Clinical Policy: Corneal Remodeling (Refractive Surgery)

Reference Number: QCP.CP.021
Effective Date: 09/18/1995
Date of Last Revision: 03/01/2022

CPT Codes: 0099T, 65710, 65730, 65750, 65755-65757, 65760, 65765, 65767, 65770-65772, 65775, 65785, S0800, S0810, S0812, 0402T
Document:BI135:00

Public Statement

Effective Date:

a) This policy will apply to all services performed on or after the above revision date which will become the new effective date.
b) For all services referred to in this policy that were performed before the revision date, contact customer service for the rules that would apply.

Corneal remodeling is used to treat a variety of corneal problems including improving visual acuity. Most benefit plans exclude coverage for surgery to achieve vision correction without glasses, such as RK, PRK and LASIK. (Complications resulting from non-covered refractive surgery will not be covered.)

Surgery for the correction of irregular or deformed corneas following covered surgery is covered. Surgery for the restoration of vision lost because of corneal opacity is covered. Other corneal surgery will not be covered without pre-authorization.

Medical Statement

i. **Post-Cataract or Post-Transplant Corneal Surgery**
Correction of surgically induced astigmatism with a corneal relaxing incision or corneal wedge resection (65772, 65775) 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:
   A. The degree of astigmatism must be 3.00 diopters or greater; ***and***
   B. The member must be intolerant of glasses or contact lenses.

ii. **Phototherapeutic Keratectomy (S0812)**
Phototherapeutic keratectomy (PTK) is considered medically necessary for members with **any** of the following corneal conditions. Preauthorization is required.
   A. Superficial corneal dystrophy (including granular, lattice, and Reis-Bückler`s dystrophy); **or**
   B. Epithelial membrane dystrophy; **or**
   C. Irregular corneal surfaces due to Salzmann`s nodular degeneration or keratoconus nodules; **or**
   D. Corneal scars and opacities (including post-traumatic, post-infectious, post-surgical, and secondary to pathology); **or**

E. E. 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.

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.

If used unilaterally PTK will induce a certain degree of anisometropia since it induces a shift in refraction to the hyperopic (farsighted) side. This hyperopic shift might be welcomed in Myopes but may be problematic for emmetropes or low Myopes.

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

iii. **Refractive Surgery**

QualChoice standard benefit plans and traditional benefit plans exclude coverage of " any surgery mainly to correct refractive errors." These exclusions apply to radial keratotomy (RK), astigmatic keratotomy (AK), photorefractive keratectomy (PRK), Photoastigmatic keratectomy (PARK), laser-in-situ Keratomileusis (LASIK), Keratomileusis, Epikeratophakia, intrastromal corneal ring segments, and other refractive surgical procedures.

For plans that **do not** have a specific contractual exclusion of refractive surgery, refractive surgery is considered not medically necessary. Spectacles or contact lenses have been shown to provide more accurate corrections of refractive errors than can refractive surgery.

Although the safety of refractive surgical procedures is improving, these procedures are associated with significant risks of degradation of best corrected visual acuity, as well as glare, induced regular or irregular astigmatism, regression of effect, visual aberations (including transient or permanent glare or starburst/halo effect), and decreased contrast sensitivity. According to the AAO Preferred Practice Pattern on Refractive Errors, "[s]pectacles are the simplest and safest means of correcting a refractive error."

- **Radial keratotomy (RK) (65771)** involves the use of radial incisions in the cornea to
  I. Radial keratotomy is not considered medically necessary for treatment of myopia ranging from -2.00 to -8.00 diopters because this refractive error can be corrected satisfactorily with eyeglasses or contact lenses.
  II. Radial keratotomy is considered investigational for treatment of myopia greater than -8.00 diopters and it is also considered investigational for treatment of all other refractive errors.

