Clinical Policy: Refractive Surgery

Reference Number: HNCA.CP.MP.391
Effective Date: 11/07 Coding Implications
Last Review Date: 02/25 Revision Log
See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Note that this policy addresses medical necessary indications for refractive surgery. Coverage for procedures to solely eliminate the need for glasses or contact lenses is subject to plan coverage documents. Please refer to benefits coverage documents for specific coverage of these procedures.

Refractive surgery is a method for correcting or improving vision. Various refractive procedures include laser-assisted in situ keratomileusis (LASIK), epithelial laser-assisted in situ keratomileusis (Epi-LASIK), laser epithelial keratomileusis (LASEK), photorefractive keratectomy (PRK), epikeratoplasty, photoastigmatic keratectomy (PARK or PRK-A) and phototherapeutic keratectomy (PTK).

Policy/Criteria
I. It is the policy of Health Net of California that refractive surgery, specifically LASIK, Epi-LASIK, LASEK, PARK/PRK-A and PRK is medically necessary when the following indications are met:
A. Prior cataract, corneal or scleral buckling surgery for retinal detachment have been performed on the eye and all of the following are noted:
1. The medical record documents symptoms due to aniseikonia or anisometropia between the two eyes.
2. The medical record documents inadequate functional vision with contact lens and eyeglasses
3. The post-operative refractive error has changed by $\geq$ 3 diopters (D) between the eyes when compared to the preoperative refractive error

B. Following a corneal transplant for trauma, infection, keratoconus or a complication of surgery resulting in blurred or distorted images when all of the following are met:
1. The patient is left with significant astigmatism of $\geq$ 3 diopters (D)
2. Patient cannot function with glasses and contact lenses are intolerable
3. Testing has concluded that the patient will function better

II. It is the policy of Health Net of California that refractive surgery with PTK is medically necessary when any of the following is met:
A. Scarring and opacity of the cornea including post-traumatic, postinfectious, postsurgical and secondary to pathology
B. Irregular corneal surface due to salzmann's nodular degeneration
C. Epithelial membrane dystrophy or superficial corneal dystrophy
D. Recurrent corneal erosions when conservation measures and other surgical treatments have been shown to be unsuccessful

III. It is the policy of Health Net of California that correction of surgically induced astigmatism from previous surgery (such as cataract surgery, medically necessary refractive surgery, scleral buckling for retinal detachment, or corneal transplant) with a corneal relaxing incision or a corneal wedge resection is medically necessary when any of the following are met:

A. Patient has had previous penetrating keratoplasty or corneal transplant or cataract surgery
B. The degree of astigmatism is $\geq$ 3 diopters
C. The patient is intolerant of glasses and contact lenses or they do produce adequate functional vision.

IV. Epikeratoplasty
It is the policy of Health Net of California that epikeratoplasty is considered as medically necessary for the following indications:

A. congenital aphakia or acquired aphakia
B. following cataract surgery in patients unable to receive intraocular lens
C. for the treatment of scarred corneas and corneas affected with endothelial dystrophy

V. It is the policy of Health Net of California that current evidence does not support the use of refractive surgery for indications other than those listed above.

Background
Refractive errors are common disorders of the eye whereby objects, either distant, close or both, appear blurred. The main types of refractive errors are myopia (nearsightedness), hyperopia (farsightedness), presbyopia (loss of near vision with age), and astigmatism. Refractive surgery is a method of modifying the refractive status of the eye, and it includes various procedures such as keratorefractive surgery related to the cornea, refractive keratoplasty, or corneal refractive surgery. The most frequently performed procedures for low to moderate myopia utilize the excimer laser, which was first approved for this purpose by the FDA in 1995. A surface ablation technique, photorefractive keratectomy (PRK), was the first procedure performed; subsequently, LASIK has become the most commonly performed keratorefractive surgery. Other kerato-refractive procedures to correct low to moderate myopia include variations of PRK such as laser epithelial keratomileusis (LASEK) and epi-LASIK.

Radial keratotomy (RK) is a surgical procedure for nearsightedness. Using a high-powered microscope, precise micro-incisions (usually 8 or fewer) are placed on the peripheral surface of the cornea in a spoke like pattern. The micro-incisions allow the central cornea to flatten, thus reducing the convexity of the cornea, which produces an improvement in vision. Variants are known as mini RK, hexagonal RK and astigmatic RK.

Photo Refractive Keratectomy (PRK) was the initial procedure used to reshape the cornea for the correction of myopia, hyperopia, and astigmatism. An excimer laser is used to ablate or remove micro thin outer layer of the cornea, changing its refractive power. Phototherapeutic keratectomy (PTK) is an additional type of laser eye surgery to treat various ocular disorders by removal of superficial corneal opacities and surface irregularities.

