

Policy Name:	Medical Po	licy: Refractive Corneal Surgery	Policy #:	MP-67	
Policy Information					
Owner Department:		Medical UM & Systems Department			
Owner:		Assigned Medical Director			
Electronic Signature/Date:		Krystal Revai (06/26/2023), Lori Slaughter	(06/22/2023)		

If there is a discrepancy between a medical policy and a patient's policy or plan document/summary plan description, the policy or plan document/summary plan descriptions provisions and limitations will govern the determination of benefits.

Purpose of the Policy

To make utilization decisions, Health Alliance uses written criteria based on sound clinical evidence for appropriately applying the criteria.

Statement of the Policy

To apply objective and evidence-based criteria when determining the medical appropriateness of health care services.

Examples of refractive surgery include provisionally covered phototherapeutic keratectomy (PTK) used to correct corneal diseases and many other non-covered refractive procedures commonly done to correct a refractive error and eliminate or reduce the need for glasses or contact lenses such as: photorefractive keratectomy (PRK, CPT-4 65400), photoastigmatic keratectomy (PARK), radial keratotomy (RK, 65771), and laser in situ keratomileusis (LASIK, 65760).

Intrastromal corneal ring segments (INTACS) are two semicircular arches made of synthetic material implanted into channels inside the corneal stroma to strengthen and reshape the cornea and help restore it to its natural shape for treatment of keratoconus.

NOTE: Please refer to plan documents for prior authorization necessity/status.

Interpretations

1. Phototherapeutic keratectomy (PTK) is covered for any of the following conditions:

- 1.1 Treatment of severe recurrent corneal erosions when all conservative measures have failed; or
- 1.2 Corneal scars and opacities; or
- 1.3 Epithelial membrane dystrophy, or
- 1.4 Irregular corneal surfaces due to Salzmann's nodular degeneration or keratoconus nodules; or
- 1.5 Superficial corneal dystrophy; and,
- 1.6 Prior approval by a Medical Director is required.
- 1.7 PTK performed to correct a refractive error and eliminate or reduce the need for glasses or contact lenses is NOT covered as they are not medically necessary (See <u>Statement of the Policy</u> above).

- 2. Phototherapeutic keratectomy is provisionally covered when the member has a history of surgical treatment of cataract, cornea, or scleral buckle for retinal detachment in the affected eye and clinical documentation supports evidence of symptoms that are due to:
- 2.1 Significant aniseikonia (eyes with unequal retinal imaging) or
- 2.2 Significant anisometropia (eyes with refractive powers that differ), and
- 2.3 Clinical documentation supports failure of prescription utilization (contact lenses, eye glasses or a combination of both) to achieve 20/40, or better visual function, and
- 2.4 Prior approval by a Medical Director is required.

3. Refractive Corneal Surgery for treatment of Keratoconus includes:

- 3.1 INTACS are covered in patients with myopia or astigmatism with keratoconus who are no longer able to achieve adequate vision using contact lenses or spectacles, have corneal thickness of 450 microns or greater, and for whom a corneal transplantation is the only remaining option. (Ref. #6)
- 3.2 Corneal Cross-Linking procedures (conventional epithelium-off) using riboflavin and ultraviolet light performed for keratoconus is covered when the member has progressive keratoconus who is failing conservative treatment with eyeglasses or rigid contact lenses and in the previous twelve months has:
 - 3.2.1 An increase of 1.00 diopter or more in the steepest keratometry measurement, OR
 - 3.2.2 A reduction in uncorrected visual acuity or best spectacle corrected acuity by more than one line, AND
 - 3.2.3 A clear central cornea with thickness of at least 400 microns (Ref. #4)
- 3.3 Corneal Cross-Linking procedures (epithelium-on) using riboflavin and ultraviolet light performed for keratonconus is not covered as is considered investigational (<u>Ref. #9</u>)
- 3.4 Corneal Cross-linking procedures for post-LASIK-related corneal ectasia are not covered per the Complications Arising from Non-Covered Services policy within the first 24 months from the time of the original LASIK procedure as 80% of post-LASIK corneal ectasia cases present within that timeframe. Corneal Cross-Linking for ectasia will be covered after 24 months from a LASIK procedure as corneal ectasia presenting after that timeframe may be caused by factors other than the LASIK procedure itself. (Ref. #10, 11)
- 4. Endothelial Keratoplasty (Descemet's stripping endothelial keratoplasty [DSEK], Descemet's stripping automated endothelial keratoplasty [DSAEK], and Descemet's membrane endothelial keratoplasty [DLEK]) are covered when
- 4.1 There is endothelial failure in an otherwise healthy cornea, AND
- 4.2 One of the following is present:
 - 4.2.1 Rupture of Descemet's membrane, OR
 - 4.2.2 Severe Corneal edema, OR
 - 4.2.3 Bullous keratoplathy, OR
 - 4.2.4 Mechanical complications due to corneal graft or ocular lens prostheses, OR
 - 4.2.5 Endothelial corneal dystrophy and other posterior corneal dystrophies.

