have failed to halt the erosions

PTK for treatment of infectious keratitis is not medically necessary and, because it has not been shown to be safe and effective for this indication, is considered experimental and investigational.

Performance of PTK in combination with collagen cross-linkage is not medically necessary and considered experimental and investigational.

Refractive surgeries, including the following procedures are considered not medically necessary:

1. Photorefractive Keratectomy (PRK)
2. Laser in situ Keratomileusis (LASIK)
3. Laser Epithelial Keratomileusis (LASEK)
4. Radical Keratomy (RK)
5. Laser Thermokeratoplasty (LTK)
6. Phakic Intraocular Lens (IOL) Implantation
7. Clear Lens Extraction (CLE),
8. Phakic Intraocular Lens Implantation,
9. Intracorneal Inlays
10. Automated Lamellar Keratoplasty (ALK)
11. Hexagonal keratotomy
12. Conductive keratoplasty (CK)
13. Minimally invasive radial keratotomy (mini-RK)

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. DESCRIPTION

Background:

The basic parts of the human eye include the cornea, pupil, lens, retina, and the optic nerve. The cornea and lens work together to focus and bend, (refract) light entering the eye to form a single focal point of an image on the retina that is then sent via the optic nerve to the brain. The overall shape of the eye and imperfections of the cornea or lens can result in refractive error. With a refractive error, instead of the focal point focusing directly on the retina, the image focal point lands in front, behind, or on multiple points of the retina resulting in a blurred image.[5]

A refractive error (ametropia) is a disorder that occurs when parallel rays of light entering the non-accommodating eye are not focused on the retina. There are different types of refractive errors: Myopia (nearsightedness), hyperopia (farsightedness), astigmatism (distortion due to two different focal points), and presbyopia (aging lens is unable to focus up close).

According to the American Academy of Ophthalmology (Preferred Practice Pattern Report on Refractive Errors), three quarters of Americans over the age of 40 have refractive errors greater than 0.5 diopters (D). It has been estimated that 150 million Americans currently use some form of eyewear to correct refractive errors, and of this number, 36 million use contact lenses. In 2000, nearly 1.3 million laser in situ keratomileusis (LASIK) procedures were performed in the United States. In a 2003 survey of U.S. ophthalmology surgeons, LASIK was the most commonly performed refractive surgery. Photorefractive keratectomy (PRK) and laser subepithelial keratomileusis (LASEK) are the most common alternatives to LASIK.[5]

The term refractive surgery describes various procedures that modify the refractive error of the eye. Most of these procedures involve altering the cornea and are collectively referred to as keratorefractive surgery, refractive keratoplasty, or refractive corneal surgery. Refractive surgery may be considered when a patient wishes to be less dependent on spectacles or contact lenses, or when there are occupational or cosmetic reasons not to wear spectacles. Refractive surgery is an elective procedure.

The most commonly performed procedures utilize the excimer laser, which was first approved for this purpose by the United States Food and Drug Administration (FDA) in 1995. Photorefractive keratectomy (PRK) was the first procedure performed; subsequently, laser in situ keratomileusis (LASIK) has become the most commonly performed keratorefractive surgery. Other keratorefractive procedures include laser epithelial keratomileusis (LASEK), insertion of intrastromal corneal ring segments (ICRS; trade name INTACS), minimally invasive radial keratotomy (mini-RK), hexagonal keratotomy, conductive keratoplasty (CK), clear lens extraction (CLE), and radial keratotomy (RK).

V. CODING INFORMATION

ICD-10 Codes that <u>may</u> support medical necessity of the following codes:

H17.9	Unspecified corneal scar and opacity
H17.89	Other corneal scars and opacities
H17.811 - H17.819	Minor opacity of cornea
H17.821 - H17.829	Peripheral opacity of cornea
H17.00 – H17.03	Adherent leukoma
H17.10 - H17.13	Central corneal opacity
H18.899	Other specified disorders of cornea, unspecified eye
A18.59	Other tuberculosis of eye
H18.40	Unspecified corneal degeneration
H18.831 - H18.839	Recurrent erosion of cornea
H18.421 - H18.429	Band keratopathy
H18.43	Other calcerous corneal degeneration
H18.441 - H18.449	Keratomalacia

H18.451 - H18.459	Nodular corneal degeneration
H18.461 - H18.469	Peripheral corneal degeneration
H18.49	Other corneal degeneration
H18.50x – H18.59x	Hereditary corneal dystrophies
Z94.7	Corneal transplant status

ICD-10 Codes that do not support medical necessity of the following procedures**:**
The following procedures are NOT covered when billed with these dx:

H52.00 - H52.03	Hypermetropia
H52.10 - H52.13	Myopia
H52.201 - H52.209	Astigmatism, Unspecified
H52.211 - H52.219	Irregular Astigmatism
H52.221- H52.229	Regular astigmatism
H52.31	Anisometropia
H52.32	Aniseikonia
H52.4	Presbyopia
H52.6	Other disorders of refraction
H52.7	Unspecified disorder of refraction
Z01.00 - Z01.01	Encounter for examination of eyes and vision

CPT/HCPCS Codes:

0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed) (*Not covered for Priority Health Medicaid)*
65770	Keratoprosthesis
65772	Corneal relaxing incision for correction of surgically induced astigmatism
65775	Corneal wedge resection for correction of surgically induced astigmatism
S0812	Phototherapeutic keratectomy (PTK) *(not billable for Priority Health Medicare, not covered for Priority Health Medicaid)*
66999	Unlisted procedure, anterior segment of eye *(Explanatory notes must accompany claim)*

ICD-10 Codes that apply:

H18.601 – H18.609	Keratoconus, unspecified
H18.611 – H18.619	Keratoconus, stable
H18.621 - H18.629	Keratoconus, unstable
H18.40	Unspecified corneal degeneration
Q13.4	Other congenital corneal malformations

CPT/HCPCS Codes - *This procedure covered only for the diagnoses above when criteria is met.*

65785	Implantation of intrastromal corneal ring segments

CPT/HCPCS Codes – *Not Covered:*

65760	Keratomileusis
65765	Keratophakia
65767	Epikeratoplasty
65771	Radial keratotomy
S0800	Laser in situ keratomileusis (LASIK)
S0810	Photorefractive keratectomy (PRK)

VI. REFERENCES

1. American Academy of Ophthalmology. Refractive Errors. Preferred Practice Pattern. San Francisco, CA: AAO; 2002.
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4. The Cochrane Database of Systematic Reviews, Shortt, A. J. and B. D. S., Allan, Photorefractive keratectomy (PRK) versus laser-assisted in-situ keratomileusis (LASIK) for myopia, Issue 2, 2006.
5. Hayes Inc., Medical Technology Directory. Laser In Situ Keratomileusis, Lansdale, PA: September 9, 2002.
6. Gilchrist, B., Drug Treatment of the Complications of Refractive Surgery: LASIK, LASEK, and PRK, World of Drug Information, Vol 16, Issue 2, June 2005.
7. St. Anthony's Complete Guide to Medicare Coverage Issues. National coverage decision (NCD 80.7) 2-43: Refractive keratoplasty. May 1, 1997. Reston, VA: Ingenix, Inc, May 2006