Laser Assisted In Situ Keratomileusis (LASIK) is similar to PRK, in which the excimer laser and microkeratome are combined for vision correction. The microkeratome is used to shave a thin slice and create a hinged flap in the cornea. The flap is pushed back and the exposed cornea is reshaped by the laser. The flap is replaced, without sutures, to heal back into position. Epi-LASIK is a newer procedure in which an epikeratome, a mechanized blunt blade similar to the LASIK microkeratome, is used. The laser ablation is then performed on the surface and the epithelial flap is retained.

Laser-assisted sub-epithelial keratomileusis (LASEK) is a modification of PRK, where a dilute alcohol solution is applied to the corneal epithelium, then an epithelial trephineis used to loosen and roll up the epithelium without removing it. Eximer laser ablation is then performed, and the epithelium is repositioned over the central corneal stroma.

Photorefractive Keratectomy and photoastigmatic keratectomy (PARK or PRK-A) are performed to correct refractive errors by the use of a computer controlled excimer laser to reshape or flatten the cornea. Each pulse removes a microscopic amount of tissue by evaporating it, producing very little heat, and usually leaving underlying tissue almost untouched.

Epikeratoplasty (EKP) involves the placement of cadaver corneal tissue over a diseased cornea as a means to correct aphakia, keratoconus and pterygium.

*American Academy of Ophthalmology(AAO) (*Keratorefractive Surgery)
AAO notes “that the most frequently performed procedures for low to moderate myopia utilize the excimer laser, which was first approved for this purpose by the FDA in 1995. A surface ablation technique, photorefractive keratectomy (PRK), was the first procedure performed; subsequently, LASIK has become the most commonly performed keratorefractive surgery. Other keratorefractive procedures to correct low to moderate myopia include variations of PRK called laser epithelial keratomileusis (LASEK) and epi-LASIK…. A Cochrane review in 2016 found no difference in efficacy between LASEK and PRK in correcting myopia. Similarly, a 2017 Cochrane review found no comparable difference between LASEK and LASIK in correcting myopia, and earlier Cochrane reviews found no comparable difference between LASIK and PRK. Based on these systematic reviews, LASEK, PRK, and LASIK may be equally effective in correcting myopia. (I-, moderate quality, strong recommendation). Therefore, selection of a surgery can be dependent on individual patient characteristics or surgeon preferences”

National Institute for Clinical Excellence (2006)
“In photorefractive surgery, corneal re-shaping is achieved using excimer laser ablation. Excimer laser techniques include photorefractive keratectomy (PRK), laser epithelial keratomileusis (LASEK) and laser in situ keratomileusis (LASIK). In seven randomised controlled trials (RCTs) included in the review, there were no significant differences between the three procedures in the proportion of eyes treated for myopia or myopic astigmatism achieving the predicted refractive outcome. Data from more than 2000 eyes treated with PRK for myopia showed that a median of 69% of eyes had achieved within 0.5 D of their intended correction, and that 89% had achieved within 1.0 D. Data from case series of more than 1800 eyes undergoing LASEK for myopia or astigmatism showed that a median of 75% of eyes were within 0.5 D and a median of 92% of eyes were within 1.0 D of their intended correction at 3–6 months follow-up.

Data from eyes treated with LASIK for myopia or astigmatism showed that 77% (7309/9542) were within 0.5 D and 91% (8109/8885) were within 1.0 D of their intended correction at 3–12 months. One RCT found LASEK to be significantly more accurate than PRK for eyes with hyperopia."

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2015, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
65400	Excision of lesion, cornea (keratectomy, lamellar, partial), except pterygium
65710	Keratoplasty (corneal transplant) anterior lamellar
65760	Keratomileusis
65765	Keratophakia
65767	Epikeratoplasty
65772	Corneal relaxing incision
65775	Corneal wedge resection
66999	Unlisted procedure, anterior segment of eye
HCPCS Codes	**Description**
S0800	Laser in situ keratomileusis (LASIK)
S0810	Photorefractive keratectomy
S0812	Phototherapeutic keratectomy (PTK)

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10 Code	Description
H27.00 – H27.03	Aphakia
H33.XX	Retinal detachment
H52.X	Disorder of refraction and accommodation
H52.01	Hypermetropia, right eye
H15.53	Granular corneal dystrophy
H15.54	Lattice corneal dystrophy
H17.X	Corneal scars and opacities
H17.11	Central corneal opacity, right eye
H17.12	Central corneal opacity, left eye
H17.13	Central corneal opacity, bilateral
H17.821	Peripheral opacity of cornea, right eye