- **Astigmatic keratotomy (AK) (65772)** (arcuate incision, corneal wedge resection) is a refractive surgical procedure similar to RK that is used to reduce astigmatism.
  I. Astigmatic keratotomy may be covered when performed for the correction of surgically induced astigmatism following medically indicated cataract removal or corneal transplant surgery (see criteria above).
  II. Astigmatic keratotomy is considered investigational for treatment of all other refractive errors
- **Laser-In-Situ Keratomileusis (LASIK) (65760 or S0800)** is a type of laser surgery of the cornea to correct refractive errors, in which a slice of the patient`s cornea is removed, shaped to the desired curvature with an excimer laser, and then sutured back to the remaining cornea.
  I. Laser-in-situ Keratomileusis is considered not medically necessary for treatment of myopia between -1.0 and -15.0 diopters, with or without astigmatism up to 5.0 diopters, because this can be corrected satisfactorily with eyeglasses or contact lenses.
  II. Laser-in-situ Keratomileusis is also considered not medically necessary for treatment of hyperopia up to + 6.0 diopters with or without astigmatism up to 5 diopters.
  III. Laser-in-situ Keratomileusis is considered investigational for treatment of myopia greater than -15.0 diopters or hyperopia greater than + 6.0 diopters, for treatment of persons with astigmatism greater than 5.0 diopters, and for all other refractive errors.
- **Standard Keratomileusis (ALK) (65760)** where the cornea is shaped with a microkeratome rather than with a laser,
  I. ALK is considered investigational for treatment of all refractive errors. In current clinical practice, ALK is being replaced by laser in situ Keratomileusis.
- **Epikeratoplasty (Epikeratophakia) (65767)** is a refractive surgical procedure that involves placement of a pre-carved donor corneal lens on the surface of a patient`s eye. Epikeratoplasty (Epikeratophakia) requires preauthorization.
  I. Epikeratophakia may be covered for the treatment of childhood aphakia since contact lenses are difficult for children to use and intraocular lens implants may result in long-term complications in children.
  II. May also be covered when used on scarred corneas and corneas affected with endothelial dystrophy.
  III. May be covered in the treatment of adult aphakia, where reentering the eye could affect outcome (e.g., vitreous in the anterior chamber, history of uveitis, disorganized anterior chamber that cannot support an intraocular lens, significant corneal endothelial disease, or gross corneal irregularity after trauma);.
  IV. This procedure is considered investigational for correction of refractive errors and for all other cases of adult aphakia.

- **Keratophakia (65765)** involves implantation of a donor cornea within the corneal stroma to modify its refractive power.
  I. Keratophakia is considered investigational for correction of refractive errors.
- **Lamellar Keratoplasty (non-penetrating Keratoplasty) (65710)** is a corneal transplant procedure in which a partial thickness of the cornea is removed and the diseased tissue is replaced with a partial-thickness donor cornea. The donor eye is prepared by making a partial thickness trephine incision in the cornea and dissecting free the lamellar button. Lamellar Keratoplasty (non-penetrating Keratoplasty) requires preauthorization.
  I. This procedure may be covered for a number of corneal diseases, including scarring, edema, thinning, distortion, dystrophies, degenerations, and keratoconus.
  II. Utilization has been very low on this procedure. We will pay and audit claims and clinical records as indicated.
  III. It is considered investigational when performed solely to correct astigmatism and other refractive errors.
- **Penetrating Keratoplasty (PK) (Corneal Transplantation, Perforating Keratoplasty) (65730, 65750, 65755)** is a corneal transplant procedure involving replacement of the full thickness of the cornea with donor cornea, but retaining the peripheral cornea.
  I. PKs are covered to improve poor visual acuity caused by an opaque cornea.
  II. Penetrating Keratoplasty is covered when used to remove active corneal disease, such as persistent severe bacterial, fungal, or amebic inflammation of the cornea (keratitis) after appropriate antibiotic therapy.
  III. Penetrating Keratoplasty has also been performed to restore altered corneal structure or to prevent loss of the globe that has been punctured.
  IV. PK is covered for bullous keratopathy, keratoconus, corneal scar with opacity, keratitis, corneal transplant rejection, Fuch`s dystrophy, corneal degeneration, other corneal dystrophies, corneal edema, and herpes simplex keratitis.
  V. Historically, utilization of this procedure has been rare. We will continue to cover without preauthorization, but will audit claims and clinical records as indicated.
  VI. Penetrating Keratoplasty is considered investigational when performed solely to correct astigmatism or other refractive errors.
- **Photorefractive Keratectomy (PRK) (S0810)** is a refractive surgical procedure involving the reshaping of the surface of the cornea with an excimer laser to correct mild-to-moderate myopia. Photoastigmatic keratectomy (PARK or PRK-A) is a refractive surgical procedure to correct myopia with astigmatism.
  I. These procedures are considered not medically necessary for patients with hyperopia of up to 6.0 diopters and myopia of up to -10.0 diopters, with or without astigmatism up to 4.0 diopters, because the refractive corrections achieved with PRK and PARK are less precise than that achieved by eyeglasses or contact lenses.
  II. Photorefractive keratectomy and PARK are considered investigational for patients with hyperopia greater than 6.0 diopters, myopia greater than -10.0 diopters, astigmatism greater than 4.0 diopters, and for all other refractive errors.

