CORNEAL HYSTERESIS AND INTRAOCULAR PRESSURE MEASUREMENT

Policy Number: 2014T0133M
Effective Date: July 1, 2014

INSTRUCTIONS FOR USE
This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee’s document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee’s specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage.
**COVERAGE RATIONALE**

Measurement of corneal hysteresis is unproven and not medically necessary for the diagnosis and management of corneal disorders and glaucoma.

There is insufficient evidence to evaluate corneal hysteresis measurement for the purpose of assessing corneal viscoelasticity. Studies do not demonstrate that the measurement of corneal hysteresis impacts health outcomes such as improving vision or increasing the detection of ocular disorders. Further investigation that demonstrates the clinical usefulness of this procedure is necessary before it can be considered proven.

Measurement of ocular blood flow by intraocular pressure sampling using an ocular blood flow tonometer is unproven and not medically necessary for the diagnosis and management of glaucoma and other ocular disorders.

There is insufficient evidence to evaluate ocular blood flow measurement. Studies do not demonstrate that the measurement of ocular blood flow improves health outcomes such as improving vision or increasing the detection of glaucoma and other ocular disorders. Further clinical trials demonstrating the clinical usefulness of this procedure are necessary before it can be considered proven.

Monitoring of intraocular pressure during vitrectomy is unproven and not medically necessary.

There is insufficient evidence to indicate that intraocular pressure improves health outcomes such as visual acuity recovery in patients who undergo vitrectomy. Additional clinical trials are required to determine if monitoring of intraocular pressure during vitrectomy accurately measures intraocular pressure and if it improves visual acuity recovery after vitrectomy.

Continuous monitoring of intraocular pressure for 24 hours or longer in patients with glaucoma is unproven and not medically necessary.

There is insufficient evidence to conclude that continuous monitoring of intraocular pressure improves health outcomes in patients with glaucoma. Further studies are needed to evaluate the long-term safety and tolerability of continuous monitoring of intraocular pressure before it can be implemented in clinical practice.

**APPLICABLE CODES**

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>67299</td>
<td>Unlisted procedure, posterior segment</td>
</tr>
<tr>
<td>0181T</td>
<td>Corneal hysteresis determination, by air impulse stimulation, bilateral, with interpretation and report</td>
</tr>
<tr>
<td>0198T</td>
<td>Measurement of ocular blood flow by repetitive intraocular pressure sampling, with interpretation and report</td>
</tr>
<tr>
<td>0329T</td>
<td>Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report</td>
</tr>
</tbody>
</table>

*CPT® is a registered trademark of the American Medical Association.*
DESCRIPTION OF SERVICES

Corneal hysteresis (CH) measurement assesses corneal resistance to deformation. CH has been proposed as a possible indicator of the viscoelastic properties in the cornea. The Ocular Response Analyzer® is an instrument that measures corneal hysteresis by using a rapid air impulse to apply force to the cornea. An advanced electro-optical system then monitors the deformation. Two independent pressure values are derived from the inward and outward applanation events. The difference between these two pressure values is corneal hysteresis. Low CH demonstrates that the cornea is less capable of absorbing (damping) the energy of the air pulse. Abnormalities in corneal hysteresis have been detected in a variety of corneal diseases, including keratoconus, Fuchs' dystrophy, and in post-LASIK patients. Glaucoma is another potential indication for corneal hysteresis measurement. The preferred method of measuring intraocular pressure is using a contact applanation method such as a Goldmann tonometer. Corneal compensated intraocular pressure (IOP), derived from the CH measure has been suggested as a superior measurement of IOP compared to the Goldmann tonometer measurement.

The ocular blood flow (OBF) tonometer measures intraocular pressure (IOP) and pulsatile OBF. It has been proposed that the IOP and OBF test results taken together increase the detection rate for glaucoma when compared to traditional tonometry, which measures only average IOP. The ocular Blood Flow Analyzer (BFA) (Paradigm Medical Industries, Inc.) is an electronic pneumotonometer that measures IOP 200 times per second over a period of 5-15 seconds and automatically measures OBF. The BFA is basically an OBF tonometer, using a pneumatic mode of operation.

IOP monitoring during vitrectomy may be accomplished indirectly by placing disposable blood pressure transducers into the line tubing utilized for vitrectomy infusion. It may also be monitored by inserting a catheter pressure transducer directly into the vitreous by an extra pars plana incision. In either approach, pressure measurements are obtained simultaneously during the various stages of the vitrectomy, including air-fluid exchange and gas-forced fusion. Monitoring IOP during vitrectomy surgery has been proposed to measure fluctuations in IOP that may have an adverse effect on retinal and optic nerve function and visual acuity recovery.

