09.03.01 Computer-Assisted Corneal Topography

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Original Effective Date: November 1997

Review Date: May 2025

Revised: January 2023

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Related Policies:

09.03.13 Optical Coherence Tomography of the Anterior Eye Segment

Summary

Description

Computer-assisted corneal topography (also known as corneal topography, computerized corneal topography, computer-assisted keratography, 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 a single RCT and multiple nonrandomized

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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. There are other uses for computer assisted corneal topography for other conditions (i.e., as bullous keratopathy, corneal dystrophies, corneal ectasia, microphthalmia, post-traumatic corneal scarring, Sjögren's syndrome or transplanted corneal scarring) which have no identified RCTs or systematic reviews. 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. However, even though there is a paucity of data in the peer-reviewed scientific literature for those who have disorders of corneal topography who receive computer-assisted corneal topography/photokeratoscopy, for certain carefully-selected individuals this testing is widely considered to be in accordance with generally accepted standards of medical practice in the United States and will be considered medically necessary when the criteria below are met (see Policy).

Additional Information

None

OBJECTIVE

The objective of this evidence review is to evaluate whether computer-assisted corneal topography improves net health outcomes for individuals with disorders of corneal topography, such as keratoconus.

PRIOR APPROVAL

Not applicable.

POLICY

Evaluation

Computer-assisted corneal topography may be considered medically necessary to evaluate the following corneal conditions:

- Bullous keratopathy
- Corneal dystrophies
- Corneal ectasia
- Keratoconus for an initial diagnosis and monitoring disease progression
- Irregular corneal astigmatism
- Post-traumatic corneal scarring
- Transplanted cornea complications

Investigational

Computer-assisted corneal topography is considered investigational when the above criteria has not been met as the evidence is insufficient to determine the effects of the technology on net health outcomes.

POLICY GUIDELINES

Coding

See the Codes table for details.

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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. 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.

- **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 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.
- **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.
- **Photokeratoscopy** (also known as Computer Assisted Video Keratography [CAVK] and corneal mapping) 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.

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Regulatory Status

A number of corneal topography devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (Table 1). In 1999, the Orbscan® (manufactured by Orbtek, distributed by Bausch and Lomb) was cleared by the FDA. The second-generation Orbscan II is a

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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.

Please note the table below is not intended to be an all-inclusive list.

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

Corneal Topography			
Device	**Manufacturer**	**Clearance Year**	**Indication**
ALLEGRO OCULYZER	WAVELIGHT AG	2007	To scan, map and display the geometry of the anterior segment of the eye. 510 (k) Number: K071183
ANTERIOR EYE-SEGMENT ANALYSIS SYSTEM	NIDEK INC.	1999	To scan, map and display the geometry of the anterior segment of the eye. 510 (k) Number: K991284
ARGOS	SANTEC CORPORATION	2019/2015	To scan, map and display the geometry of the anterior segment of the eye. 510 (k) Number: K191051 / K150754
CM 3910 ROTATING DOUBLE SCHEIMPFLUG CAMERA	SIS LTD. SURGICAL INSTRUMENT SYSTEMS	2005	To scan, map and display the geometry of the anterior segment of the eye. 510 (k) Number: K051940
Galilei G6 Lens Professional	SIS AG, SURGICAL INSTRUMENT SYSTEMS	2019	To scan, map and display the geometry of the anterior segment of the eye. 510 (k) Number: K182659
HEIDELBERG ENGINEERING SLITLAMP-OCT (SL-OCT)	HEIDELBERG ENGINEERING	2006	To scan, map and display the geometry of the anterior segment of the eye. 510 (k) Number: K052935
Hp-Oct	Cylite Pty Ltd	03/08/2024	Non-contact imaging and analysis of ocular structures. 510 (k) Number: K231760
MS-39	C.S.L. S.R.O.	09/01/2023	To capture scans of the anterior segment of the eye. Number: K221601

