

Corporate Medical Policy

Refractive Surgery

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Description of Procedure or Service

The term refractive surgery describes various procedures that modify the refractive error of the eye. Refractive surgery involves surgery performed to reshape the cornea of the eye (refractive keratoplasty) or the way the eye focuses light internally. Vision occurs when light rays are bent or refracted by the cornea and lens and received by the retina, (the nerve layer at the back of the eye), in the form of an image, which is sent through the optic nerve to the brain. Refractive errors occur when the eye cannot properly focus light and images appear out of focus.

The main types of refractive errors are myopia (nearsightedness), hyperopia (farsightedness) and astigmatism (distortion). Presbyopia (aging eye) is a problem of the lens and is characterized by the inability to bring close objects into focus. Refractive errors are generally corrected with glasses or contact lenses. Refractive keratoplasty includes all surgical procedures on the cornea to improve vision by changing the shape, and thus the refractive index, of the corneal surface. Refractive keratoplasties can be broadly subdivided into keratomies, i.e., corneal incisions; keratectomies, i.e., removal of corneal epithelium; and keratomileusis, i.e., reshaping a stromal layer of the cornea.

Refractive keratoplasties include the following surgeries:

Radial keratotomy (RK) is a surgical procedure for nearsightedness. Using a high-powered microscope, the physician places micro-incisions (usually 8 or fewer) on the surface of the cornea in a pattern much like the spokes of a wheel. The incisions are very precise in terms of depth, length, and arrangement. The micro-incisions allow the central cornea to flatten, thus reducing the convexity of the cornea, which produces an improvement in vision.

Photorefractive Keratectomy (PRK) uses a computerized laser to reshape the central cornea to a flattened shape for people who are myopic and a more curved surface for people who are hyperopic. Photorefractive Keratectomy techniques may also be used to correct astigmatism (Photoastigmatic keratectomy or PARK). The excimer laser is well-suited for cornea reshaping, because the removal of just tiny amounts of tissue can produce the results needed to correct refractive errors. The excimer laser produces a beam of ultraviolet light in pulses that last only a few billionths of a second. Each pulse removes a microscopic amount of tissue by evaporating it, producing very little heat, and usually leaving underlying tissue almost untouched. Overall, the surgery takes approximately 10-20 minutes; however, the use of the laser beams lasts only 15-40 seconds.

Automated Lamellar Keratoplasty (ALK) can correct farsightedness. For the treatment of moderate farsightedness, the cornea is opened across the top to form a type of "cap", using an automated instrument. When the "cap" is positioned back into its original location on the top of the eye, microscopic scar tissue is formed, causing the "cap" to bulge out. This corrects the overly flattened cornea that is associated with farsightedness. Almost like Velcro, the cornea and the cap adhere to each other, eliminating the need for sutures. Normally one eye is treated at a time, with about 3-4 weeks allowed between each eye surgery. To ease any discomfort, the eye is anesthetized with special drops, and the patient is given a mild sedative to remain relaxed and unaware throughout the procedure.

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Minimally Invasive Radial Keratotomy (mini-RK) is intended in cases of nearsightedness to alter the cornea's shape and consequently the refraction by reducing the millimeters of cornea that are incised.

Hexagonal Keratotomy is a form of refractive corneal surgery used to treat naturally occurring farsightedness and presbyopia (loss of accommodation in the eyes in advancing age) following radial keratotomy. A hexagonal pattern of intersecting incisions in the cornea is used in performing this procedure.

All of the above procedures can be used alone or in combination to produce the optimal result for a given patient.

Other procedures that are used to correct vision under this medical policy are as follows:

Keratomileusis has been proposed for nearsightedness and aphakic hyperopia. This procedure is a keratoplasty in which a slice of the patient's cornea is removed, frozen, shaped to the desired curvature and then sutured back on the remaining cornea.

Laser-assisted in-situ keratomileusis, (LASIK) keratoplasty 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 reflected back, the exposed cornea is reshaped by the laser, and the flap is replaced, without sutures, to heal back into position.

Laser-assisted sub-epithelial keratomileusis, (LASEK) is the detachment of the epithelium with the use of an alcohol solution that softens the epithelium and allows it to be rolled back into a flap. The flap of epithelium is then repositioned over the cornea following excimer ablations. LASEK is a recent modification of PRK that attempts to preserve the epithelium.