Devices, including contact lens sensors, are being developed to monitor eye pressure in glaucoma patients for 24 hours or longer. Currently, the Triggerfish® contact lens sensor (CLS) (Sensimed, Lausanne, Switzerland) is the only commercially available device that has been shown to be able to provide 24 hour IOP data. This device has not been approved by the U.S. Food and Drug Administration (FDA). The Triggerfish CLS is a disposable silicone contact lens with an embedded micro-electromechanical system, which measures changes in corneal curvature induced by variations in IOP. An antenna, mounted around the eye, receives the data, which are then transmitted to a recorder for analysis. These devices are being studied to determine if they improve detection and allow earlier treatment of glaucoma patients. See the following Web site for more information: http://www.sensimed.ch/en/products/sensimed-triggerfishr.html. Accessed April 2014

CLINICAL EVIDENCE

The clinical evidence was reviewed on April 13, 2014 with no additional information identified that would change the unproven and not medically necessary conclusion.

Corneal Hysteresis Measurement

In a systematic review and meta-analysis, Cook et al. (2012) assessed the agreement of tonometers available for clinical practice with the Goldmann applanation tonometer (GAT), the most commonly accepted reference device. A total of 102 studies, including 130 paired
comparisons, were included, representing 8 tonometers: dynamic contour tonometer, noncontact tonometer (NCT), ocular response analyzer, Ocuton S, handheld applanation tonometer (HAT), rebound tonometer, transpalpebral tonometer, and Tono-Pen. The agreement (95% limits) varied across tonometers: 0.2 mmHg (-3.8 to 4.3 mmHg) for the NCT to 2.7 mmHg (-4.1 to 9.6 mmHg) for the Ocuton S. The estimated proportion within 2 mmHg of the GAT ranged from 33% (Ocuton S) to 66% and 59% (NCT and HAT, respectively). Substantial inter- and intraobserver variability were observed for all tonometers. The authors concluded that the NCT and HAT seem to achieve a measurement closest to the GAT. However, there was substantial variability in measurements both within and between studies.

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, particularly in NTG. DCT was closest to Goldmann IOP and had the lowest variance. CCT was significantly different between the 3 conditions as was CH and CRF. According to the authors, this study suggests 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.

In a prospective longitudinal observational study, Sullivan-Mee et al. (2012) examined the factors that influence intraocular pressure (IOP) measurement agreement between Goldmann applanation (GAT), Ocular Response Analyzer (ORA), and Pascal Dynamic Contour tonometers (DCT). The study included 243 eyes in 243 subjects. The authors identified 5 factors, including corneal hysteresis, by multivariate regression as being independently associated with disagreement in intraocular pressure results as measured by different types of instruments. The authors stated that further study is needed to explain the residual disagreements among these instruments.

Kaushik et al. (2012) evaluated corneal biomechanical properties across the glaucoma spectrum and studied the relationship between these measurements and intraocular pressure in a prospective cross-sectional study that included 323 participants. Based on the results of the study, the investigators concluded that intraocular pressure measurements from the Ocular Response Analyzer are not interchangeable with, and are unlikely to replace, Goldmann applanation tonometry at the present time.

In a prospective, cross-sectional study, Chou et al. (2011) compared intraocular pressure measurements after penetrating keratoplasty (PK) and analyzed effects and correlation of corneal thickness and curvature on these measurements. Thirty-one eyes of 31 participants with previous PK were evaluated with Goldmann applanation tonometry (GAT), TonoPen XL, Pascal Dynamic Contour tonometer (PDCT), and Ocular Response Analyzer. The Ocular Response Analyzer showed the least agreement with GAT. According to the authors, TonoPen or PDCT are the most suitable alternatives for measuring IOP in PK eyes where GAT readings are difficult to obtain.

Mansouri et al. (2011) investigated 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 suspect glaucoma were included in the study. The investigators found only a weak relationship between
Corneal biomechanical parameters and measures of structural and functional damage in glaucoma.

Xu et al. (2011) evaluated ocular pressure using the ocular response analyzer (ORA) in 60 normal participants and 60 glaucoma patients. According to the authors, the measurement reliability of ORA was only moderate. Eyes with large ocular pulse amplitude were associated with high IOP measurement variability. The authors stated that taking average of multiple repeated measurements is important for reliable measurement of ORA.

