

Medicare Part C Medical Coverage Policy

Refractive Surgical Procedures

Original Date: July 16, 1990 Review Date: October 18, 2024 Next Review: October 2025

*** This policy was implemented in the absence of National Coverage Determinations (NCD) or Local Coverage Determinations (LCD) coverage criteria. This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ***

DESCRIPTION OF PROCEDURE OR SERVICE

Refractive surgery refers to surgical procedures that change the refractive state of the eye and thereby correct vision problems such as nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. Such procedures may be carried out using specialized lasers, conventional instrumentation, or a combination of modalities. In most cases, refractive surgical procedures are performed for the purpose of reducing dependence on glasses or contact lenses.

Refractive Surgical Procedures include:

LASIK (laser in-situ keratomileusis) LASEK (laser epithelial keratomileusis) Epi-LASIK PRK (photorefractive keratectomy) PARK (photoastigmatic keratectomy) Astigmatic keratotomy (AK) Femtosecond laser astigmatic keratotomy (FLAK) Limbal relaxing incisions (LRI) Epikeratophakia Intrastromal corneal ring segments (INTACS) ReLEx (refractive lenticule extraction) Conductive keratoplasty Phakic intraocular lens implantation / implantable contact lens Clear lens extraction / refractive lens exchange Presbyopic lens exchange Scleral expansion surgery

Obsolete refractive procedures include radial keratotomy and standard keratomileusis. Both have been replaced by procedures that are more effective, more predictable and less prone to complications.

POLICY STATEMENT

Coverage will be provided for refractive surgical procedures when it is determined that such procedures are medically necessary, as outlined in the following guidelines and medical criteria.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE

Refractive surgical procedures are considered medically necessary in only a limited number of well-defined clinical scenarios, as outlined below.

- 1) LASIK, Epi-LASIK, LASEK, and PRK may be covered when ALL of the following are met:
 - a) Have undergone prior cataract extraction, full thickness corneal transplantation or scleral buckling surgery;
 - b) Are found to have post-surgical anisometropia of greater than 3 diopters; and
 - c) Are experiencing intolerable aniseikonia and/or binocular diplopia, not correctable with glasses or contact lenses.
- 2) PARK, AK, FLAK and LRI may be covered in members who have undergone prior full thickness corneal transplantation and have been left with greater than 3 diopters of surgically-induced astigmatism and persistent visual blurring / distortion, not correctable with glasses or contact lenses.
- 3) PRK may be covered when the procedure is used to treat corneal disease. In this context, it is referred to as phototherapeutic keratectomy, or PTK. PTK is considered medically necessary when employed in the treatment of the following pathologic conditions:
 - Superficial corneal scars and opacities

- Recurrent corneal erosion syndrome when more conservative measures (e.g. lubrication, hypertonic saline, bandage contact lenses, anterior stromal micro-puncture, and debridement of abnormal epithelium) have failed to prevent erosions
- Salzmann's nodules
- Reis-Buckler dystrophy
- Granular dystrophy (anterior stromal)
- Lattice dystrophy (anterior stromal)
- Band keratopathy
- 4) Intrastromal corneal ring segments may be covered in adult members with keratoconus who:

a) Have experienced progressive deterioration of vision;

b) Are no longer able to achieve adequate vision with glasses or contact lenses;

c) Have clear central corneas; and

d) Have a documented corneal thickness of at least 450 microns at the proposed incision site.

WHEN COVERAGE WILL NOT BE APPROVED

Refractive procedures performed to correct refractive errors and/or reduce dependence on glasses, contact lenses, or other prosthetic devices are specifically excluded from coverage.

Astigmatic keratotomy (AK), Femtosecond laser astigmatic keratotomy (FLAK) and Limbal relaxing incisions (LRI) performed in conjunction with cataract surgery are considered not medically necessary.

Radial keratotomy and keratoplasty to treat refractive defects are not covered.

Keratophakia (65765) and Keratomileusis (65760) are not covered by Medicare

SPECIAL NOTES

This policy does not apply to requests for eye refraction (92015).