- **Intrastromal Corneal Ring Segments (INTACS) (65785)** (Addition Technology, Sunnyvale, CA) have been approved by the FDA for adults with mild myopia (from -1.0 to -3.0 diopters) that have less than 1 diopter of astigmatism. Intrastromal corneal ring segments. Intrastromal corneal ring segments (INTACS) require preauthorization.
  I. **INTACS** are considered not medically necessary for patients with mild myopia.
  II. INTACS are considered experimental and investigational for children, for patients with moderate to severe myopia (greater than -3.0 diopters), for patients with more than 1 diopter of astigmatism, and for hyperopia.
  III. Intrastromal corneal ring segments are considered medically necessary for reduction or elimination of myopia or astigmatism in persons with keratoconus who are no longer able to achieve adequate vision using contact lenses or spectacles and for whom corneal transplant is the only remaining option.
- **Conductive Keratoplasty** involves the application of radiofrequency thermal energy to increase the curvature of the cornea and thereby reduce hyperopia. Conductive keratoplasty using the ViewPoint CK System (Refractec Inc., Irvine, CA) has been approved by the FDA for treatment of patients who are at least 40 years of age, who have mild to moderate hyperopia (0.75 D to 3.25 D), who have 0.75 D or less astigmatism, and whose eyesight has changed very little over the previous 12 months (as demonstrated by a change of less than 0.50 D in refraction).
  I. Conductive Keratoplasty is considered not medically necessary for the above indications.
  II. Conductive Keratoplasty is considered experimental and investigational for all other indications.
- **Orthokeratology** involves the application of sequentially flatter hard contact lenses to flatten the cornea and thereby reduce myopic refractive error. It is considered investigational. The AAO Preferred Practice Pattern on Refractive Errors states that "Attempts to predict which patients will respond to orthokeratology based on ocular biomechanical or biometric parameters have not been successful. The effects of orthokeratology have been unpredictable and poorly controlled. … This approach is not recommended."
- **Scleral Expansion Surgery** is considered experimental and investigational for presbyopia. Scleral expansion surgery involves making small incisions in the eye and inserting bands to stretch the part of the sclera that lies beneath the ciliary muscles that control accommodation.
- **Intraocular Lens Implants (clear lens extraction)** (aphakic intraocular lenses (IOLs)) are considered **not** medically necessary for correction of presbyopia, hyperopia, and myopia because these refractive errors can be corrected satisfactorily with eyeglasses or contact lenses.
- **Implantable Contact Lenses** (without lens extraction) (phakic intraocular lenses (IOLs) (e.g., Artisan lens, Verisye lens) has been approved by the FDA for adult patients who have myopia ranging from -5 to -20 diopters with less than or equal to 2.5 diopter of astigmatism. Implantable contact lenses are considered not medically necessary for myopia ranging from -5 to -20 diopters in persons with 2.5 diopters of astigmatism or

less because external contact lenses or eyeglasses produce equivalent therapeutic results for treatment of refractive errors. Implantable contact lenses are considered experimental and investigational for other indications.

1. **Endothelial Keratoplasty (65756):**

Endothelial Keratoplasty (Descemet`s stripping endothelial Keratoplasty (DSEK), Descemet`s stripping automated endothelial Keratoplasty (DSAEK), and Descemet`s membrane endothelial Keratoplasty (DLEK) require preauthorization. These procedures are considered medically necessary for the following indications in persons with endothelial failure and otherwise healthy corneas:

1. Bullous keratopathy;
2. Corneal edema;
3. Endothelial corneal dystrophy and other posterior dystrophies;
4. Mechanical complications due to corneal graft or ocular lens prostheses;
5. Rupture of Descemet`s membrane.

