

(90305)

Medical Benefit		Effective Date: 01/01/13	Next Review Date: 07/19
Preauthorization	No	Review Dates: 05/07, 07/08, 05/09, 05/10, 05/11, 01/12, 09/12, 07/13, 07/14, 07/15, 07/16, 07/17, 07/18	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With disorders of corneal topography 	Interventions of interest are: <ul style="list-style-type: none"> Computer-assisted corneal topography/photokeratotomy 	Comparators of interest are: <ul style="list-style-type: none"> Manual corneal topography measurements 	Relevant outcomes include: <ul style="list-style-type: none"> Test accuracy Other test performance measures Functional outcomes

DESCRIPTION

Computer-assisted corneal topography (also called photokeratotomy or videokeratotomy) provides a quantitative measure of corneal curvature. Measurement of corneal topography is being evaluated to aid the diagnosis of and follow-up for corneal disorders such as keratoconus, difficult contact lens fits, and pre- and postoperative assessment of the cornea, most commonly after refractive surgery.

SUMMARY OF EVIDENCE

For individuals who have disorders of corneal topography who receive computer-assisted corneal topography/photokeratotomy, the evidence includes only a few studies. Relevant outcomes are test accuracy, other test performance measures, and functional outcomes. With the exception of refractive surgery, a procedure not discussed herein, no studies have shown clinical benefit (e.g., a change in treatment decisions) based on a quantitative evaluation of corneal topography. In addition, a large prospective series found no advantage with use of different computer-assisted corneal topography methods over manual corneal keratometry. Computer-assisted corneal topography lacks evidence from appropriately constructed clinical trials that could confirm whether it improves outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

Computer-assisted corneal topography is considered **not medically necessary** to detect or monitor diseases of the cornea.

BACKGROUND**DETECTION AND MONITORING DISEASES OF THE CORNEA**

Corneal topography describes measurements of the curvature of the cornea. An evaluation of corneal topography is necessary for the accurate diagnosis and follow-up of certain corneal disorders, such as keratoconus, difficult contact lens fits, and pre- and postoperative assessment of the cornea, most commonly after refractive surgery.

Assessing corneal topography is a part of the standard ophthalmologic examination of some patients.^{1,2} Corneal topography can be evaluated and determined in multiple ways. Computer-assisted corneal topography has been used for early identification and quantitative documentation of the progression of keratoconic corneas, and evidence is sufficient to indicate that computer-assisted topographic mapping can detect and monitor disease.

Various techniques and instruments are available to measure corneal topography: keratometer, keratoscope, and computer-assisted photokeratoscopy.

The keratometer (also referred to as an ophthalmometer), the most commonly used instrument, projects an illuminated image onto a central area in the cornea. By measuring the distance between a pair of reflected points in both of the cornea's two principal meridians, the keratometer can estimate the radius of curvature of two meridians. Limitations of this technique include the fact that the keratometer can only estimate the corneal curvature over a small percentage of its surface and that estimates are based on the frequently incorrect assumption that the cornea is spherical.

The keratoscope reflects a series of concentric circular rings off the anterior corneal surface. Visual inspection of the shape and spacing of the concentric rings provides a qualitative assessment of topography.

A photokeratoscope is a keratoscope equipped with a camera that can provide a permanent record of the corneal topography. Computer-assisted photokeratoscopy is an alternative to keratometry or keratoscopy for measuring corneal curvature. This technique uses sophisticated image analysis programs to provide quantitative corneal topographic data. Early computer-based programs were combined with keratoscopy to create graphic displays and high-resolution, color-coded maps of the corneal surface. Newer technologies measure both curvature and shape, enabling quantitative assessment of corneal depth, elevation, and power.

REGULATORY STATUS

A number of devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 1999, the Orbscan® (manufactured by Orbtex, distributed by Bausch and Lomb) was cleared by the Food and Drug Administration. The second-generation Orbscan II is a hybrid system that uses both projective (slit scanning) and reflective (Placido) methods. The Pentacam® (Oculus) is one of a number of rotating Scheimpflug imaging systems produced in Germany. In 2005, the Pentacam HR was released with a newly designed high-resolution camera and improved optics. FDA product code: MXK.

RELATED PROTOCOL

Implantation of Intrastromal Corneal Ring Segments

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are

considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Morrow GL, Stein RM. Evaluation of corneal topography: past, present and future trends. *Can J Ophthalmol.* Aug 1992;27(5):213-225. PMID 1393805
2. Wilson SE, Klyce SD. Advances in the analysis of corneal topography. *Surv Ophthalmol.* Jan-Feb 1991;35(4):269-277. PMID 2011820
3. Martinez-Abad A, Pinero DP, Ruiz-Fortes P, et al. Evaluation of the diagnostic ability of vector parameters characterizing the corneal astigmatism and regularity in clinical and subclinical keratoconus. *Cont Lens Anterior Eye.* Apr 2017;40(2):88-96. PMID 27931882
4. Weber SL, Ambrosio R, Jr., Lipener C, et al. The use of ocular anatomical measurements using a rotating Scheimpflug camera to assist in the Esclera(R) scleral contact lens fitting process. *Cont Lens Anterior Eye.* Apr 2016;39(2):148-153. PMID 26474924
5. Bhatoa NS, Hau S, Ehrlich DP. A comparison of a topography-based rigid gas permeable contact lens design with a conventionally fitted lens in patients with keratoconus. *Cont Lens Anterior Eye.* Jun 2010;33(3):128-135. PMID 20053579
6. DeNaeyer G, Sanders DR, Farajian TS. Surface coverage with single vs. multiple gaze surface topography to fit scleral lenses. *Cont Lens Anterior Eye.* Jun 2017;40(3):162-169. PMID 28336224
7. Bandlitz S, Baumer J, Conrad U, et al. Scleral topography analysed by optical coherence tomography. *Cont Lens Anterior Eye.* Aug 2017;40(4):242-247. PMID 28495356
8. Lee H, Chung JL, Kim EK, et al. Univariate and bivariate polar value analysis of corneal astigmatism measurements obtained with 6 instruments. *J Cataract Refract Surg.* Sep 2012;38(9):1608-1615. PMID 22795977
9. de Sanctis U, Donna P, Penna RR, et al. Corneal astigmatism measurement by ray tracing versus anterior surface-based keratometry in candidates for toric intraocular lens implantation. *Am J Ophthalmol.* May 2017;177:1-8. PMID 28185842
10. Ophthalmic Technology Assessment Committee Cornea Panel American Academy of Ophthalmology. Corneal topography. *American Academy of Ophthalmology. Ophthalmology.* Aug 1999;106(8):1628-1638. PMID 10442914