

REFRACTIVE KERATOPLASTY / LASIK

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Summary of Changes

Additions:

Added Section II. GOVERNMENTAL REGULATIONS.

• Enhanced Description section.

Clarifications:

 Restructured Section I. POLICY/CRITERIA to include specific inclusions and limitations/exclusions sections.

I. POLICY/CRITERIA

A. INCLUSIONS:

1. <u>Refractive Keratoplasty</u>: Refractive keratoplasty, including **phototherapeutic keratectomy (PTK),** may only be considered medically necessary when it is being used to treat specific lesions of the cornea, remove scar tissue from the visual field, or otherwise address an abnormality of the eye.

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

- a. Superficial corneal dystrophy, including granular, lattice and Reis-Buckler's dystrophy
- b. Epithelial membrane dystrophy
- c. Irregular corneal surfaces due to Salzmann's nodular degeneration or keratoconus nodules
- d. Corneal scars and opacities including post-traumatic, post infectious, post-surgical and secondary to pathology
- e. 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
- 2. <u>Post-Cataract or Post-Transplant Corneal Surgery:</u> Correction of surgically induced astigmatism with a corneal relaxing incision or corneal wedge resection is considered medically necessary when all of the following apply:

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- a. One of the following:
 - member had previous penetrating keratoplasty (corneal transplant) within the past 60 months, OR,
 - Member had cataract surgery within the last 36 months,
- b. Both of the following:
 - The degree of astigmatism is 3.00 diopters or greater, AND,
 - 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.

3. <u>Intrastromal corneal ring segments (INTACS):</u> These 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.

B. LIMITATIONS AND EXCLUSIONS

- 1. <u>Cosmetic refractive surgical procedures</u>: Refractive surgical procedures performed solely to correct myopia (nearsightedness), hyperopia (farsightedness), astigmatism (imperfection in the curvature of the cornea), or presbyopia (gradual loss of ability to focus on nearby objects, acquired with age) are considered not medically necessary.
- 2. **PTK for treatment of infectious keratitis**: PTK has not been shown to be safe and effective for this indication and is therefore considered experimental and investigational and not medically necessary.
- 3. <u>PTK in combination with collagen cross-linkage</u> is not medically necessary and considered experimental and investigational.
- 4. <u>The following refractive surgical procedures</u> are considered not medically necessary:
 - a. Photorefractive Keratectomy (PRK)
 - b. Laser in situ Keratomileusis (LASIK)
 - c. Laser Epithelial Keratomileusis (LASEK)
 - d. Radial Keratotomy (RK)
 - e. Laser Thermokeratoplasty (LTK)
 - f. Phakic Intraocular Lens (IOL) Implantation
 - g. Clear Lens Extraction (CLE)
 - h. Phakic Intraocular Lens Implantation
 - i. Intracorneal Inlays
 - j. Automated Lamellar Keratoplasty (ALK)
 - k. Hexagonal keratotomy

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- 1. Conductive keratoplasty (CK)
- m. Minimally invasive radial keratotomy (mini-RK)

II. GOVERNMENTAL REGULATIONS

Centers for Medicare & Medicaid Services (CMS)

National Coverage Determinations (NCDs)		
Refractive Keratoplasty <u>80.7</u>		
Local Coverage Determinations (LCDs)		
CGS Administrators, LLC	None identified	
First Coast Service Options, Inc.	None identified	
National Government Services, Inc	None identified	
Noridian Healthcare Solutions	None identified	
Novitas Solutions, Inc.	None identified	
Palmetto GBA	None identified	
WPS Insurance Corporation	None identified	

III. 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.

IV. 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.

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* 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.

V. 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.

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. Phototherapeutic keratectomy (PTK) should not be

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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. 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. In these cases, refractive surgery is considered 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).

Refractive Surgeries

Photorefractive Keratectomy (PRK)

Definition: A type of surface ablation laser eye surgery where the corneal epithelium is removed and an excimer laser reshapes the underlying corneal stroma.

Key Points: No corneal flap is created. Longer recovery time than LASIK. Suitable for patients with thinner corneas.

Laser in situ Keratomileusis (LASIK)

Definition: A laser-assisted procedure where a corneal flap is created, the underlying stroma is reshaped with an excimer laser, and the flap is repositioned. Key Points: Faster visual recovery than PRK. Risk of flap-related complications.

Laser Epithelial Keratomileusis (LASEK)

Definition: A hybrid of PRK and LASIK where the epithelium is loosened with alcohol, moved aside, and replaced after laser ablation.

Key Points: Preserves more corneal tissue than LASIK. Less painful than PRK but slower recovery than LASIK.

Radial Keratotomy (RK)

Definition: A non-laser procedure involving radial incisions in the cornea to flatten it and correct myopia.

Key Points: Largely obsolete. Can lead to long-term instability and fluctuating vision.

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Laser Thermokeratoplasty (LTK)

Definition: Uses a holmium laser to apply heat to the peripheral cornea, causing collagen shrinkage and central corneal steepening.

Key Points: Temporary correction, mainly for hyperopia. Results often regress over time.

Phakic Intraocular Lens (IOL) Implantation

Definition: Involves implanting a synthetic lens inside the eye without removing the natural lens.

Key Points: Suitable for high refractive errors. Preserves accommodation. Requires a healthy anterior chamber.

Clear Lens Extraction (CLE) / Phakic Intraocular Lens Implantation

Definition: Removal of the eye's natural lens (even if clear) and replacement with an IOL, similar to cataract surgery.

Key Points: Used for very high refractive errors or presbyopia. Eliminates accommodation.

Intracorneal Inlays

Definition: Small devices implanted into the corneal stroma to improve near vision, typically for presbyopia.

Key Points: Preserves distance vision. Can be removed if needed.

Automated Lamellar Keratoplasty (ALK)

Definition: A mechanical microkeratome creates a corneal flap and removes a disc of stromal tissue to reshape the cornea.

Key Points: Precursor to LASIK. Less precise than laser-based methods.

Hexagonal Keratotomy

Definition: A variation of RK involving hexagonal incisions to flatten the central cornea.

Key Points: Rarely used today. Associated with unpredictable outcomes.

Conductive Keratoplasty (CK)

Definition: Uses radiofrequency energy to shrink peripheral corneal collagen, steepening the central cornea.

Key Points: Temporary correction for hyperopia or presbyopia. Non-laser, non-invasive.

Minimally Invasive Radial Keratotomy (mini-RK)

Definition: A modified RK technique using fewer and shallower incisions. Key Points: Aimed at reducing complications of traditional RK. Still largely outdated.



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VI. **CODING INFORMATION**

ICD-10 Codes that may suppo	rt medical necessity	of the following codes:
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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:*

The following procedures are \underline{NOI} covered when blued with these ax:	
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) (<i>Not covered for Priority Health Medicaid</i>)
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



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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)

VII. REFERENCES

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