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Corneal Topography			
Device	**Manufacturer**	**Clearance Year**	**Indication**
MYAH	VISIA Imaging S.R.L.	03/01/2022	To measure the axial length of the eye in a population age 5 and above; to capture and store digital images of meibomian glands in adults. Number: K211868
Myopia Master	OCULUC OPTIKERATE GMBH	07/14/2021	To measure the axial length of the eye. Number: K202989
NGDI (NEXT GENERATION DIAGNOSTIC INSTRUMENT)	BAUSCH & LOMB	2004	To scan, map and display the geometry of the anterior segment of the eye. 510 (k) Number: K040913
ORBSCAN	TECHNOLAS PERFECT VISION GMBH	1999	To scan, map and display the geometry of the anterior segment of the eye. 510 (k) Number: K984443
ORBSCAN II	BAUSCH & LOMB	____________	A hybrid system that uses both projective (slit scanning) and reflective (Placido) methods.
PATHFINDER	MASSIE RESEARCH LABORATORIES INC.	2004	To scan, map and display the geometry of the anterior segment of the eye. 510 (k) Number: K031788
Pentacam AXL	OCULUS OPTIKGERATE GMBH	2016	To scan, map and display the geometry of the anterior segment of the eye. 510 (k) Number: K152311
Pentacam AXL Wave	OCULUS OPTIKGERATE GMBH	10/21/2020	To scan, map and display the geometry of the anterior segment of the eye. Number: K201724
PENTACAM SCHEIMPFLUG CAMERA	OCULUS OPTIKGERATE GMBH	2003	To scan, map and display the geometry of the anterior segment of the eye, a rotating imaging system. 510 (k) Number: K030719
VX130 Ophthalmic Diagnostic Device	LUNEAU SAS	2017	To scan, map and display the geometry of the anterior segment of the eye. 510 (k) Number: K162067

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RATIONALE

Computer-Assisted Corneal Topography

Clinical Context and Test Purpose
The purpose of computer-assisted corneal topography is to provide a diagnostic option that is an alternative to or an improvement on existing therapies, such as manual corneal topography measurements, in individuals with disorders of corneal topography.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with disorders of corneal topography/photokeratoscopy.

Interventions
The test being considered is computer-assisted corneal topography/photokeratoscopy.

Comparators
Comparators of interest include manual corneal topography measurements.

Outcomes
The general outcomes of interest are test accuracy, other test performance measures, and functional outcomes.

Identifying clinically validity and usefulness requires short-term follow-up. Evaluating functional outcomes may require longer follow-up.

Study Selection Criteria
Below are selection criteria for studies to assess whether a test is clinically valid.

- The study population represents the population of interest. Eligibility and selection are described.
- The test is compared with a credible reference standard.
- If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
- Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (e.g., receiver operating characteristic, area under receiver operating characteristic, c-statistic, likelihood ratios) may be included but are less informative.
- Studies should also report reclassification of diagnostic or risk category.

Review of Evidence
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Martinez-Abad et al. (2017) sought to determine whether 3 vector parameters: ocular residual astigmatism, topography disparity, and corneal topographic astigmatism (anterior and total) could serve to detect clinical and subclinical keratoconus. One hundred sixty-one eyes were studied in this retrospective comparative study; 61 eyes (38 patients) with keratoconus; 19 eyes (16 patients) with subclinical keratoconus; and a control group of 100 healthy eyes. All study participants underwent a thorough eye exam; further, software was used (iASSORT) to calculate ocular residual astigmatism, topography

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disparity, and corneal topographic astigmatism. Using a receiver operating characteristic curve analysis, the diagnostic capabilities of the 3 parameters were measured; to further assess diagnostic ability, a cutoff was determined that correlated to the highest sensitivity and specificity of the curve. Results showed that ocular residual astigmatism and topography disparity had good diagnostic capability to detect keratoconus (ocular residual astigmatism: cutoff, 1.255 diopters; sensitivity: 82%; specificity: 92%; topography disparity: cutoff, 1.035 diopters; sensitivity, 78.5%; specificity, 86%). Corneal topographic astigmatism did not show potential as a diagnostic tool. The authors concluded that TD and ORA were beneficial tools for detecting subclinical keratoconus.

Section Summary: Clinically Valid

One study has been identified evaluating computer-assisted corneal topography as a clinically valid solution for diagnosing disorders of corneal topography. In it, authors concluded that topography disparity and ocular residual astigmatism, 2 vector parameters that could serve to detect clinical and subclinical keratoconus, were beneficial tools for detecting the disorder.

Clinically Useful

A test is clinically useful if use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for individuals managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

Contact Lens Fitting

In a study of computer-assisted corneal topography, Bhatoa et al (2010) assessed the design of gas-permeable contact lens in 30 patients with keratoconus who were recruited in 2005 and 2006. The report indicated that the subjects were consecutive, although patients whose topographic plots could not be used were excluded (number not described). The fit of the new lens was compared with the fit of the patient’s habitual lens (randomized order on the same day). Clinical evaluation showed a good fit (no or minor modification needed) for more than 90% of the computer-designed lens. However, the progression of keratoconus caused a bias favoring the most recently fitted lens, confounding comparison between the new computer-designed lens and the patient’s habitual lens. Trial design and reporting limitations limit conclusions that can be drawn from this study.

