Computer-Assisted Corneal Topography

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This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and be updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

DESCRIPTION

Computer-assisted corneal topography (also known as corneal topography, computerized corneal topography, computer-assisted keratography, or videokeratography) is a computer-assisted diagnostic technique in which it is a representation of the geometrical properties of the corneal surface. The technique helps measure and evaluate the corneal shape and curvature as an alternative to manual keratometry. An evaluation of corneal topography is necessary for the accurate diagnosis and follow-up of certain corneal disorders, such as keratoconus, and pre- and postoperative assessment of the cornea. Various techniques and instruments are available to measure corneal topography:

- **Computer-Assisted Photokeratoscopy** (also known as Computer Assisted Video Keratography [CAVK] and corneal mapping) is an alternative to keratometry or keratoscopy in 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.

- **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. 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, are limitations of this technique.
- **Keratoscope** is an instrument that 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.

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 patients with disorders of corneal topography.

The question addressed in this evidence review is: Does computer-assisted corneal topography improve health outcomes for patients 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.

Interventions
The test being considered is computer-assisted corneal topography Patients with disorders of the eye which are actively managed by ophthalmologists, optometrists, and primary care providers.

Comparators
Comparators of interest include manual corneal topography measurements. Patients with disorders of the eye which are actively managed by ophthalmologists, optometrists, and primary care providers

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.

Literature

Astigmatism

(2017) De Sanctis et al. 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 individuals (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

(2017) Martinez-Abad et al. 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 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.

(2015) Lee et al. reported on a prospective comparative study of six 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), raytracing 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.

Keratoconus
(2020) Ono et al. completed an observational study and examined the characteristics of anterior and posterior corneal topography in keratoconic eyes more than 30 years after PK. Patients who maintained clear grafts for more than 30 years after PK were included and divided into the keratoconus (KC) group or other diseases (Others) group, based on the primary indication; 26 eyes of 26 patients were included. The KC group and the other group included 14 eyes and 12 eyes, respectively. The KC group subjects were younger at the time of surgery (p = 0.03). No differences were observed in best-spectacle-corrected VA, keratometric power, and central-corneal-thickness. Based on corneal topography using Fourier harmonic analyses, regular astigmatism in the anterior cornea was significantly larger (p = 0.047) and the spherical component in the posterior cornea was significantly lower (p = 0.01) in the KC group. The area under the receiver operating characteristic curve (AUC) of the spherical component, regular astigmatism, asymmetry component, and higher-order irregularity were 66.07 %, 63.10 %, 57.14 %, and 59.23 %, respectively, in the anterior cornea and 80.65 %, 52.98 %, 63.10 %, and 63.99 %, respectively, in the posterior cornea. The authors concluded that these findings suggested that Fourier harmonic analysis of corneal topography could be useful for patients with KC long after PK. Moreover, these researchers stated that prospective, clinical studies that examine more items, compare the pre-operative and post-operative data, and detect risk factors for recurrence are needed. The authors stated that this study had several drawbacks. First, the study design was retrospective, and the number of patients was small (n = 26) owing to the rarity of patients who have maintained clear grafts for more than 30 years after PK. These findings successfully disclosed significant differences in some parameters with Fourier harmonic analysis, although the small patient number could have resulted in a low detection power. Second, the frequency at which corneal topographic analysis was conducted was limited. With relatively stable corneal surfaces, patients did not need to frequently visit a medical facility and undergo corneal topographic analysis. Third, some patients underwent PK at another institution and their data were unavailable for pre-operative and post-operative comparison.

(2015 An UpToDate review by Wayman and colleagues on "Keratoconus states "Corneal topography -- The introduction of corneal topography has helped in the identification of subtle presentations, which can lead to an earlier diagnosis. Major topographic patterns found in keratoconus include asymmetric bowtie, with or without inferior steepening, and skewed radial axes. However, once the diagnosis is made, serially corneal topography is of little value in following patients".

