# Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 7/1/23**
**(See policy history boxes for previous effective dates)**

# Title: Corneal Hysteresis Measurement for Glaucoma

## Description/Background

Corneal hysteresis is an assessment of the cornea's ability to absorb and dissipate energy. The cornea's viscoelasticity measurement is the difference (measured in mm Hg) between the pressure at which the cornea bends inward during an air jet applanation (the abnormal flattening of a convex surface) and the pressure at which it bends out. The difference in intraocular pressure recorded during inward and outward flattening (applanation) is corneal hysteresis. The measurement is made during rapid motion of the cornea in response to the short duration (20-ms) air impulse. The air impulse causes the cornea to move inward, through applanation of the convex surface of the eye and into slight concavity. Milliseconds after applanation, the air pump shuts off and the cornea moves through a second applanation, while returning from concavity to its normal convex curvature. The rapid motion of the cornea during deformation creates velocity (rate)-dependent forces that oppose the pressure force created by the air impulse. These opposing forces absorb energy from the air impulse, causing time delays (hysteresis) in the occurrence of the applanation events. The differences in the pressures reflect the viscoelastic biomechanical property of the cornea.

Glaucoma is the second leading cause of blindness. Unfortunately, there is not a cure (yet), everyone is at risk and there may be virtually no warning. According to the Glaucoma Research Foundation, "it is estimated that over 3 million Americans have glaucoma, but only half of those know they have it". Glaucoma is a group of diseases that damage the eye's optic nerve and can result in vision loss and blindness. Untreated glaucoma will gradually cause damage to the eye(s), impairing vision in such a way that goes unnoticed until it is in an advanced stage.

Currently, intraocular pressure (IOP) is the most significant risk factor for glaucoma and is the only parameter for which treatment has been demonstrated to decrease glaucoma incidence and progression. IOP is the only modifiable risk factor for the development and progression of glaucoma.

The Goldman applanation tonometer (GAT) is currently, the most widely used method of measuring fluid inside the eye (intraocular pressure). GAT is considered the gold standard for evaluating IOP, which can lead to glaucoma. The tonometer makes a static measurement of the intraocular pressure (IOP) by the force required to flatten a fixed area of the cornea. The GAT determines the IOP indirectly by measuring the force required to applanate the cornea. The accuracy of GAT depends on many factors, including corneal thickness, corneal curvature, corneal structure and axial length.

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## Regulatory Status:

The Ocular Response Analyzer® (Reichert, Inc) was approved by the United States Food and Drug Administration (2004) through the premarket approval process. The FDA approved label indicates that the ORA device is intended to measure intraocular pressure of the eye and the biomechanical response of the cornea, for the purpose of aiding in the diagnosis and monitoring of glaucoma. An FDA approved update (2008) was received allowing for measurement of intraocular pressure of the eye and biomechanical response of the cornea. Product code: HKX

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## Medical Policy Statement

Corneal hysteresis testing is considered experimental/investigational. It has not been scientifically demonstrated to be as effective as standard testing.

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## Inclusionary and Exclusionary Guidelines

N/A

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## CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

### *Established codes:*

N/A

### *Other codes (investigational, not medically necessary, etc.):*

92145

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## Rationale

Martinez-de-la-Casa et al (2004) compared intraocular pressure (IOP) measurements obtained with ocular response analyzer (ORA) and the Goldmann applanation tonometer (GAT). ORA readings were consistently higher than GAT measurements (Goldmann-correlated IOP − IOP

GAT mean difference, 7.2 ± 3.5 mm Hg; corneal-compensated IOP – IOP GAT mean difference, 8.3 ± 4.0 mm Hg) However, differences were not constant and increased with increasing IOP GAT readings, both with respect to Goldmann-correlated IOP (slope = 0.623, P < 0.0001) and corneal-compensated IOP (slope = 0.538, P < 0.0001). Both pressure measurements provided by the ORA showed significant correlation with CCT (CCT versus Goldmann-correlated IOP: r = 0.460, P = 0.001; CCT versus corneal-compensated IOP: r = 0.442, P = 0.001). No significant effects of corneal curvature or refraction on any of the pressures were observed. Authors concluded that ORA significantly overestimates IOP compared with the GAT. Differences between both sets of measures increase as the GAT-determined IOP increases. ORA readings seem to be affected by central corneal thickness.