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable codes:

66999 (unlisted procedure, anterior segment of eye) 65772 (corneal relaxing incision for surgically-induced astigmatism)

65785 (implantation of intrastromal corneal ring segments)

The Plan 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.

References:

- Medicare National Coverage Determination for Refractive Keratoplasty (ID #80.7); Effective date: 5/1/1997: Accessed via Internet site <u>NCD - Refractive Keratoplasty (80.7) (cms.gov) on 09/27/2024</u>
- 2. American Academy of Ophthalmology Refractive Errors and Refractive Surgery Preferred Practice Pattern 2017. Accessed at http://www.aaojournal.org/article/S0161-6420(22)00867-3/fulltext on 09/27/2024.

Policy Implementation/Update Information:

- Revision Dates:
 June 24, 1996; May 19, 1998; November 3, 2003; June 22, 2005; May 2007: Formatting changes; no criteria changes made; September 2009: Re-worded when coverage will be approved section; No criteria changes made; Formatting changes. December 8, 2011: Revised criteria to be consistent with CMS coverage policy.

 Revision Date:
 August 19, 2015; Updated Description of Procedure/Service section with current NCD language for staff clarification, removed PTK coverage criteria under Indications For coverage section, as no CMS language referencing this as criteria and added coverage of keratoplasty that treats specific corneal lesions per CMS guidance, updated section When Coverage Will Not Be Approved with identified procedures per NCD that are listed as non-covered by Medicare.

 Revision Date:
 December 21, 2016: Definition Section: Added "Refractive Surgical Procedures include radial keratotomy and
- Revision Date: December 21, 2016: Definition Section: Added "Refractive Surgical Procedures include radial keratotomy and standard keratomileusis. Both have been replaced by procedures that are more effective, more predictable and less prone to complications." Added "Refractive Surgical Procedures include" and a list. Removed the old paragraph format. Indications for Coverage section: "Refractive surgical procedures are considered medically necessary in only a limited number of well-defined clinical scenarios, as outlined below." (List with criteria). Removed old verbiage and included more updated information per American Academy of Ophthalmology. When Coverage will not be approved: Added Astigmatic keratotomy (AK), Femtosecond laser astigmatic keratotomy (FLAK) and Limbal relaxing incisions (LRI) performed in conjunction with cataract surgery are considered not medically necessary.
- Revision Date: January 16, 2019; No Critéria updates. Updated Reference #2 as the link was no longer accurate as this resource had been updated.

Revision Date: January 20, 2021; Annual Review; Added 1) a. "full thickness" corneal transplantation. 2)" full thickness" corneal transplantation- to distinguish from other transplant procedures like DSEK and DMEK per Ext. Physician Consultant. Removed 3) "Epikeratophakia may be covered in aphakic adult patients who are not candidates for secondary implantation of an intraocular lens due to one or more contraindications (e.g. vitreous in the anterior chamber, history of uveitis, severe anatomic abnormalities of the anterior chamber, significant corneal endothelial disease, or gross post-traumatic corneal irregularity)." Per consultant as this is no longer performed in the US.

Revision Date: January 18, 2023; Annual Review; External Physician Reviewed: did not recommend any changes; Minor Revisions only; Removed 65765 epikeratophakia under applicable codes; Updated reference #2 to reflect updated link

<u>Revision Date:</u> November 14, 2023: Added the following statement to the beginning of policy: "This policy was implemented in the absence of National Coverage Determinations (NCD) or Local Coverage Determinations (LCD) coverage criteria." Statement added to align with the 2024 CMS Final Rule.

Revision Date: October 18, 2024: Annual Review. External Physician Reviewed and suggested to add "when ALL of the following are met" under criteria #1. Link under references was updated.

Approval Dates:

Medical Coverage Policy Committee: October 18, 2024

Physician Group Advisory/UM Committee: November 14, 2023

Policy Owner: Beth Sell, BSN, RN, CCM, CPC-A Medical Policy Coordinator