Keratophakia is a procedure in which the patient's cornea is removed followed by placement of a frozen, shaped donor cornea beneath the recipient's cornea, which is then reattached. The technique has been proposed for aphakic hyperopia.

Epikeratoplasty (or Epikeratophakia) involves suturing a prelathed donor cornea onto the surface of the patient's cornea. This procedure has been proposed as a means of correcting adult and pediatric aphakia, keratonus (a conical protrusion of the cornea, caused by thinning of the stroma, and resulting in major changes in the refractive power of the eye), and nearsightedness.

Clear lens extraction (CLE) is virtually the same as for the removal of cataracts. It involves removing the eye's natural crystalline lens and replacing it with a plastic prescription lens implant. The only difference is that the natural lens being replaced by the CLE procedure is clear, while a cataract lens is cloudy.

Phakic intraocular lens implantation (P-IOL) is also known as Intraocular Contact Lens and abbreviated as P-IOL. This is a tiny plastic lens that is placed inside the eye in front of the natural crystalline lens to provide additional refractive change. A phakic intraocular lens is placed either immediately behind or in front of the iris.

Conductive keratoplasty (CK) is a refractive surgery procedure for hyperopia and astigmatism that uses a probe to apply high frequency radio waves into the corneal tissue, causing shrinkage. This controlled shrinkage will reshape the cornea to accommodate refractive error.

Laser thermal keratoplasty (LTK) uses a noncontact laser (Holmium laser) that is used to shrink the peripheral area of the cornea. This makes the shape of the cornea steeper and corrects mild to moderate cases of farsightedness. The laser works when moisture in the cornea absorbs energy from the laser pulses, causing corneal tissue to heat up and shrink. The application of energy is accomplished without physically contacting the cornea with instrumentation or other apparatus.

Astigmatic keratotomy (AK) is a refractive surgical procedure in which microscopic incisions are placed in the peripheral cornea to create a more spherical shape. Similar to Radial Keratotomy.

Intracorneal inlays are micro-thin disc shaped lens developed by Anamed, Inc. They are manufactured in varying powers like a contact lens or glasses. The inlay is inserted into the cornea through a flap. The flap is created in an identical fashion to the LASIK procedure. Unlike LASIK, which removes corneal

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tissue to alter the corneal curvature, the Intracorneal Inlay is an additive procedure. The inlay acts as a supplemental lens to focus images clearly within the eye. No tissue is removed or destroyed in the implantation process.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Epikeratoplasty (Epikeratophakia) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

BCBSNC will not provide coverage for any of the other listed procedures (Radial keratotomy, photorefractive keratectomy, automated lamellar keratoplasty, minimally invasive radial keratotomy, hexagonal keratotomy, keratomileusis, LASIK, LASEK, keratophakia, clear lens extraction, phakic intraocular lens implantation, conductive keratoplasty, laser thermal keratoplasty, astigmatic keratotomy, intracorneal inlays). These procedures are intended to correct refractive errors and thus are generally excluded from most benefit plans. Further, the procedures are considered not medically necessary, since more conservative measures, (e.g., glasses or contact lenses) can correct the vast majority of refractive errors.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Refractive Surgery is covered

Epikeratoplasty (Epikeratophakia) may be considered medically necessary in patients meeting the following medical criteria:

- Patients that otherwise would be candidates for corneal transplants
- Patients diagnosed with keratoconus
- Pediatric aphakia (absence of the lens in the eye)

When Refractive Surgery is not covered

For any procedure other than Epikeratoplasty (Epikeratophakia) and then only for the diagnoses or conditions noted above

Radial keratotomy, photorefractive keratectomy, automated lamellar keratoplasty, minimally invasive radial keratotomy, hexagonal keratotomy, keratomileusis, LASIK, LASEK, keratophakia, clear lens extraction, phakic intraocular lens implantation, conductive keratoplasty, laser thermal keratoplasty, astigmatic keratotomy, and intracorneal inlays are generally excluded from most benefit plans.