Endothelial Keratoplasty procedures are considered experimental and investigational for conditions with concurrent endothelial disease and anterior corneal disease, including anterior corneal dystrophies, anterior corneal scars from trauma or prior infection, ectatic conditions of the cornea such as keratoconus, pellucid marginal degeneration and ectasia after previous laser vision correction surgery, and for all other indications.

1. **Keratoprosthesis (65770)**:
    1. Keratoprosthesis requires preauthorization. This procedure is covered for individuals where:
        I. The cornea is severely opaque and vascularized; AND
        II. The patient has had 2 or more prior failed corneal transplants
    2. Treatment should be restricted to centers experienced in treatment this condition and staffed by surgeons adequately trained in techniques addressing implantation of this device.
    3. Any other use is considered experimental.

1. **Corneal Cross-Linking (0402T)**
    1. Corneal collagen crosslinking is a minimally invasive surgical procedure to strengthen the corneal collagen bonds. It is used to slow the progression of Keratoconus, Pellucid Marginal Degeneration and Terrien Marginal Degeneration in younger patients, as well as, post LASIK corneal ectasia. The procedure most often involves the removal of the corneal epithelium, the application of riboflavin (Vit B 2) and the activation of the riboflavin with UV- A light. It was approved by the FDA in 2016.
    2. QualChoice requires prior authorization for corneal collagen crosslinking, a fellowship-trained cornea surgeon, and a diagnosis of Keratoconus, Pellucid Marginal Degeneration or Terrien Marginal Degeneration in a young patient. QualChoice does not cover corneal collagen crosslinking for post LASIK ectasias since QualChoice does not cover refractive surgery. QualChoice does not cover corneal collagen crosslinking for older patients since the aging process already causes strengthening of the collagen crosslinks.

Codes Used In This BI:

65710	Corneal transplant
65730	Corneal transplant
65750	Corneal transplant
65755	Corneal transplant
65756	Corneal trnspl endothelial
65757	Prep corneal endo allograft
65760	Revision of cornea
65765	Revision of cornea
65767	Corneal tissue transplant
65770	Revise cornea with implant
65771	Radial keratotomy
65772	Correction of astigmatism
65775	Correction of astigmatism
S0800	Laser in situ Keratomileusis
S0810	Photorefractive keratectomy
S0812	Phototherap keratect
0099T	Refractive Surgery (deleted 1/1/16)
65785	Implantation of intrastromal corneal ring segments (new code 1/1/16)
0402T	Collagen cross-linking cornea

Reference

1. U.S. Food and Drug Administration, Center for Devices and Radiologic Health. ViewPoint™ CK System. Summary of Safety and Effectiveness and Labeling. PMA No. P010018. Rockville, MD: FDA; April 11, 2002. Available at: http://www.fda.gov/cdrh/pdf/p010018.html
2. Waring GO. The challenge of corneal wound healing after excimer laser refractive corneal surgery. J Refract Surg. 1995; 11(5). Available at: http://www.slackinc.com/eye/jrs/vol115/9ed2.htm
3. Silverio Healthcare Management Services. Corneal relaxing incisions. AccuLibrary. AccuChecker [website]. Miami, FL: Silverio and Associates; 2001. Available at: http://www.accuchecker.com/AccuLibrary/articles/eyeocularsurgcornealrelaxingincisions.asp
4. American Academy of Ophthalmology (AAO). Policy Statement: Use of unapproved lasers and software for refractive surgery. San Francisco, CA: AAO; revised October 2001.
5. Sugar A, Rapuano CJ, Culbertson WW, et al. Laser in situ Keratomileusis for myopia and astigmatism: Safety and efficacy: A report by the American Academy of Ophthalmology. Ophthalmology. 2002; 109(1):175-187.
6. National Institute for Clinical Excellence (NICE). Laser in situ Keratomileusis for the treatment of refractive errors. Interventional Procedure Guidance 102. London, UK: NICE; December 2004. Available at: http://www.nice.org.uk/page.aspx?o=236088