Congdon et al (2006) reported on a retrospective study of patients who underwent measurement of hysteresis on the Reichert Ocular Response Analyzer and measurement of central corneal thickness (CCT) by ultrasonic pachymetry. The study had 230 subjects with a diagnosis of primary open-angle glaucoma (POAG) or suspected POAG. In multivariate generalized estimating equation models a lower corneal hysteresis value was associated with visual field progression (p=0.03.) When axial length was included in the model, hysteresis was not a significant risk factor (p=0.09). A thinner CCT but not hysteresis, was associated with visual field progression. The conclusion was that a thinner CCT was associated with the state of glaucoma damage as indicated by cup-to-disc ratio (CDR), and the axial length and corneal hysteresis were associated with progressive visual field worsening. However, the relationship between corneal features and glaucoma is more complex than simple anatomic thickness. While it is not yet entirely clear what the corneal hysteresis measures, it does appear that this variable describes the response of the cornea to rapid deformation.

Mansouri et al (2011) analyzed the association between corneal biomechanical parameters using the Ocular Response Analyzer (ORA) and glaucoma severity in an observational cross sectional study. Two hundred ninety-nine eyes of 191 patients with confirmed or suspected glaucoma were evaluated. The authors opined that the findings “suggested a weak overall association between corneal biomechanics and disease severity.”

Nessim et al (2012) analyzed the relationship between measured intraocular pressure (IOP) and central corneal thickness (CCT), corneal hysteresis (CH) and corneal resistance factor (CRF) in ocular hypertension (OHT), primary open-angle (POAG) and normal tension glaucoma (NTG) eyes using multiple tonometry devices. Right eyes of patients diagnosed with OHT ($n$ = 47), normal tension glaucoma ($n$ = 17) and POAG ($n$ = 50) were assessed. IOP was measured in random order with four devices: Goldmann applanation tonometry (GAT); Pascal® dynamic contour tonometer (DCT); Reichert® ocular response analyser (ORA); and Tono-Pen® XL. CCT was then measured using a hand-held ultrasonic pachymeter. CH and CRF were derived from the air pressure to corneal reflectance relationship of the ORA data. Compared to the GAT, the Tonopen and ORA Goldmann equivalent (IOPg) and corneal compensated (IOPcc) measured higher IOP readings ($F$ = 19.351, $p$ < 0.001), particularly in NTG ($F$ = 12.604, $p$ < 0.001). DCT was closest to Goldmann IOP and had the lowest variance. CCT was significantly different ($F$ = 8.305, $p$ < 0.001) between the 3 conditions as was CH ($F$ = 6.854, $p$ = 0.002) and CRF ($F$ = 19.653, $p$ < 0.001). IOPcc measures were not affected by CCT. The DCT was generally not affected by corneal biomechanical factors. The authors concluded that “as the true pressure of the eye cannot be determined non-invasively, measurements from any tonometer should be interpreted with care, particularly when alterations in the corneal tissue are suspected.”

De Moraes et al (2012) studied the relationship between central corneal thickness and corneal hysteresis and their impact on the rate of visual field changes in patients with glaucoma. A significant and moderate correlation was observed between corneal hysteresis and central corneal thickness. Corneal hysteresis was more strongly associated with visual field progression. However, it is not known whether there is a cause-effect relationship between visual field progression and corneal hysteresis.