Touboul et al. (2011) estimated the ability of the Ocular Response Analyzer parameters to aid in the diagnosis of keratoconus in pre-laser in situ keratomileusis (LASIK) patients. The study group comprised 103 eyes and the control group, 97 eyes. Corneal hysteresis had a sensitivity of 66% with a specificity of 67%. The authors stated that despite low sensitivity and specificity, some parameters provided by the corneal analyzer offered high negative likelihood ratios and deserve more study with bigger samples.

Mangouritsas et al. (2009) evaluated corneal hysteresis values (CH) using the ocular response analyser (ORA) in non-glaucomatous and glaucomatous eyes and their relationship with central corneal thickness (CCT). Corneal hysteresis, intraocular pressure (IOP) as measured by Goldmann applanation tonometry (GAT) and CCT were prospectively evaluated in 74 non-glaucoma subjects with IOP less than 21 mmHg and in 108 patients with treated primary open-angle glaucoma (POAG). One eye in each subject was randomly selected for inclusion in the analysis. According to the investigators it can be assumed that diverse structural factors, in addition to thickness, determine the differences in the corneal biomechanical profile between non-glaucomatous and glaucomatous eyes. The investigators concluded that corneal hysteresis could be a useful tool in the diagnosis of glaucoma. However, further research is needed to confirm these findings.

In a prospective study, Kopito et al. (2010) analyzed the reproducibility of corneal hysteresis (CH), corneal resistance factor (CRF), Goldmann-correlated intraocular pressure (IOPg) and corneal-compensated intraocular pressure (IOPcc) obtained with the ocular response analyzer (ORA). The study was non-masked and included eight successive examinations with the ORA device in 60 normal eyes. The investigators concluded that the ORA device provides reproducible information on viscoelastic properties of the cornea in normal eyes notably CRF and CH. IOPcc was less reproducible. Four measurements per eye were necessary to reach a 10% precision and six measurements for 5% precision. These findings require confirmation in a larger study.

Renier et al. (2010) compared the intra-ocular pressure (IOP) obtained by ocular response analyzer (ORA), dynamic contour tonometer (DCT), and Goldmann applanation tonometer (GAT) in 102 patients (47 with primary open-angle glaucoma and 55 healthy controls). According to the investigators, the results of the study showed a low degree of agreement between IOP measured by ORA, DCT and GAT. DCT and corneal compensated ORA (ORAcc) over-estimated the IOP compared to GAT.

Carbonaro et al. (2010) compared the reliability of the gold standard Goldmann applanation tonometer (GAT), with that of the ocular response analyser (ORA), and the dynamic contour tonometer (DCT). A total of 694 subjects were included in the study. The agreement between the three methods was assessed using the Bland-Altman method. The study found similar reliability in all three tonometers. Bland-Altman plots showed the three instruments to have 95% limits of agreement outside the generally accepted limits, which means they are not interchangeable. GAT measurements were found to be significantly lower than the two newer instruments.

Sullivan-Mee et al. (2009) prospectively compared the intraocular pressure measurement variability between Goldmann applanation tonometry (GAT), Pascal dynamic contour tonometry (DCT), and ocular response analyzer (ORA) tonometry in 60 patients with ocular hypertension,
glaucoma suspect, primary open-angle, or normal pressure glaucoma. According to the investigators, although some inter-method variability differences were identified, all 3 methods demonstrated clinically acceptable measurement repeatability and reproducibility. This result, in conjunction with the finding that variability was not different between eyes, examiners, or measurement sets, suggests that DCT and ORA are reliable enough to be clinically useful. The limitations of this study include its semi-randomization of methods, as ORA was always performed first followed by either DCT or GAT, which were randomly obtained.

Shah et al. (2008) compared hysteresis and corneal resistance factor (CRF) in normal tension glaucoma (NTG), primary open angle glaucoma (POAG) and ocular hypertension (OHT) eyes measured by the ocular response analyser as part of a prospective, cross-sectional and comparative clinical trial that included 216 eyes with POAG, 68 eyes with NTG and 199 eyes with OHT. According to the authors, ocular response analyzer measurement may be useful in the future for monitoring intraocular pressure, especially in eyes with corneal rigidity, but additional studies are needed to establish relevance of these measurements.

