Protocol

Corneal Topography/Computer-Assisted Corneal Topography/Photokeratoscopy

(90305)

Medical Benefit		**Effective Date**: 01/01/13	**Next Review Date**: 07/23
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, 07/19, 07/20, 07/21, 07/22	

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.

RELATED PROTOCOL

Implantation of Intrastromal Corneal Ring Segments

Populations	Interventions	Comparators	Outcomes
Individuals: • With disorders of corneal topography	Interventions of interest are: • Computer-assisted corneal topography/photokeratoscopy	Comparators of interest are: • Manual corneal topography measurements	Relevant outcomes include: • Test accuracy • Other test performance measures • Functional outcomes

DESCRIPTION

Computer-assisted corneal topography (also called photokeratoscopy or videokeratography) 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/photokeratoscopy, 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 that the technology results in an improvement in the net health outcome.

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 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 2 principal meridians, the keratometer can estimate the radius of curvature of 2 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 Orbtek, distributed by Bausch and Lomb) was cleared by the FDA. The second-generation Orbscan II is a hybrid system that uses both projective (slit scanning) and reflective (Placido) methods. The Pentacam® (Oculus) is 1 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.

Table 1. Corneal Topography Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510.k No.	Indication
Galilei G6 Lens Professional	Sis Ag, Surgical Instrument Systems	07/25/2019	K182659	To scan, map and display the geometry of the anterior segment of the eye
VX130 Ophthalmic Diagnostic Device	Luneau SAS	4/24/2017	K162067	To scan, map and display the geometry of the anterior segment of the eye
Pentacam AXL	Oculus OptikGerate GMBH	1/20/2016	K152311	To scan, map and display the geometry of the anterior segment of the eye
ARGOS	Santec Corporation	05/16/2019 10/2/2015	K191051 K150754	To scan, map and display the geometry of the anterior segment of the eye
Allegro Oculyzer	Wavelight Ag	7/20/2007	K071183	To scan, map and display the geometry of the anterior segment of the eye
Heidelberg Engineering Slitlamp-Oct (Sl-Oct)	Heidelberg Engineering	1/13/2006	K052935	To scan, map and display the geometry of the anterior segment of the eye
Cm 3910 Rotating Double Scheimpflug Camera	Sis Ltd. Surgical Instrument Systems	9/28/2005	K051940	To scan, map and display the geometry of the anterior segment of the eye
Pathfinder	Massie Research Laboratories Inc.	9/2/2004	K031788	To scan, map and display the geometry of the anterior segment of the eye
NGDI (Next Generation Diagnostic Instrument)	Bausch & Lomb	7/23/2004	K040913	To scan, map and display the geometry of the anterior segment of the eye
Pentacam Scheimpflug Camera	Oculus OptikGerate GMBH	9/16/2003	K030719	To scan, map and display the geometry of the anterior segment of the eye
Anterior Eye-Segment Analysis System	Nidek Inc.	8/6/1999	K991284	To scan, map and display the geometry of the anterior segment of the eye
Orbscan	Technolas Perfect Vision GMBH	3/5/1999	K984443	To scan, map and display the geometry of the anterior segment of the eye

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Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services 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.

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