9.03.05 Corneal Topography/Computer-Assisted Corneal Topography/Photokeratoscopy

**Summary**
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, corneal injury induced irregular astigmatism, and pre- and postoperative assessment of the cornea, most commonly after refractive surgery.

Analysis of a limited published research database indicates that there is clinical utility for corneal topography and that there are benefits in specific clinical situations:

2. Advanced keratoconus where a custom contact lens or scleral lens is being designed to avoid surgical intervention.
3. Corneal injury resulting in decreased vision where irregular astigmatism is suspected.
4. Decreased vision of unclear etiology where corneal ectasia is suspected but cannot be confirmed by keratometry.

Corneal topography is used as screening device in candidates for refractive surgery (a service not generally covered as a health insurance benefit).

For routine eye evaluations there is a lack of scientific evidence from appropriately constructed clinical trials that confirm improved health outcomes using computer assisted corneal topography. Therefore this procedure is considered **not medically necessary** for routine evaluations to detect or monitor diseases of the cornea.
9.03.05 Corneal Topography/Computer-Assisted Corneal Topography/ Photokeratoscopy

FDA REGULATORY STATUS

A number of devices have received clearance for marketing through the U.S. Food and Drug Administration (FDA) 510(k) mechanism. The Orbscan (manufactured by Orbtek and distributed by Bausch and Lomb) received FDA clearance in 1999. 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. FDA product code: MXK.

POLICY STATEMENT

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Computer–assisted corneal topography may be medically necessary in certain clinical settings:

2. Advanced keratoconus where a custom contact lens or scleral lens is being designed to avoid surgical intervention.
3. Corneal injury resulting in decreased vision where irregular astigmatism is suspected.
4. Decreased vision of unclear etiology where corneal ectasia is suspected but cannot be confirmed by keratometry.

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

BENEFIT APPLICATION

The BCBS FEP contract stipulates that FDA-approved biologics, drugs and certain devices may not be considered investigational when used for their intended purpose and thus these products may only be assessed based on medical necessity.

RATIONALE

Literature Review

Detection and Monitoring Diseases of the Cornea

Assessing corneal topography has been done for many years and is a part of the standard ophthalmologic examination of some patients. (1, 2) However, 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 topographical mapping can detect and monitor disease.

Literature reviewed on PubMed through January 29, 2016, identified two studies on quantitative evaluation of the corneal topography using computer-assisted corneal topography. Both studies reported utility for the diagnosis of corneal disorders and planning of treatment by evaluating the effects of corneal topographical abnormalities in diseased corneas more accurately and non-invasively. (3, 4)

Ginka and Zasshi showed optical characteristics of the anterior and posterior surfaces of the cornea in patients with keratoconus or transparent marginal corneal degeneration. (3) Their findings clarified the
characteristics of serial alterations of high-order aberration in normal eyes, dry eye with tear deficiency and dry eye with tear evaporation. The effects of internal lubricating agents on soft contact lenses were also evaluated objectively. Corneal topographic analyses of the anterior and posterior surfaces in eyes with keratoconus or following keratoplasty were possible even when it was difficult for conventional corneal topographers to analyze accurately.

A study by Karnowski K, Kaluzny B J, Szkulmowski M, et al, reported quantitative analysis of corneas with pathological changes with three different instruments: The high-speed swept source (SS) optical coherence tomography (OCT), a Placido-based topographer, and a rotating Scheimpflug camera system. They demonstrated the applicability of the SS OCT for quantitative evaluation of the cornea. Based on their results they concluded SS OCT could be used for elevation-based topography and the evaluation of the corneal structure, to include the epithelium. Because a decrease in epithelial thickness masks the presence of an underlying cone on front surface topography, it was determined that SS OCT may be helpful in detecting keratoconus at an early stage.

**Contact Lens Fitting in Patients with Keratoconus**

A 2010 study was identified on computer-assisted corneal topography for the design of gas-permeable contact lens in 30 patients with keratoconus, who were recruited for the study in 2005-2006. (5) The report indicates that the subjects were consecutive, although patients whose topographical 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 the comparison between the new computer-designed lens and the patient's habitual lens. This study has substantial limitations in both design and reporting.

**Corneal Astigmatism Measurements for Toric Intraocular Lens Implantation**

In 2012, Lee et al. reported a prospective comparative study of 6 methods of measuring corneal astigmatism for the purpose of toric intraocular lens implantation. (6) 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). All measurements were masked to the results for the other instruments. The study found no significant difference between the different instruments, indicating no advantage to computerized corneal topography compared to manual keratometry.

**Summary of Evidence**

Analysis of a limited published research database indicates that there is clinical utility for corneal topography and that there are benefits in specific clinical situations:

2. Advanced keratoconus where a custom contact lens or scleral lens is being designed to avoid surgical intervention.
3. Corneal injury resulting in decreased vision where irregular astigmatism is suspected.
4. Decreased vision of unclear etiology where corneal ectasia is suspected but cannot be confirmed by keratometry.

Corneal topography is used as screening device in candidates for refractive surgery (a service not generally covered as a health insurance benefit).
For routine eye evaluations there is a lack of scientific evidence from appropriately constructed clinical trials that confirm improved health outcomes using computer assisted corneal topography. Therefore this procedure is considered not medically necessary for routine evaluations to detect or monitor diseases of the cornea.

**SUPPLEMENTAL INFORMATION**

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in February 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

**Practice Guidelines and Position Statements**

The American Academy of Ophthalmology (AAO) Ophthalmic Technology Assessment titled Corneal Topography OTA (1999, Maintained 2008) the standard specific applications for corneal topography are as follows (7):

- “To screen patients for irregular astigmatism, corneal warpage, and keratoconus prior to refractive surgery; to evaluate the cornea after refractive and cataract surgery and to understand patients’ visual complaints; to direct management after penetrating keratoplasty; to plan astigmatic surgery; to fit contact lenses in patients with irregular astigmatism; to evaluate unexplained visual loss and to determine visual complications from corneal dystrophies, scars, pterygia, recurrent erosions, and chalazia.

Further research is needed to evaluate these and other clinical applications for the optimal use of corneal topography.”

In the 2010 (and reaffirmed in 2015) AAO Preferred Practice Pattern publication from the AAO titled Comprehensive Adult Medical Eye Evaluation, lists the components of a comprehensive eye exam. (8) It goes on to state that, "Based on the patient's history and findings, additional tests or evaluations might be indicated to evaluate further a particular structure or function. These are not routinely part of the comprehensive medical eye clinical evaluation. Specialized clinical evaluation may include the following". A second list of specialized evaluations includes "Analysis of the corneal shape (e.g., keratometry and/or corneal topography)".

**Medicare National Coverage**

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

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**REFERENCES**

9.03.05 Corneal Topography/Computer-Assisted Corneal Topography/ Photokeratoscopy


### POLICY HISTORY

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<thead>
<tr>
<th>Date</th>
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