Weber et al (2016) reported on a prospective, observational study evaluating the association between computer-assisted corneal topography measurements (Pentacam) and scleral contact lens fit. The study included 47 patients (63 eyes) with a variety of indications for scleral contact lenses, most commonly (n=24 eyes) keratoconus. Pentacam measurements correlated with a subset of the scleral contact lens parameters (corneal astigmatism, anterior chamber depth, and corneal height; p<.001, not adjusted for multiple comparisons) for the group as a whole.

DeNaeyer et al (2017) investigated the use of the sMap3DTM system (Precision Ocular Metrology), which measures the surface of the eye for patients in need of a scleral contact lens fitting. The sMap3D captures a series of images to produce a single, wide-field topographic “stitched” image of all captured images. To create these images, the patient is asked to provide several “gazes” (gaze up, gaze down, gaze straight). Twenty-five eyes (23 patients) were examined using the sMap3D. The “stitched” image produced by the sMap3D was then compared with the single captured straight-gaze image. At a diameter of 10 mm from the corneal center, both straight-gaze image and the sMap3D-stitched image displayed

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100% coverage of the eye. However, at 14 mm, the straight-gaze image only mapped 68% of the eye; at 15 mm, 53%; at 16 mm, 39%, and at 20 mm, 6%. For the stitched image produced by sMap3D, coverage was: at 14 mm, 98%; at 15 mm, 96% ; at 16 mm, 93% ; and at 20 mm, 32%. While there was a significant drop off in coverage between 16 mm and 20 mm for the sMap3D image, the stitched image was considerably more accurate than the straight-gaze image. Tables 2 and 3 provide a summary of the above study characteristics and results.

Bandlitz et al (2017) studied the profile of the limbal sclera in 8 meridians by using spectral domain optical coherence tomography and a confocal scanning laser ophthalmoscope. The objective of this study was to evaluate the relationship between central corneal radii, corneal eccentricity, and scleral radii to improve soft and scleral contact lenses. The limbal scleral radii of 30 subjects were measured. Eight meridians, each 45° apart, were scanned, and it was determined that corneal eccentricity and scleral radii did not correlate in any of the meridians. The authors concluded that the independence between meridians might prove useful in fitting soft and scleral contact lenses.

Table 2. Summary of Key Study Characteristics

Study	Study Type	Country	Dates	Participants	Treatment 1	Treatment 2	Follow-Up
Bhatoa et al. (2010)	Randomized, prospective	U.K.	2005 - 2006	Patients with keratoconus (n=30)	Gas-permeable contact lenses made using Fitscan RGP fitting software	Patients habitual RGP contact lenses	NR
Weber et al. (2016)	Prospective, observational	Brazil	2013	Patients with a variety of indications for scleral contact lenses (n=47 patients, 63 eyes)	Pentacam derived topography variables for SCL fit	NA	NR
DeNaeyer et al. (2017)	Retrospective	U.S.	2016	Patients presenting for scleral lens fitting (n=23 patients, 25 eyes)	sMap3D stitched imaging	Straight-gaze imaging	NR

NA: not applicable; NR: not reported; RGP: rigid gas permeable; SCL: scleral contact lens; U.K.: United Kingdom; U.S.: United States.

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Table 3: Summary of Key Study Results

Study	Agreement Levels between Techniques	Correlations between SCL Parameters and ACD and Hm	Eye Coverage at 10, 14, 16, and 20 mm
Bhatoa et al. (2010)	74% to 100%		
Weber et al. (2016)		p<.001, each	
DeNaeyer et al. (2017)			
Straight-gaze			100%, 68%, 39%, 6%
Stitched			100%, 98%, 93%, 32%

ACD: anterior chamber depth; Hm: Pentacam-measured corneal height; SCL: scleral contact lens.

Corneal Astigmatism Measurements for Toric Intraocular Lens Implantation

Lee et al (2012) reported on a prospective comparative study of 6 methods for measuring corneal astigmatism to guide toric intraocular lens implantation. Astigmatism was evaluated in 257 eyes (141 patients) using manual keratometry, auto keratometry, partial coherence interferometry (IOLMaster®), ray-tracing aberrometry (iTrace®), scanning-slit topography (Orbscan), and Scheimpflug imaging (Pentacam). Each instrument's measurements were masked to the results for the other instruments. The study found no significant difference between instruments, indicating no advantage to computerized corneal topography over manual keratometry.

