Kansas City

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Corneal Topography / Computer-Assisted Corneal Topography/Photokeratoscopy

Policy Number: 9.03.05
Origination: 10/2000
Last Review: 10/2018
Next Review: 10/2019

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for corneal topography.

When Policy Topic is covered

Not Applicable.

When Policy Topic is not covered

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

Considerations

Non-computer assisted corneal topography is considered part of the evaluation/and management services of general ophthalmological services (CPT codes 92002–92014), and therefore this service should not be billed separately. There is no separate CPT code for this type of corneal topography.

Description of Procedure or Service

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

Computer-assisted topography/photokeratoscopy provides a quantitative measure of corneal curvature. Measurement of corneal topography is being evaluated for the diagnosis and follow-up of corneal disorders such as keratoconus, difficult contact lens fits, and pre- and postoperative assessment of the cornea, most commonly after refractive surgery.

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 service not discussed herein, no studies have shown clinical benefit (eg, 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.

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 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 FDA. 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.

Rationale

This evidence review was created in November 1997 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through January 26, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

We evaluated the literature with a focus on the question most pertinent to this evidence review: Does quantitative measurement result in a management change that improves health outcomes?

Computer-Assisted Corneal Topography/Photokeratoscopy

Detecting Keratoconus

Martinez-Abad et al (2017) sought to determine whether 3 vector parameters—ocular residual astigmatism (ORA), topography disparity (TD), and corneal topographic astigmatism (anterior and total)—could serve to detect clinical and subclinical keratoconus.[3] 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 ORA, TD, 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 ORA and TD had good diagnostic capability to detect keratoconus (ORA: cutoff, 1.255 diopters [D]; sensitivity: 82%; specificity: 92%; TD: cutoff, 1.035 D; 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.

Contact Lens Fitting

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.[4] 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; $p<0.001$, not adjusted for multiple comparisons) for the group as a whole.

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.[5] 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, progression of keratoconus causes 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 gaps limit conclusions that can be drawn from this study.

DeNaeyer et al (2017) investigated the use of the sMap3D system (Precision Ocular Metrology), which measures the surface of the eye for patients in need of a scleral contact lens fitting.[6] 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 (from 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 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: at 14 mm, 98% coverage; at 15 mm, 96% coverage; at 16 mm, 93% coverage; and at 20 mm, 32% coverage. 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.

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.[7] The objective of this study was to evaluate the relation between central corneal radii, corneal eccentricity, and scleral radii 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.

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 (IOL) implantation.[8] Astigmatism was evaluated in 257 eyes (141 patients) using manual keratometry, autokeratometry, 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 IOL implantation.[9] The authors compared 2 methods for measuring corneal astigmatism: (1) corneal astigmatism total corneal refractive power (CA_{TCRP}), which uses a ray-tracing method that sends light through the cornea; and (2) corneal astigmatism simulated keratometry (CA_{SimK}), 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 individuals (60 eyes) remained for IOL implantation. For a patient to qualify for toric IOL implantation, corneal astigmatism had to be greater than 1 D. Using corneal astigmatism total corneal refractive power CA_{TCRP}, 17 eyes were found with greater than 1 D; using CA_{SimK}, 13 eyes were found with greater than 1 D. However, of the 77 IOL implantation candidates, the CA_{SimK} method assessed 17 patients to have corneal astigmatism less than or equal to 1 D. Moreover, the CA_{SimK} method found 13 of 123 patients who were *not* candidates for implantation to have astigmatism greater than 1 D. This difference suggested potential issues with patient selection criteria.

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 (eg, 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.

Supplemental Information

Practice Guidelines and Position Statements

A 1999 American Academy of Ophthalmology (AAO) assessment indicated that computer-assisted corneal topography evolved from the need to measure corneal curvature and topography more comprehensively and accurately than keratometry and that corneal topography is used primarily for refractive surgery.[10] AAO indicated several other potential uses: (1) to evaluate and manage patients following penetrating keratoplasty, (2) to plan astigmatic surgery, (3) to evaluate patients with unexplained visual loss and document visual complications, and (4) to fit contact lenses. However, the AAO assessment noted the lack of data supporting the use of objective measurements (as opposed to subjective determinants, like subjective refraction) of astigmatism.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in February 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

References

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Billing Coding/Physician Documentation Information

92025	Computerized corneal topography, unilateral or bilateral, with interpretation and report
	ICD-10 Codes
H16.001-H16.9	Keratitis code range
H17.00-H17.9	Corneal scars and opacities code range
H18.001-H18.9	Other disorders of cornea code range

Non-computer-assisted corneal topography is considered part of the evaluation/and management services of general ophthalmologic services (CPT codes 92002–92014), and therefore this service should not be billed separately.

Additional Policy Key Words

N/A

Policy Implementation/Update Information

10/1/00	New policy added to the Medical section. Considered inclusive to the E/M service.
10/1/01	No policy statement changes.
10/1/02	No policy statement changes.
10/1/03	No policy statement changes.
10/1/04	No policy statement changes. Added S-code.

10/1/05	No policy statement changes.
10/1/06	No policy statement changes.
10/1/07	Policy statement revision made and implemented on the date noted below.
5/1/08	Policy statement revised to include computerized corneal topography which is considered investigational. Non-computerized corneal topography remains a component of the evaluation/and management services of general ophthalmologic services.
10/1/08	No policy statement changes.
10/1/09	No policy statement changes.
11/1/09	Policy statement changed from investigational to not medically necessary. This change is effective 12/1/2009.
10/1/10	No policy statement changes.
10/1/11	No policy statement changes.
10/1/12	No policy statement changes.
10/1/13	No policy statement changes.
10/1/14	No policy statement changes.
10/1/15	No policy statement changes.
10/1/16	No policy statement changes. Added Corneal Topography/ to title.
10/1/17	No policy statement changes.
10/1/18	No policy statement changes.