(2012) Choi and Kim examined the longitudinal changes in corneal topographic indices over time in patients with mild keratoconus (KC) and determined predictive factors for the increase in corneal curvature. These investigators retrospectively reviewed the data of 94 eyes of patients with mild KC who had undergone computerized video-keratography (Orbscan IIz; Bausch & Lomb Surgical, Rochester, NY) at least twice at an interval of greater than or equal to 1 year. Patients with an increase of greater than or equal to 1.50 diopters (D) in the central keratometry (K) were placed in the progression group, and the others were placed in the non-progression group. In each group, the quantitative topographic parameters were compared and tested as predictive factors for KC progression. Additionally, corneal astigmatic changes were evaluated by means of vector analysis. In total, 94 eyes of 85 patients were included -- 25 of 94 (26.5 %) eyes showed progression of the central K greater than or equal to 1.50 D; progression took 3.5 years on average. Median time to progression by Kaplan-Meier analysis was 12 years. Significant predictors for KC progression were as follows: highest point on the anterior elevation from the anterior best-fit sphere (BFS), greater than or equal to 0.04 mm; irregularity index at 3 mm, greater than or equal to 6.5 D; irregularity index at 5 mm, greater than or equal to 6.0 D; thinnest pachymetry, less than 350 μm at baseline examination; yearly change rate of anterior BFS, greater than or equal to 0.1 D/year; central K, greater than or equal to 0.1 D/year; simulated K in maximum, greater than or equal to 0.15 D/year; simulated K in minimum, greater than or equal to 0.2 D/year; and anterior chamber depth, greater than or equal to 0.0 mm/year. The dominant with-the-rule pattern of astigmatism at the baseline examination was changed to an oblique pattern of astigmatism at the last examination. The authors concluded that mild KC tended to be progressive in approximately 25 % of patients, and progression lasted 3.5 years on average. They stated that longitudinal changes in the corneal topography quantitative indices can be used as predictors of KC progression.

(2012) Sedghipour et al. also published an article that reviewed corneal topography and use of the KISA% index in diagnosing keratoconus. This study compared the sensitivity and specificity of the KISA% index with the keratometry (K) value, inferior-superior (I-S) value, relative skewing of the steepest radial axes (SRAX), and keratometric astigmatism (AST) indices in 25 patients presenting with bilateral keratoconus. The authors concluded that the keratoconus percentage index (KISA%) was significantly more sensitive and specific than the other indices examined. Furthermore, it was significantly better at predicting positive and negative results than the other indices included in the study.

(2010) Bhatoa et al. completed a study of computer-assisted corneal topography and 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 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 limitations limit conclusions that can be drawn from this study.

Microphthalmia
(2015) Hu et al. determined the typical corneal changes in pure microphthalmia using a corneal topography system and identified characteristics that may assist in early diagnosis. Patients with pure microphthalmia and healthy control subjects underwent corneal topography analysis to determine degree of corneal astigmatism (mean A), simulation of corneal astigmatism (sim A), mean keratometry (mean K), simulated keratometry (sim K), irregularities in the 3 - and 5-mm zone, and mean thickness of 9 distinct corneal regions. Patients with pure microphthalmia (n = 12) had significantly higher mean K, sim K, mean A, sim A, 3.0 mm irregularity and 5.0 mm irregularity, and exhibited significantly more false keratoconus than controls (n = 12). There was a significant between-group difference in the morphology of the anterior corneal surface and the central curvature of the cornea. The authors concluded that changes in corneal morphology observed in this study could be useful in borderline situations to confirm the diagnosis of pure microphthalmia. These preliminary findings need to be validated by well-designed studies.

Miscellaneous
UpToDate (2018, reviewed December 2021) Arryo et al completed a Retinal Detachment review and does not mention corneal topography as a management tool. (*Accessed January 2022*)

UpToDate (2018, reviewed December 2021) Baer et al completed a Diagnosis and classification of Sjögren's syndrome review and does not mention corneal topography as a management tool. (*Accessed January 2022*)

Scleral Indications
(2017) Bandlitz et al. 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.

(2017) DeNaeyer et al. 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. 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. In conclusion it appears that a single straight-gaze image would introduce significant measurement inaccuracy in fitting scleral lenses using the sMap3D while a 3-gaze stitched image would not.

(2016) Weber et al. 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; $p<0.001$, not adjusted for multiple comparisons) for the group as a whole. In conclusion, there was a positive correlation between the LSD and ACD, even as LD and ACD in the keratoconus group. Thus, these results suggest that certain Pentacam measurements can be good predictors of the most appropriate Esclera lens to be fitted in keratoconus patients. A potential limitation noted is the small sample size of the studied patients.