Benefits for the treatment of side effects and complications of non-covered services (e.g., refractive surgery) are excluded in most BCBSNC certificates. Therapeutic contact lenses, sometimes known as "bandage" lenses are special lenses worn for therapeutic reasons. The U.S. Food and Drug Administration approve contact lenses that are indicated for therapeutic use as bandage lenses. The bandage lenses may be rigid gas permeable contact lenses or soft (hydrophilic) contact lenses and they may also have approval to correct vision conditions. Examples of therapeutic contact lenses are Bausch & Lomb's Plano T, Wesley Jensen/CIBA Vision's CSI-EW, CIBIA Vision's Protek, Coopervision's Permalens for Therapeutic Extended Wear, and Vistacon's Acuvue Oasis to name a few. The Boston Scleral Lens (BSL) is the only rigid gas permeable scleral contact lens that is

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commercially available in the U.S. The use of therapeutic (bandage) contact lenses following refractive surgery is not covered.

Policy Guidelines

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 in persons with otherwise non-diseased corneas.

Phototherapeutic keratectomy is addressed in a separate policy, Phototherapeutic Keratoplasty.

The correction of astigmatism resulting from trauma or from previous eligible surgery, (e.g., cataract removal, corneal transplant) is eligible for payment under codes 65772-65775. The astigmatism in these cases is considered a complication of the first surgery or the result of trauma.

The procedures listed in the "Description" section should not be confused with corneal transplants (also called keratoplasties) which are eligible services under codes 65710, 65730, 65750, 65755.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 65760, 65765, 65767, 65771, C1780, S0596, S0800, S0810

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

For Policy entitled: Refractive Keratoplasty

BCBSA Medical Policy Reference Manual - 7/96

Medical Director Review - 12/96

Medical Policy Advisory Group - 12/99

Specialty Matched Consultant Advisory Panel - 4/2001

BCBSA Medical Policy Reference Manual, 12/18/02; 9.03.02

Specialty Matched Consultant Advisory Panel - 3/2003

For Policy renamed: Refractive Surgery

American Academy of Ophthalmology. Preferred Practice Pattern: Refractive errors. (2002).

Retrieved on 2/3/05 from

<http://www.aao.org/aao/education/library/ppp/loader.cfm?url=/commonspot/security/get-file.cfm&PageID=23356>

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 4/1/05

Specialty Matched Consultant Advisory Panel - 4/6/09.

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 9/16/10

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Specialty Matched Consultant Advisory Panel- 6/2011.
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 9/13/12
Specialty Matched Consultant Advisory Panel- 10/2012
Specialty Matched Consultant Advisory Panel review- 6/2013
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 9/12/13
Specialty Matched Consultant Advisory Panel review- 6/2014
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 9/11/14
Specialty Matched Consultant Advisory Panel review- 6/2015
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 3/10/16
Specialty Matched Consultant Advisory Panel review- 6/2016
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 3/9/17
Specialty Matched Consultant Advisory Panel review- 6/2017
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 3/8/18
Specialty Matched Consultant Advisory Panel review- 6/2018
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 3/14/19
Specialty Matched Consultant Advisory Panel review- 6/2019
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 3/12/20
Specialty Matched Consultant Advisory Panel review- 6/2020
Medical Director review 6/2020
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 3/11/21
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.14, 4/8/21(Archived)
Specialty Matched Consultant Advisory Panel review- 6/2021
Medical Director review 6/2021
Specialty Matched Consultant Advisory Panel review- 6/2022
Medical Director review 6/2022

Policy Implementation/Update Information

For Policy entitled: Refractive Keratoplasty

4/81	Original Policy: Experimental/Investigative
6/83	Reaffirmed: Experimental/Investigative
3/85	Revised: Radial Keratotomy Experimental/Investigative
3/88	Evaluated for Epikeratophakia: Investigational
3/88	Evaluated for Radial Keratotomy: Investigational
8/88	Evaluated for Keratophakia: Investigational
8/88	Evaluated for Keratomileusis: Investigational

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- 12/96 Revised: Reaffirmed policy and combined local and National Association policies. Epikeratophakia allowed for specific conditions.
- 6/97 Revised: Procedure was removed from the investigational list and revised to state that BCBSNC certificates do not provide benefits for refractive errors.
- 6/98 Reaffirmed: added definition of Keratoconus in section regarding Epikeratophakia.
- 11/99 Revised. Radial Keratotomy, Keratomileusis, and keratophakia changed from investigational to non-covered.
- 12/99 Medical Policy Advisory Group
- 1/00 Revised to add code S0800.
- 10/00 System coding changes.
- 4/01 Specialty Matched Consultant Advisory Panel review. No change in criteria. Policy reoutlined for clarity.
- 7/03 Specialty Matched Consultant Advisory Panel review 3/24/03. Added Laser in-situ keratomileusis (LASIK) to the following sections: Description, Policy (as not covered) and When not covered. Corrected description of Keratomileusis and Keratophakia. Description section revised for clarity. Under Policy and When not Covered listed all of the non-covered procedures. Policy status changed to "Active policy, no longer scheduled for routine literature review." Key words added.

