Name of Policy: Corneal Hysteresis

Policy #: 354
Category: Medicine

Latest Review Date: July 2011
Policy Grade: Active Policy but no longer scheduled for regular literature reviews and updates.

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**

Glaucoma is one of the leading causes of blindness. The National Eye Institute reports that more than 2 million Americans have been diagnosed with glaucoma and another 2 million have the disease and are not diagnosed. It is estimated that more than 3 million Americans will have glaucoma by 2020. Glaucoma is a group of diseases that affects the optic nerve. It is generally caused by ocular hypertension as in the most common type, primary open angle glaucoma (POAG) but not always. Glaucoma can damage your vision gradually and may not be diagnosed until at an advanced state. Another type of glaucoma is acute angle-closure glaucoma and presents with completely different symptoms such as severe eye pain and nausea and vomiting. A third, much less common type of glaucoma, is low-tension glaucoma and is believed to be related to not enough blood reaching the optic nerve.

Hysteresis is a property of physical systems that do not instantly follow the forces applied to them. The reaction is slow or does not return completely to the original state. Another defines it as the lagging of an effect behind its cause. Corneal hysteresis (CH) is a measure of viscous damping in the corneal tissue. It is the energy absorption capability of the cornea. Corneal hysteresis is determined through inducing the cornea to move following an air pulse. The difference in pressure values at the inward and outward applanation (flattening of the cornea by pressure) event times is defined as corneal hysteresis and the average provides a corrected intraocular pressure (IOP) measurement for an accurate IOP monitoring. Corneal hysteresis is determined by the viscoelastic properties of the corneoscleral shell.

The Goldman applanation tonometry is the most widely used method of measuring intraocular pressure and it is also known that corneal parameters affect the accuracy of this instrument. This instrument is the gold standard in glaucoma measurement.

The Reichert Ocular Response Analyzer (ORA) received 510(k) clearance from the U.S. Food and Drug Administration on January 20, 2004. The approved indications are measurement of intraocular pressure and assessment of biomechanical response of the cornea as tools in the diagnosing and monitoring of patients with glaucoma. There is no requirement by the 510(k) clearance process to submit evidence of extensive safety and efficacy. The measurement of CH by the ORA device has also been proposed as a method to evaluate the potential for post-surgical complications in patients being considered for refractive surgery and for assessing the biomechanical properties of the cornea in keratoconus.

Keratoconus is a noninflammatory condition of unknown etiology affecting the central cornea characterized by thinning and bulging of the cornea. It may significantly affect vision due to irregular astigmatism and corneal scarring. Keratoconic eyes are known to be less rigid and more elastic than normal eyes and possibly may have a different hysteresis than normal eyes. One possible measure of ocular rigidity in keratoconus is hysteresis.

**Policy:**

**Corneal hysteresis measurement does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational**.
Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

**Key Points:**
It has been known for over 30 years that central corneal thickness (CCT) affects IOP measurement. Results from the Ocular Hypertension Treatment Study (OHTS) demonstrated that CCT is an important and independent risk factor for progression to initial glaucoma damage in persons with ocular hypertension. The association between CCT and glaucoma include, thinner corneas give lower IOP levels and may be subjected to less aggressive IOP-lowering therapy. Thinner corneas may be a risk factor due to an association with the response of the corneoscleral shell and the ocular vasculature to IOP-induced stress. Patients with thick corneas as determined by corneal pachymetry and ocular hypertension are not as likely to be at risk for progression of glaucoma.

Congdon et al (2006) reported on an observational study to measure the impact of CCT and corneal hysteresis as anatomic and physiologic parameters to the clinical features and history of progressive worsening among patients with glaucoma, ocular hypertension, or suspected glaucoma. They concluded that the relationship between corneal features and glaucoma is more complex than simple anatomic thickness. The authors also concluded that it is not clear what corneal hysteresis measures but that it does appear that this variable describes the response of the cornea to rapid deformation. In this study, hysteresis was more closely associated with eyes that demonstrated progressive change than was the CCT. They have also proposed that their results may give information about responsiveness of the eye to mean IOP or changes in IOP and should refocus interest to the behavior of the cornea rather than just the thickness of the cornea. The authors did cite several limitations to their study. This includes patient selection for the study as the participants were from an urban area serviced by a tertiary care facility. The data or clinical information gathered for the study was based on retrospective chart review. There was no standardized protocol for the measurement of some key outcomes. This study was only to report associations among corneal thickness, corneal deformability, and glaucoma damage. There was determination of how to direct patient care or to improve patient outcome.

Other published peer-reviewed literature consisted of studies evaluating correlations and associations between CH and established measures of intraocular pressure and CCT (Kotecha, 2006; Medeiros, 2006; Shah, 2006, 2007). These studies also do not demonstrate how CH measurement can be used to enhance patient management and improve patient health outcome.

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The American Academy of Ophthalmology (AAO) does not mention measurement of CH in its Preferred Practice Pattern for the evaluation and management of Primary Open Angle Glaucoma.

2011 Update
Some of the recently published peer-reviewed literature consists of studies that evaluate correlations and associations between CH and established measures of intraocular pressure and CCT. (Vanderwalle, 2009; Mangouritsas, 2009; Kopito, 2010; Renier, 2010; Carbonaro, 2010; Sullivan-Mee, 2009; Shah, 2008; Bayer, 2010; Schweitzer, 2010; Saad, 2009; Fontes, 2011; Bayoumi, 2010; Lau and Pye, 2011). These studies do not demonstrate how CH measurement can be used to enhance patient management and improve health outcomes. There is insufficient evidence available from the peer-reviewed literature to validate the clinical role for measurement of corneal hysteresis.

Key Words:
Glaucoma, corneal hysteresis, corneal, intraocular pressure, IOP, primary open angle glaucoma, POAG, keratoconus, Goldman tonometer, Reichert Ocular Response Analyzer, ORA, Ocular Response Analyzer

Approved by Governing Bodies:

Benefit Application:
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity. Pre-certification requirements: Not applicable
CPT Codes: 0181T Corneal hysteresis determination, by air impulse stimulation, bilateral, with interpretation and report

References:


**Policy History:**

Medical Policy Group, April 2009 (1)

Medical Policy Administration Committee, May 2009

Available for comment May 12-June 24, 2009

Medical Policy Group, July 2011; Updated Key Points and References

Medical Policy Group, September 2012: **Effective September 14, 2012 this policy is no longer scheduled for regular literature reviews and updates.**

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.*