de Sanctis et al (2017) reported on corneal astigmatism in patients seeking toric intraocular lens implantation. The authors compared 2 methods for measuring corneal astigmatism: (1) corneal astigmatism total corneal refractive power, which uses a ray-tracing method that sends light through the cornea; and (2) corneal astigmatism simulated keratometry, which is a surface-based exterior measurement that measures the steep radius of the anterior cornea. Both methods relied on the camera system (Pentacam HR) to calculate vector differences. Of 200 patients, 77 (60 eyes) remained for intraocular lens implantation. For a patient to qualify for toric intraocular lens implantation, corneal astigmatism had to be greater than 1 diopter. Using corneal astigmatism total corneal refractive power, 17 eyes were found with greater than 1 diopter; using corneal astigmatism simulated keratometry, 13 eyes were found with greater than 1 diopter. However, of the 77 intraocular lens implantation candidates, the corneal astigmatism simulated keratometry method assessed 17 patients to have corneal astigmatism less than or equal to 1 diopter. Moreover, the corneal astigmatism simulated keratometry method found 13 of 123 patients who were not candidates for implantation to have astigmatism greater than 1 diopter. This difference suggested potential issues with patient selection criteria.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. As the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

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A chain of evidence would demonstrate that computer-assisted corneal topography can identify individuals with disorders of corneal topography who would not otherwise be identified that treatments are available for these individuals that would not otherwise be given to individuals with disorders of corneal topography, and that these treatments improve health outcomes. Therefore, a chain of evidence cannot be created for clinical utility.

Section Summary: Clinically Useful

Direct evidence for the clinical usefulness of computer-assisted corneal topography in diagnosing those with disorders of corneal topography is lacking. A chain of evidence for clinical validity provides a chain of evidence on clinical usefulness of this testing.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

The American Academy of Ophthalmology (AAO)

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Cataracts

In 2021 the AAO Preferred Practice Pattern® Guidelines for Cataract in the Adult Eye stated, “When postoperative visual improvement is less than anticipated, the ophthalmologist may perform additional diagnostic testing to evaluate the cause. For example, if maculopathy is suspected, OCT or fluorescein angiography would be appropriate to diagnose cystoid or diffuse macular edema, epiretinal membranes, or AMD. Likewise, corneal topography *could* help diagnose irregular corneal astigmatism. Automated visual fields may help diagnose a neuro-ophthalmic abnormality. Other testing may be conducted if appropriate.”

Corneal Edema and Opacification (Initial Evaluation)

In 2023 the AAO Preferred Practice Pattern® Full Set review on corneal edema and opacification (initial evaluation) topography is recommended as a diagnostic test.

Corneal Ectasia

In 2023 the AAO Preferred Practice Pattern® Full Set review on corneal ectasia states the following: Initial evaluation of the patient who has symptoms and signs of corneal ectasia should include the relevant aspects of the comprehensive medical eye evaluation. The diagnosis of corneal ectasia is usually based on a typical patient history and characteristic findings on topography and tomography.

Dry Eye Syndrome

In December 2023 the AAO Preferred Practice Pattern® Full Set reviewed Dry Eye Syndrome but provided no specific recommendation for computerized corneal topography.

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Refractive Management/Intervention

In December 2024 the AAO Preferred Practice Pattern® Full Set on Refractive Summary Benchmarks for Guidelines recommends computerized corneal topography/tomography for the initial physical exam.

National institute for Health and Care Excellence (NICE)

IN 2017 NICE issued a guideline called “Cataracts in adults: management” under preoperative assessment and biometry. “Consider corneal topography for people having cataract surgery:

- who have abnormally flat or steep corneas
- who have irregular corneas
- who have significant astigmatism
- who have had previous corneal refractive surgery or
- if it is not possible to get an accurate keratometry measurement”

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at https://www.clinicaltrials.gov/

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	92025	Computerized corneal topography, unilateral or bilateral, with interpretation and report
HCPCS		
	No code(s)	

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Codes	Number	Description
Type of Service	Ophthalmology	
Place of Service	Physician's Office	

POLICY HISTORY

Date	Reason	Action
May 2025	Annual Review	Policy Renewed
May 2024	Annual Review	Policy Renewed
May 2023	Annual Review	Policy Renewed
January 2023	Annual Review	Policy Revised
May 2022	Interim Review	Policy Revised
January 2022	Annual Review	Policy Revised
January 2021	Annual Review	Policy Renewed
January 2020	Annual Review	Policy Renewed
January 2019	Annual Review	Policy Renewed
January 2018	Annual Review	Policy Revised
January 2017	Annual Review	Policy Renewed
January 2016	Annual Review	Policy Revised
January 2015	Annual Review	Policy Revised
February 2014	Annual Review	Policy Renewed
March 2013	Annual Review	Policy Renewed
March 2012	Annual Review	Policy Renewed
April 2011	Annual Review	Policy Renewed

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New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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