Schweitzer et al. (2010) evaluated the performance of the Ocular Response Analyzer (ORA) in the screening of forme fruste keratoconus (FFKc) in a retrospective comparative study that included 180 eyes. ORA preoperative data were analyzed for 125 normal control eyes (64 patients) undergoing laser in situ keratomileusis (LASIK) without corneal ectasia after 24 months of follow-up and 55 case eyes with unilateral keratoconus from a database. All eyes were matched in four groups of central corneal thickness (CCT). Corneal hysteresis (CH), the corneal resistance factor (CRF), the air pressure curve, and the infrared signal were compared between FFKc and normal eyes in each group. Based on the results of the study, the investigators concluded that the ORA provides additional information in the screening of FFKc, with an accurate analysis of the corneal biomechanical properties according to CCT, air pressure, and infrared curves. According to the investigators, further studies are required to confirm these results and to follow the corneal topography and the ORA parameters over time for both groups.

Saad et al. (2009) retrospectively reviewed data of 504 eyes separated into three groups: normal (n=252), keratoconus suspect (n=80) and keratoconus (n=172). Corneal hysteresis (CH) and corneal resistance factor (CRF) were measured by the Ocular Response Analyzer (ORA). The mean CH and CRF were significantly different between the 3 groups. The investigators concluded that CH and CRF alone cannot be used to identify keratoconus suspect corneas.

Fontes et al. (2011) compared corneal hysteresis (CH) and corneal resistance factor (CRF) in eyes with keratoconus with CH and CRF in matched controls, and estimated the sensitivity and specificity of these parameters for discriminating between the two groups. This prospective, comparative case series included 19 eyes of 19 patients with keratoconus and 19 eyes of 19 healthy sex-, age-, and central corneal thickness (CCT)-matched patients who underwent a complete clinical eye examination, corneal topography, tomography, and biomechanical evaluation. The investigators concluded that corneal hysteresis and CRF were statistically lower in the keratoconus group compared with the control group. Given the large overlap, both CH and CRF had low sensitivity and specificity for discriminating between groups.

There is insufficient evidence available from the peer-reviewed literature to validate the clinical role for measurement of corneal hysteresis.

**Professional Societies**
The American Academy of Ophthalmology (AAO) does not address corneal hysteresis measurement in its Preferred Practice Pattern for the evaluation and management of Primary Open-Angle Glaucoma.
Measurement of Ocular Blood Flow by Intraocular Pressure Sampling

In a cross-sectional study, Resch et al. (2011) correlated ocular blood flow parameters with parameters of optic nerve head (ONH) morphology and visual field performance. A total of 103 patients with primary open angle glaucoma were included. Choroidal and ONH blood flow was assessed using laser Doppler flowmetry. Retinal blood velocities and retinal vessel diameters were measured with laser Doppler velocimetry and a Retinal Vessel Analyzer, respectively. Among all measured ocular hemodynamic parameters, the ONH blood flow was most strongly correlated to structural parameters of ONH damage and visual field loss. Reduced retinal vessel diameters were only slightly correlated with the degree of glaucomatous damage. The authors concluded that reduced blood flow in the ONH was associated with an increasing amount of visual field defect and morphological changes of the ONH. Retinal vessel diameters were only marginally associated with glaucomatous optic nerve damage. According to the authors, based on retinal vessel diameter determination alone, it is not possible to assess whether reduced retinal blood flow is causative or secondary in glaucoma.

Januleviciene et al. (2011) evaluated hemodynamic parameters as possible predictors for glaucoma progression in an 18-month randomized double-masked cohort study including 30 open-angle glaucoma patients. Intraocular pressure (IOP), arterial blood pressure (BP), ocular and diastolic perfusion pressures (OPP, DPP), color Doppler imaging, pulsatile ocular blood flow analysis, scanning laser polarimetry, and Humphrey visual field evaluations were included. The authors concluded that structural changes consistent with glaucoma progression correlate with non-IOP-dependent risk factors. The authors stated that larger group studies with longer followup, standardization of measurement techniques for glaucoma progression, and ocular blood flow parameters are required to elicit a clear understanding of vascular risk factors in glaucoma progression.

Tonnu et al. (2005) compared the inter-method agreement in intraocular pressure (IOP) measurements made with four different tonometric methods: the Goldmann applanation tonometer (GAT), Tono-Pen XL, ocular blood flow tonograph (OBF), and Canon TX-10 non-contact tonometer (NCT). These methods were compared in a randomized order in one eye of each of 105 patients with ocular hypertension or glaucoma. Three measurements were made with each method, and by each of two independent GAT observers. There was good interobserver agreement with the GAT and moderate agreement between the NCT and GAT. According to the authors, the differences between the GAT and OBF and between the GAT and Tono-Pen probably preclude the OBF and Tono-Pen from routine clinical use as objective methods to measure IOP in normal adult eyes.

