Clinical Policy: Refractive Surgery

Reference Number: HNCA.CP.MP. 391
Effective Date: 11/07
Last Review Date: 01/20

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

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 and phototherapeutic keratectomy (PTK). These procedures are subject to plan coverage documents to determine medical necessity vs to eliminate the need for glasses.

Policy/Criteria

I. It is the policy of Health Net of California that refractive surgery, specifically LASIK, Epi-LASIK, LASEK, 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 with a corneal relaxing incision or a corneal wedge resection is medically necessary when all of the following are met:

A. Patient has had previous penetrating keratoplasty or corneal transplant $\leq$ 60 months ago or cataract surgery $\leq$ 36 months ago
B. The degree of astigmatism is $\geq$ 3 diopters
C. The patient is intolerant of glasses and contact lenses

IV. Epikeratoplasty
It is the policy of Health Net of California that epikeratoplasty (65767) is considered as medically necessary for EITHER of the following indications:

A. acquired or congenital aphakia
B. aphakia following cataract surgery in patients unable to receive intraocular lens

V. It is the policy of Health Net of California that refractive surgery is not medically necessary or investigational for any other circumstances than those specified above unless otherwise specified in member benefits.

Background
PRK was the initial procedure used to reshape the cornea for the correction of severe myopia, hyperopia, and astigmatism. An excimer laser is used to ablate a thin outer layer of the cornea, changing the cornea's refractive power. Since there is no flap creation with PRK, the entire thickness of the underlying stroma is available for treatment, which be beneficial if the cornea is too thin for LASIK. [3]

LASIK is similar to PRK, except a flap is created within the cornea with either a laser or a blade. This is the most common type of refractive surgery, and the initial recovery is quicker. However, complications could result from the flap, which may require conversion to PRK. Sub-Bowman keratomileusis is a modification of LASIK that involves creation of a thin flap in the corneal stroma, at or just beneath the level of Bowman's membrane.[3]

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.[3]

LASEK is a modification of PRK, in which the corneal epithelium is kept off the eye, while corneal stroma is being reshaped. There is no corneal flap created. [3]

PTK is an additional type of laser eye surgery to treat various ocular disorders by removing tissue from the cornea. PTK allows the removal of superficial corneal opacities and surface irregularities.[3]

Epikeratoplasty (or Epikeratophakia**)** involves placement of a precarved donor corneal lens on the surface of a patient's eye for treatment of childhood aphakia because contact lenses are

difficult for children to use, and intraocular lens implants may result in long-term complications in children. This procedure may be used on scarred corneas and corneas affected with endothelial dystrophy. Epikeratophakia may also be considered acceptable in cases of adult aphakia when the secondary implantation of an intraocular lens might affect outcome (e.g., history of uveitis, significant corneal endothelial disease, and gross corneal irregularity after trauma

A systematic review and meta-analysis was done on 12 studies used for used for comparing PRK (499 eyes) with LASEK (512 eyes) for myopia. LASEK-treated eyes had no significant benefits over PRK-treated ones with regard to clinical outcomes. Less corneal haze was observed in LASEK-treated eyes at 1 to 3 months after surgery.[3, 8]

A Cochrane review noted that although no robust, reliable conclusions could be reached, the non-randomised trials reviewed appear to be in agreement that hyperopic-PRK and hyperopic-LASIK are of comparable efficacy. High quality, well-planned open RCTs are needed in order to obtain a robust clinical evidence base.[7]

American Academy of Ophthalmology
PTK is an important option for patients with painful recurrent erosions, and offers an alternative to lamellar or penetrating keratoplasty for the correction of corneal opacities and surface irregularities.[4]

American Society for Cataract and Refractive Surgery
Excimer laser-based refractive surgery techniques are safe and effective for correction of ametropia.[2]

National Institute for Clinical Excellence
Photorefractive laser surgery is used to treat refractive errors such as myopia, astigmatism and hyperopia. Excimer laser ablation is used for corneal re-shaping, and includes PRK, LASEK, and LASIK.[5]

Coding Implications
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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

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
H33.0X	Retinal detachment with retinal break
H33.011	Retinal detachment with single break, right eye
H33.012	Retinal detachment with single break, left eye
H33.013	Retinal detachment with single break, bilateral
H33.021	Retinal detachment with multiple breaks, right eye
H33.022	Retinal detachment with multiple breaks, left eye
H33.023	Retinal detachment with multiple breaks, bilateral
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
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

ICD-10 Code	Description
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
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

References

1. American Academy of Ophthalmology. Refractive Errors and Refractive Surgery PPP. 2013.
2. American Society for Cataract and Refractive Surgery. Refractive Surgery Outcomes in Patients with Low Refractive Errors. 2016.
3. Bower KS. Laser Refractive Surgery. UpToDate. April 27, 2016.
4. Sumit G, McColgin AZ, Steinert RF, et al. Phototherapeutic Keratectomy. American Academy of Ophthalmology. 2016.
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. 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.

8. 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.
9. American Academy of Ophthalmology. Epikeratoplasty. Ophthalmology. 1996;103(6):983-991.

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.

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