7. Mathews S. Scleral expansion surgery does not restore accommodhuman presbyopia. Ophthalmology. 1999; 106:873-877.
8. Qazi MA, Pepose JS, Shuster JJ. Implantation of scleral expansion band segments for the treatment of presbyopia. Am J Ophthalmol. 2002; 134:808-815.
9. National Institute for Clinical Excellence (NICE). Scleral expansion surgery for presbyopia. Interventional Procedure Guidance No. 70. London, UK: NICE; July 2004. Available at: http://www.nice.org.uk/page.aspx?o=56720
10. Colin J, Cochener B, Savary G, Malet F. Correcting keratoconus with intracorneal rings. J Cataract Refract Surg. 2000; 26(8):1117-1122.
11. Colin J, Cochener B, Savary G, et al. INTACS inserts for treating keratoconus: One-year results. Ophthalmology. 2001; 108(8):1409-1414.
12. Colin J, Velou S. Utilization of refractive surgery technology in keratoconus and corneal transplants. Curr Opin Ophthalmol. 2002; 13(4):230-234.
13. Boxer Wachler BS, Christie JP, Chandra NS, et al. Intacs for keratoconus. Ophthalmology. 2003; 110(5):1031-1040.
14. Colin J, Velou S. Current surgical options for keratoconus. J Cataract Refract Surg. 2003; 29(2):379-386.
15. Colin J, Velou S. Implantation of Intacs and a refractive intraocular lens to correct keratoconus. J Cataract Refract Surg. 2003; 29(4):832-834.
16. Siganos CS, Kymionis GD, Kartakis N, et al. Management of keratoconus with Intacs. Am J Ophthalmol.2003; 135(1):64-70.
17. Letter from Donna Bea Tillman, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, Rockville, MD, to Darlene Crockett-Billing, Regulatory Consultant, Addition Technology, and Sunnyvale, CA regarding INTACS prescription inserts for keratoconus, HDE H040002. Rockville, MD: FDA; July 26, 2004.
18. Hladun L, Harris M. Contact lens fitting over intrastromal corneal rings in a keratoconic patient. Optometry. 2004; 75(1):48-54.
19. Hofling-Lima AL, Branco BC, Romano AC, et al. Corneal infections after implantation of intracorneal ring segments. Cornea. 2004; 23(6):547-549.
20. Alio JL, Artola A, Ruiz-Moreno JM, et al. Changes in keratoconic corneas after intracorneal ring segment explanation and reimplantation. Ophthalmology. 2004; 111(4):747-751.
21. U.S. Food and Drug Administration (FDA). FDA approves implanted lens to correct nearsightedness. FDA Talk Paper. T03-38. Rockville, MD: FDA; September 13, 2004. Available at: http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01313.html.
22. Corneal cross-linking versus conventional management for keratoconus: a lifetime economic model Journal of Medical Economics 2021, Vol. 24, No.1, 410-420.

23. Corneal Collagen Crosslinking: A Systematic Review OPH. 2014; 232 (1):10-27
24. Current perspectives on corneal collagen cross linking (CXL) Subasinghe SK, Ogbuehi KC, Dias GJ. Graefes Arch Clin Exp Ophthalmol. 2018 Aug;256(8):1363-1384.
25. Pediatric keratoconus: a review of the literature. Mukhtar S, Ambati BK. Int Ophthalmol. 2018 Oct;38(5):2257-2266
26. Corneal Collagen Crosslinking for Ectasia after Refractive Surgery Ophthalmology. 2017 Oct;124(10):1440-1441.
27. Corneal Collagen Cross-linking Complications Evangelista CB, Hatch KM. Semin Ophthalmol. 2018;33(1):29-35.
28. Pediatric keratoconus: a **review** of the literature. Mukhtar S, Ambati BK. Int Ophthalmol. 2018 Oct;38(5):2257-2266

Application to Products

This policy applies to all health plans and products administered by QualChoice, both those insured by QualChoice and those that are self-funded by the sponsoring employer, unless there is indication in this policy otherwise or a stated exclusion in your medical plan booklet. Consult the individual plan sponsor Summary Plan Description (SPD) for self-insured plans or the specific Evidence of Coverage (EOC) or Certificate of Coverage (COC) for those plans or products insured by QualChoice. In the event of a discrepancy between this policy and a self-insured customer's SPD or the specific QualChoice EOC or COC, the SPD, EOC, or COC, as applicable, will prevail. State and federal mandates will be followed as they apply.

Changes: QualChoice reserves the right to alter, amend, change or supplement benefit interpretations as needed.