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- 3/3/05 Added LASEK, intrastromal corneal ring segments, clear lens extraction, phakic intraocular lens implantation, conductive keratoplasty, laser thermal keratoplasty, astigmatic keratotomy, and intracorneal inlays to the following sections: Description, Policy (as not covered) and When not covered. Description section revised to further define refractive eye surgery and the added refractive surgical procedures. Added information to Policy Guidelines section re: difference between Phototherapeutic keratectomy and Photorefractive keratectomy; correction of astigmatism resulting from trauma or from previous eligible surgery; clarification re: corneal transplants (also called keratoplasties) and refractive keratoplasties. Definitions added.
- 7/7/05 Added verbiage indicating that the implantation of intrastromal corneal ring segments is considered investigational for keratoconus to the following sections: Policy, When not Covered and Policy Guidelines. Added new CPT Category III code 0099T (Implantation of Intrastromal Corneal Ring Segments) to Billing/Coding section. Code will be effective 7/1/05. Added key word and reference source. Notification given 7/7/05. Effective date 9/15/05.
- 12/3/07 Due to evolving technology in refractive surgery this policy will be removed from "no longer scheduled for routine literature review" status and will undergo routine literature review. (pmo)
- 6/30/08 Under "Benefits Application" section, added "Most BCBSNC certificates do not provide benefits for refractive eye surgery or side effects and complications of refractive eye surgery." Under "When Not Covered" section, added that most BCBSNC certificates exclude benefits for treatment of side effects and complications of non-covered services (e.g., refractive surgery). Information added re: therapeutic contact lenses, sometimes known as "bandage" lenses. Also added "The use of therapeutic (bandage) contact lenses following refractive surgery is not covered." Key words added. (pmo)
- 8/25/08 References to INTACS (intrastromal corneal ring segments) have been removed from this policy. A separate policy entitled Implantation of Intrastromal Corneal Ring Segments; policy number SUR6382, will be issued with this update. (pmo)

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- 4/27/09 Reference source added. No other changes. (pmo)
- 6/22/10 Policy Number(s) removed (amw)
- 7/19/11 Specialty Matched Consultant Advisory Panel review 6/29/2011. Reference added. No policy statement changes. (lpr)
- 3/30/12 Added HCPCS code S0596 to Billing/Coding section for April 2012 code update. (lpr)
- 4/17/12 Added HCPCS code C1780 to Billing/Coding section for April 2012 code update. (lpr)
- 11/13/12 Specialty Matched Consultant Advisory Panel review meeting 10/17/2012. Reference updated. No change to policy statement. (lpr)
- 7/16/13 Specialty Matched Consultant Advisory panel review meeting 6/19/2013. No change to policy statement. (lpr)
- 7/15/14 Specialty matched consultant advisory panel review meeting 6/24/2014. No change to policy statement. (lpr)
- 7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. No change to policy statement. (lpr)
- 7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. No change to policy statement. (lpr)
- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/28/2017. Reference added. No change to policy statement. (lpr)
- 8/10/18 Specialty Matched Consultant Advisory Panel review 6/2018. Reference added. No change to policy statement. (lpr)
- 7/16/19 Specialty Matched Consultant Advisory Panel review 6/19/2019. Reference added. No change to policy statement. (lpr)
- 6/30/20 Specialty Matched Consultant Advisory Panel review 6/17/2020. Reference added. Removed note to reference CMP “Implantation of Intrastromal Corneal Ring Segments” due to archival. No change to policy statement. Medical Director review. (lpr)
- 7/13/21 Specialty Matched Consultant Advisory Panel review 6/16/2021. Reference added. Medical Director review 6/2021. No change to policy statement. (lpr)
- 7/26/22 Specialty Matched Consultant Advisory Panel review 6/2022. Medical Director review 6/2022. (lpr)

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