ICD-10 Code	Description
H17.822	Peripheral opacity of cornea, left eye
H17.823	Peripheral opacity of cornea, bilateral
H18.11	Bullous keratopathy, right eye
H18.12	Bullous keratopathy, left eye
H18.13	Bullous keratopathy, bilateral
H18.261	Keratoconus unstable, right eye
H18.622	Keratoconus unstable, left eye
H18.623	Keratoconus unstable, bilateral
H52.02	Hypermetropia, left eye
H52.03	Hypermetropia, bilateral
H52.11	Myopia, right eye
H52.12	Myopia, left eye
H52.13	Myopia, bilateral
H52.211	Irregular astigmatism, right eye
H52.212	Irregular astigmatism, left eye
H52.219	Irregular astigmatism, bilateral
H52.221	Regular astigmatism, right eye
H52.213	Regular astigmatism, left eye
H52.219	Regular astigmatism, bilateral
H52.31	Anisometropia
H52.32	Aniseikonia
H52.4	Presbyopia
Q12.3	Congenital aphakia
Z94.7	Corneal transplant status

Reviews, Revisions, and Approvals	Date	Approval Date
Policy Adopted from Health Net NMP#391, Refractive Surgery	1/17	
Added section on Epikeratoplasty , updated codes and references	1/18	1/18
Updated codes	1/19	1/19
Clarified that this policy addresses medical necessity for specific clinical conditions	1/20	1/20
Clarified criteria for epikeratoplasty, added codes and updated references	1/21	1/21
Added photoastigmatic keratectomy (PARK or PRK-A) to Section I. updated references and codes	1/22	1/22
Section III, removed time restrictions. Added information to background, updated codes and references	1/23	1/23
Update no changes	1/24	1/24
Update no changes	2/25	2/25

References

1. American Academy of Ophthalmology (AAO). Preferred Practice Patterns®: Refractive Errors and Refractive Surgery. 2017.

2. American Society for Cataract and Refractive Surgery. Refractive Surgery Outcomes in Patients with Low Refractive Errors. 2016.
3. Fu Y, Yin Y, Wu X et al. Clinical outcomes after small-incision lenticule extraction versus femtosecond laser-assisted LASIK for high myopia: A meta-analysis. PLoS One. 2021;16(2):e0242059.
4. Jacobs, DS et al Refractive Surgery Preferred Practice Pattern® Guidelines. American Academy of Ophthalmology 2022, American Academy of Ophthalmology (AAO)
5. National Institute for Clinical Excellence. Photorefractive laser surgery for the correction of refractive errors. Interventional procedures guidance. IPG164. March 2006. Updated January 20. 2012.
6. O'Brart DP, Shalchi Z, McDonald RJ, et al. Twenty-year follow-up of a randomized prospective clinical trial of excimer laser photorefractive keratectomy. Am J Ophthalmol 2014;158:651.
7. Raevdal P, Grauslund J, Vestergaard AH. Comparison of corneal biomechanical changes after refractive surgery by noncontact tonometry: small-incision lenticule extraction versus flap-based refractive surgery -a systematic review. Acta Ophthalmol. 2019; 97(2):127-136.
8. Settas G, Settas C, Minos E, et al. Photorefractive keratectomy (PRK) versus laser assisted in situ keratomileusis (LASIK) for hyperopia correction. Cochrane Database Syst Rev. 2012.
9. Siganos CS, Kymionis GD, Kartakis N, et al. Management of keratoconus with Intacs. Am J Ophthalmol. 2003; 135(1):64-70.
10. Sumit G, McColgin AZ, Steinert RF, et al. Phototherapeutic Keratectomy. American Academy of Ophthalmology. 2016.
11. Wen D, Mcalinden C, Flitcroft I, et al. Postoperative efficacy, predictability, safety and visual quality of laser corneal refractive surgery: A network meta-analysis. Am J Ophthalmol 2017; 178: 65-78.
12. Yan H, Gong LY, Huang W, Peng YL. Clinical outcomes of small incision lenticule extraction versus femtosecond laser-assisted LASIK for myopia: a meta-analysis. Int J Ophthalmol. 2017; 10(9):1436-1445.
13. Zhao LQ, Wei RL, Cheng JW, et al. Meta-analysis: clinical outcomes of laser-assisted subepithelial keratectomy and photorefractive keratectomy in myopia. Ophthalmology. 2010;117(10):1912.
14. Bower, KS et al Laser Refractive Surgery UptoDate, current thru Dec 22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.