Summary of Evidence

Based on the review of the peer reviewed medical literature while limitations were found in the literature related to computer-assisted corneal topography for assessing the detection of corneal diseases and irregular corneal conditions such as swelling, scarring, abrasions, deformities and irregular astigmatisms, study results have suggested for the indications below computerized corneal topography was useful in finding distortions in the curvature of the cornea monitoring eyes (e.g., a change in treatment decisions) and therefore the evidence is sufficient to determine that the technology results in meaningful improvement in the net health outcomes for the following indications:

- 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

For individuals who have disorders of the eye who receive computer-assisted corneal topography, the evidence includes a limited number of studies per the indication researched. 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 for the indications not listed above. 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.

Practice Guidelines and Position Statements

The American Academy of Ophthalmology (AAO)

- (1999) Assessment indicates 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. AAO indicates several other potential uses: (1) evaluate and manage patients following penetrating keratoplasty, (2) plan astigmatic surgery, (3) evaluate patients with unexplained visual loss and document visual complications, and (4) fit contact lenses. However, the AAO assessment noted that data are lacking to support the use of objective measurements, as opposed to subjective determinants (subjective refraction) of astigmatism. (*Accessed January 2022*)
- Cataracts
    - (2021) The American Academy of Ophthalmology Preferred Practice Pattern® Guidelines for Cataract in the Adult Eye noted the following statements:
        - 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. (*Accessed January 2022*)
- Corneal Ectasia
    - (2018) The American Academy of Ophthalmology Preferred Practice Pattern® Guidelines on Corneal Ectasia notes the following information regarding corneal topography:
        - Prevention and Early Detection:
            - Prior to refractive surgery, corneal topography and tomography performed following a period of contact lens abstinence should be reviewed for evidence of irregular astigmatism or abnormalities suggestive of keratoconus or other forms of corneal ectasia.

- Dry Eye Syndrome
    - (2018) The American Academy of Ophthalmology Preferred Practice Pattern® Guidelines for Dry Eye Syndrome provide no recommendation for computerized corneal topography. (*Accessed January 2022*)

- Glaucoma
    - (2020) The American Academy of Ophthalmology Preferred Practice Pattern® Glaucoma Summary Benchmarks optical coherence tomography (OCT) is not mentioned as a key element in the workup and management of glaucoma. (*Accessed January 2022*)

- Herpes Simplex Virus Keratitis
    - (2014) The American Academy of Ophthalmology guideline on Herpes Simplex Virus Keratitis: A Treatment Guideline does not include a recommendation for corneal topography. (*Accessed January 2022*)

- Refractive
    - (2018) The American Academy of Ophthalmology Preferred Practice Pattern® Refractive Summary Benchmarks notes the following under the initial physical exam:
        - Distance visual acuity with and without correction
        - Manifest, and when appropriate, cycloplegic refraction
        - Computerized corneal topography/tomography
        - Central corneal thickness measurement
        - Evaluation of tear film and ocular surface
        - Evaluation of ocular motility and alignment

  (*Accessed January 2022*)

National institute for Health and Care Excellence (NICE)

- (2017) NICE issued a guideline, "Cataracts in adults: management" stating:
    - 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 (*Accessed January 2022*)

Regulatory Status

Several devices have received clearance for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The table below includes some FDA approved devices. *Please note this is not intended to be an all-inclusive list.*

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
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

Corneal Topography			
Device	**Manufacturer**	**Clearance Year**	**Indication**
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 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

PRIOR APPROVAL

Not applicable.

POLICY

See related medical policies:

- 09.03.13 Optical Coherence Tomography of the Anterior Eye Segment

Evaluation

An *evaluation* using computer-assisted corneal topography may be considered **medically necessary** for the following indications:

- 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

Routine, Serial Testing

Medically Necessary

Routine, serial testing using computer-assisted corneal topography is considered **medically necessary** for the indications listed above if documentation supports a change in vision.

Not Medically Necessary
Routine, serial testing using computer-assisted corneal topography is considered **not medically necessary** for the indications listed above if documentation does not support a change in vision.

Investigational
An *evaluation* and *routine serial testing* using computer-assisted corneal topography is considered **investigational** for all other indications as the evidence is insufficient to determine the effects of the technology on net health outcomes.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 92025 Computerized corneal topography, unilateral or bilateral, with interpretation and report

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POLICY HISTORY		
Date	**Reason**	**Action**
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

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

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
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