NOTE: Medicare covers DSEK, DSAEK, and DLEK procedures; however, no criteria are stipulated defaulting to use of above criteria for Medicare Advantage members (Ophthalmology Management website).

Medicare Advantage Criteria details:

- NCD Refractive Keratoplasty (80.7) (cms.gov)
- Enter NCD or LCD ID in the Medicare website/link below for criteria details (and check for updates)
- MCD Search (cms.gov)

Codes

*Codes listed are for informational purposes only and do not necessarily indicate prior authorization is or is not required or coverage is guaranteed.

65760	Keratomileusis
65400	Excision of lesion, cornea (keractectomy, lamellar, partial), except pterygium
65771	Radial keratotomy
65785	Implantation of intrastromal corneal ring segments (INTACS)

Providers are required to indicate the diagnosis and procedure codes when requesting review of coverage.

References

- 1. Corneal Cross-Linking for the Treatment of Keratoconus". Hayes Brief, July 23, 2009 (annual review June 22, 2011).
- 2. Wayman LL. "Keratoconus". In: UpToDate, Post TW (ED.), UpToDate, Waltham, MA. (Accessed on March 9, 2019.)
- 3. Corneal Remodeling, (04/16/2012). Clinical Policy Bulletin # 0023, Aetna Inc.
- 4. Keratoconus Surgical Treatments, Humana Medical Policy, 5/26/22
- 5. <u>Refractive Errors and Refractive Surgery Preferred Practice Pattern</u>, American College of Ophthalmology,
- 6. Ophthalmology, Volume 108, Number 8, August 2001 P. 1409, INTACS Inserts for Treating Keratoconus.
- 7. Sumit G, McColgin AZ, Steinert RF. Phototherapeutic Keratectomy. San Francisco, CA: American Academy of Ophthalmology; 2013. https://www.aao.org/munnerlyn-laser-surgery-center/surface-ablation-photorefractive-keratectomy-lasek
- 8. Hayes, Inc. Hayes Technology Directory. Conventional Corneal Collagen Cross-Linking for Treatment of LASIK-Related Ectasia. Lansdale, PA; Hayes, Inc: Dec. 27, 2018.
- Hayes, Inc. Hayes Technology Directory. Comparative Effectiveness Review. Corneal Cross-Linking for the Treatment of Keratoconus. Lansdale, PA; Hayes, Inc.: February 15, 2018. Annual review: January 13, 2022.
- 10. Green stein SA, Hersh PS. Corneal crosslinking for progressive keratoconus and corneal ectasia: Summary of US multicenter and subgroup clinical trials. *Transl Vis Sci Technol.* 2021: 10(5): 13.
- 11. Randelman JB, Ruseel B, et al. Risk factors and prognosis for corneal ectasia after LASIK. *Ophthalm*;2003, 110(2): 267-275.

History

i i i stori y					
Created Date:	09/29/99				
Effective Date:	09/29/99				
Next Review Date:	06/26/2024				
Revision Date:	10/26/99	05/22/01	09/11/02 – MDC		
	07/26/06 – MDC	07/14/04 - MDC	07/25/05 – MDC		
	08/12/09 – MDC	07/13/11 – MDC	07/11/12 – MDC		
	07/08/13 – MDC	06/05/14	06/05/15		
	07/06/16	06/21/17 – MDC-Revised to add 1.7, PTK performed to correct a refractive error and eliminate or reduce the need for glasses or contact lenses is NOT covered.			
	12/13/17 – MDC-Approved without changes except for adding: NOTE: Custom InterQual Checksheet was created using the medical policy criteria below.				
	12/20/18 – MDC-Annual review, removal of Custom InterQual Checksheet language.				

04/16/19 – MDC-Language addition regarding time frame for post-LASIK corneal ectasia development, corneal cross-linking language updated.
05/19/20 – MDC-Annual review, no changes.
04/20/21 – MDC-Annual review, no changes.
06/21/22 – MDC-Annual review, revision of criteria for coverage of Corneal Cross-linking and addition of coverage of LASIK related corneal ectasia starting two years after LASIK procedure with treatment of corneal crosslinking.
06/20/23 – MDC-Annual review, Medicare information updated, no changes.