Vu et al (2013) reported on a retrospective study of a cohort of patients under evaluation for glaucoma. The study examined the association between corneal hysteresis and structural makers of glaucoma damage measured by spectral domain optical coherence tomography (SD-OCT). The study observed that corneal hysteresis correlated the most with visual field mean deviation followed by average retinal nerve fiber layer (RNFL) thickness and vertical cup to disc ratio on the open angle glaucoma group. Univariable models showed corneal hysteresis varied as a function of visual field mean deviation and average RNFL thickness. Multivariable analysis including visual field mean deviation, age and average RNFL thickness and glaucomatous status found visual field mean deviation and age retained significant associations with corneal hysteresis.

Medeiros et al (2013) prospectively studied a cohort of glaucoma patients over an average of 4.0± 1.1 years to examining corneal hysteresis as a risk factor for glaucoma progression. The Ocular Response Analyzer was used to obtain baseline measurement of corneal hysteresis. Visual field changes during the study period were determined using the Visual Field Index (VFI).The study found corneal hysteresis had a significant effect of the rate of visual field progression. Lower corneal hysteresis was associated with more rapid loss of visual field.

Zhang et al (2016) studied the relationship between corneal hysteresis (CH) and progressive retinal nerve fiber layer (RNFL) loss in a cohort of patients with glaucoma. CH measurements were acquired using the Ocular Response Analyzer and RNFL measurements were obtained using spectral domain optical coherence tomography (SD-OCT). The study found lower CH was significantly associated with faster rates of RNFL loss over time.

Hayes (2018) identified 16 studies that evaluated CH testing for diagnosis of glaucoma, or for predicting the progression or response to treatment of glaucoma. Eleven prospective or retrospective cohort studies and 5 prospective case-control studies were examined, involving from 52 to 443 patients with follow-up times ranging from zero to 6.6 years. The report concluded that the test has some capacity to diagnose glaucoma, to predict risk for glaucoma progression, and to predict response of glaucoma to certain types of treatment; however, the evidence is comprised of very poor quality and lacked the rigor to determine diagnostic or prognostic accuracy. The role of CH testing in the management of patients with glaucoma and its impact on long-term health outcomes could not be determined due to the lack of evidence on the clinical utility of this test. Additional studies are needed to determine whether corneal hysteresis provides accurate diagnosis of glaucoma, prognosis of glaucoma progression, and prognosis of response to treatment. Studies that address these prognostic uses of corneal hysteresis could help establish this technique as a reliable source of information for guidance of glaucoma management.

Wang et al (2020) analyzed 15 studies. involving 1,506 eyes in the diabetic group and 2,190 eyes in the control group, to determine the changes in corneal biomechanical parameters in

patients with diabetes mellitus in comparison with controls. The diabetic group had significantly higher corneal hysteresis (CH), the corneal resistance factor (CRF), corneal-compensated intraocular pressure (IOPcc) and Goldmann-correlated intraocular pressure (IOPg) values than the control group. The pooled mean differences were 1.34 mmHg (95% confidence interval [CI] 0.60-2.08 mmHg, P < 0.001) for IOPg and 0.85 mmHg (95% CI 0.18-1.51 mmHg, P = 0.013) for IOPcc, 0.38 mmHg (95% CI 0.01-0.75, P = 0.047) for CH and 0.63 mmHg (95% CI 0.27-0.98, P = 0.001) for the CRF. Sensitivity analyses using the leave-one-out method showed a consistent significant difference between the groups (all P < 0.001). Corneal biomechanics changed in the patients with DM. High CH, CRF, IOPcc and IOPg values may be associated factors for diabetes mellitus. Authors concluded that future studies are warranted to clarify the underlying mechanisms and explore the relationship between corneal biomechanics, glaucoma and diabetes mellitus.