In a prospective observational clinical study, Deokule et al. (2009) evaluated one randomly selected eye from 21 normal subjects, 30 glaucoma suspects based on optic disc appearance, and 22 open-angle glaucoma (OAG) patients. The pulsatile ocular blood flow (POBF), a measure of choroidal blood flow, was assessed using ocular blood flow analyzer whereas parapapillary blood flow and blood velocity of retrobulbar blood vessels were measured using scanning laser Doppler flowmetry and color Doppler imaging, respectively. POBF was significantly associated with parapapillary blood flow and temporal short posterior ciliary artery resistive index in normal subjects. Results were consistent when corrected for age, intraocular pressure, and blood pressure parameters. POBF values did not correlate with parapapillary blood flow values or temporal short posterior ciliary artery resistive index in glaucoma suspects or OAG patients. The investigators concluded that the relationships of POBF with parapapillary blood flow and calculated retrobulbar vascular resistance differs among normal subjects, glaucoma suspects, and OAG patients and this provides further evidence of vascular dysregulation in OAG.

Browning et al. (2004) compared intraocular pressure (IOP) measurements taken by the Goldmann applanation tonometer, the Tono-Pen and the ocular blood flow pneumotonometer in 127 eyes with varying central corneal thickness (CCT) due to penetrating keratoplasty (PK), keratoconus (KC), and Fuchs’ endothelial dystrophy (FED). The study found that mean IOP
measurements using the OBF pneumotonometer were significantly higher than those made using the Goldmann applanation tonometer or Tono-Pen in eyes with a variety of corneal pathologies. The OBF pneumotonometer was found to be most affected by variation in CCT. For all three instruments, the relation between IOP and CCT depended on the corneal pathology and was greatest for FED.

Erickson et al. (2010) evaluated intraocular blood flow using ocular pulse amplitude (OPA). Refractive error, corneal curvature, Goldmann applanation tonometry (GAT), dynamic contour tonometry (DCT), OPA, axial length, and central corneal thickness (CCT) measurements were obtained on 104 healthy subjects. OPA ranged from 0.7 to 4.7 mmHg and showed a significant correlation with refractive error, axial length, GAT, and DCT. Mean intraocular pressure with GAT was 15.6 mmHg. The investigators concluded that OPA provides information regarding ocular blood flow; however, more studies are needed to determine its significance in glaucoma treatment.

Perrott et al. (2007) assessed if pulsatile ocular blood flow (POBF) measurements could distinguish between 98 patients who had type 2 diabetes mellitus (DM) with and without diabetic retinopathy (DR). POBF was measured using an Ocular Blood Flow tonometer and retinopathy was assessed using retinal digital photography. Seventy-two subjects had no DR and 26 subjects exhibited mild to moderate non-proliferative DR. POBF was higher in those subjects with non-proliferative DR but did not reach significance. POBF was found to increase with level of management but not significantly so. The investigators concluded that a single measurement of POBF does not distinguish between subjects with and without mild/moderate non-proliferative DR.

There is inadequate evidence that measurement of ocular blood flow with ocular blood flow tonometry is effective for evaluating ocular disorders. Further investigation is needed to demonstrate that ocular blood flow tonometer can provide clinically useful and accurate measurements.

Professional Societies
The American Academy of Ophthalmology (AAO) does not address measurement of ocular blood flow in its Preferred Practice Pattern for the evaluation and management of Primary Open-Angle Glaucoma.

Monitoring of Intraocular Pressure during Vitrectomy
The clinical evidence was reviewed on April 13, 2014 with no additional information identified that would change the unproven and not medically necessary conclusion for monitoring of intraocular pressure during vitrectomy.

In a prospective, interventional, consecutive case series, Sugiura et al. (2011) measured ophthamodynamometric pressure (ODP) during vitrectomy in 75 patients with proliferative diabetic retinopathy (PDR). Multiple regression analysis revealed that ODP had a significant correlation with diastolic blood pressure (DBP), presence of rubeosis iridis, and severity of PDR. There is no evidence from this study that this information will affect patient management.

Moorhead et al. (2005) conducted a clinical study of 10 patients to directly measure dynamic intraocular pressure (IOP) during vitrectomy and to determine whether disposable pressure transducers placed in the infusion line can indirectly measure with accuracy the dynamic IOP during vitrectomy. The directly measured IOP varied between 0 and 120 mm Hg during vitrectomy. During fluid flow, the indirectly measured IOP, calculated from the infusion line pressures, accurately corresponded with the directly measured IOP. The investigators concluded that closed vitrectomy causes wide fluctuations in IOP. The IOP can be accurately measured during fluid flow with inline sensors. According to the authors, the physiologic significance of
these findings requires further study.

There is insufficient evidence that monitoring of intraocular pressure during vitrectomy has clinical benefit. Additional clinical trials are required to determine if monitoring of intraocular pressure during vitrectomy accurately measures intraocular pressure and if it improves outcomes such as visual acuity recovery after vitrectomy.

**Monitoring of Intraocular Pressure for 24 Hours or Longer**

Mansouri et al. (2012) examined the safety, tolerability, and reproducibility of intraocular pressure (IOP) patterns during repeated continuous 24-hour IOP monitoring with a contact lens sensor (Sensimed Triggerfish CLS). Forty patients suspected of having glaucoma (n = 21) or with established glaucoma (n = 19) were included in the study. Correlation between the 2 sessions was moderate, suggesting good reproducibility of the IOP recordings. There was also no difference in adverse events or survey scores for tolerability between those with established glaucoma compared with those with suspected glaucoma. Main adverse events were blurred vision (82%), conjunctival hyperemia (80%), and superficial punctate keratitis (15%). The authors concluded that repeated use of the contact lens sensor demonstrated good safety and tolerability. According to the authors, the recorded IOP patterns showed fair to good reproducibility, suggesting that data from continuous 24-hour IOP monitoring may be useful in the management of patients with glaucoma. Limitations of this study included the lack of a patient group without glaucoma within the cohort. Thus, the study did not address reproducibility and accuracy of IOP measurements in populations with IOP close to or within normal range.

In a prospective, observational cohort of 15 patients, Mansouri and Shaarawy (2011) reported their initial clinical results with a wireless ocular telemetry sensor (OTS) (Sensimed AG, Switzerland) for continuous intraocular pressure (IOP) monitoring in patients with open angle glaucoma. A signal was recorded in all patients. Thirteen (87%) patients completed 24 hour IOP monitoring: one patient discontinued IOP monitoring due to device intolerance, and incomplete recordings were obtained in a second patient due to technical device malfunction. In 9/13 (69%) patients, the highest signals were recorded during the nocturnal period. No serious adverse events were recorded. According to the authors, the OTS shows good safety and functionality to monitor IOP fluctuations in patients over 24 hours. The significance of this study is limited by small sample size.

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

On January 20, 2004, the Ocular Response Analyzer® (ORA) by Reichert Inc. received FDA clearance for the intended use to measure intra-ocular pressure of the eye and the biomechanical response of the cornea for the purpose of aiding in the diagnosis and monitoring of glaucoma. See the following Web site for more information: [http://www.accessdata.fda.gov/cdrh_docs/pdf3/K032799.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf3/K032799.pdf).

Accessed April 2014

On October 21, 2002 the Blood Flow Analyzer (BFA) received FDA marketing clearance. See the following Web site for more information: [http://www.accessdata.fda.gov/cdrh_docs/pdf2/k023245.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf2/k023245.pdf).

Accessed April 2014

**CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

Medicare does not have a National Coverage Determination (NCD) for corneal hysteresis and intraocular pressure measurement. Local Coverage Determinations (LCDs) do not exist at this time. However CPT 0173T, 0181T and 0198T are mentioned in the LCDs for Category III CPT Codes and Non Covered Services and Services that are Not Reasonable and Necessary and

---

**Proprietary Information of UnitedHealthcare. Copyright 2014United HealthCare Services, Inc.**
Ocular Blood Flow Tests and compliance with these policies is required where applicable.
Accessed April 2014

REFERENCES


### POLICY HISTORY/REVISION INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
</table>
| 07/01/2014 | • Reorganized policy content  
• Added benefit considerations language for Essential Health Benefits for Individual and Small Group plans to indicate:  
  o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”)  
  o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans  
  o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage  
• Updated coverage rationale; added language to indicate the unproven services are “not medically necessary”  
• Archived previous policy version 2013T0133L |