Drechsler et al (2022) evaluated 180 ultrasound biomicroscopy images from 44 eyes of 30 subjects (18 control and 12 glaucoma, mean age 5.2±8.0 years, range 0.2-25.8 years). Significant differences between congenital glaucoma cases and controls were identified in 16 of 21 measured parameters including angle-to-angle, central and peripheral corneal thicknesses, scleral integrated pixel density, anterior corneal radius of curvature, and posterior corneal radius of curvature. Eight parameters differed significantly between primary congenital glaucoma and glaucoma following congenital cataract surgery. Authors concluded that further studies are needed to determine whether corneal features associated with glaucoma can be used to diagnose or monitor progression of congenital glaucoma.

**Conclusion**
There is insufficient evidence in the peer-reviewed medical literature to establish the role of corneal hysteresis measurement in glaucoma risk assessment.

**PRACTICE GUIDELINES AND POSITION STATEMENTS**
At the present time, there are no practice guidelines or position statements that support the use of corneal hysteresis in the assessment and management of glaucoma risk or disease progression.

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## Government Regulations

### National:

There is no Medicare National Coverage Determination (NCD) for corneal hysteresis. There is a fee listed for procedure code 92145.

### Local:

**Corneal Hysteresis (L38211)** For services performed on or after: 10/14/19 **Revision Date**: 9/30/21

**Coverage Indications, Limitations, and/or Medical Necessity**
This is a NON-coverage policy for all **CORNEAL HYSTERESIS** assessments as a means of risk assessment or monitoring for progression of ophthalmic disease activity.

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated*

*and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*

## Related Policies

Continuous Intraocular Pressure Monitoring
Ophthalmologic Techniques for Evaluating Glaucoma
Optical Coherence Tomography Imaging, Anterior Eye

## References


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Acta Diabetol. 2020 Aug;57(8):973-981. doi: 10.1007/s00592-020-01481-0. Epub 2020 Mar 22. PMID: 32201905.
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*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 2/23/23, the date the research was completed.*

## Joint BCBSM/BCN Medical Policy History

| Policy Effective Date | BCBSM Signature Date | BCN Signature Date | Comments |
|---|---|---|---|
| 9/1/07 | 8/17/07 | 8/29/07 | Joint policy established |
| 9/1/08 | 7/3/08 | 7/3/08 | Routine maintenance |
| 9/1/10 | 6/19/10 | 6/22/10 | Routine maintenance |
| 5/1/12 | 2/21/12 | 2/21/12 | Routine maintenance |
| 11/1/13 | 8/22/13 | 8/27/13 | Routine maintenance |
| 3/1/14 | 12/12/14 | 12/29/14 | Routine maintenance; title changed from “Corneal Hysteresis Determination by Air Impulse Stimulation” to Corneal Hysteresis Measurement for Glaucoma”; code 0181T deleted; new code 92145 added. |
| 7/1/16 | 4/19/16 | 4/19/16 | Routine maintenance |
| 7/1/17 | 4/18/17 | 4/18/17 | Routine maintenance<br>LCD added |
| 7/1/18 | 4/17/18 | 4/17/18 | Routine maintenance |
| 7/1/19 | 4/16/19 | | Routine maintenance |
| 7/1/20 | 4/14/20 | | Routine maintenance |
| 7/1/21 | 4/20/21 | | Routine maintenance |
| 7/1/22 | 4/19/22 | | Routine maintenance |
| 7/1/23 | 4/18/23 | | Routine maintenance (slp)<br>Vendor Managed: N/A |

Next Review Date: 2nd Qtr, 2024

# BLUE CARE NETWORK BENEFIT COVERAGE
# POLICY: CORNEAL HYSTERESIS MEASUREMENT FOR GLAUCOMA

## I. Coverage Determination:

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|---|---|
| **Commercial HMO (includes Self-Funded groups unless otherwise specified)** | Not covered |
| **BCNA (Medicare Advantage)** | Refer to Medicare information under the Government Regulations section of this policy. |
| **BCN65 (Medicare Complementary)** | Coinsurance covered if primary Medicare covers the service. |

## II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.