Corneal Hysteresis and Intraocular Pressure Measurement

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Instructions for Use

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Community Plan Policy
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Coverage Rationale

The following are unproven and not medically necessary due to insufficient evidence of efficacy:

- Measurement of corneal hysteresis
- Measurement of ocular blood flow using a tonometer
- Monitoring of intraocular pressure during vitrectomy
- Continuous monitoring of intraocular pressure for ≥ 24 hours in persons with glaucoma

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan 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 claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0198T	Measurement of ocular blood flow by repetitive intraocular pressure sampling, with interpretation and report
0329T	Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report
66999	Unlisted procedure, anterior segment of eye
67299	Unlisted procedure, posterior segment
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report

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® (ORA) is an instrument that measures CH 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 CH. Low CH demonstrates that the cornea is less capable of absorbing (damping) the energy of the air pulse. Abnormalities in CH have been detected in a variety of corneal diseases, including keratoconus, Fuchs' dystrophy, and in individuals who have had laser in situ keratomileusis (LASIK). Glaucoma is another potential indication for CH measurement. The preferred method of measuring intraocular pressure (IOP) is using a contact applanation method such as a Goldmann tonometer (GAT). Corneal compensated IOP, derived from the CH measure has been suggested as a superior measurement of IOP compared to the GAT measurement.

The ocular blood flow (OBF) tonometer measures 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) 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 for 24 hours or longer in individuals with glaucoma. 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 received marketing clearance 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 for individuals with glaucoma.

Clinical Evidence

Corneal Hysteresis Measurement

Current evidence for corneal hysteresis measurement focuses on the risk, diagnosis and progression of glaucoma however, these studies do not demonstrate how corneal hysteresis measurement influences clinical management or outcomes. Additional clinical trials are necessary to determine its benefit in clinical practice.

Susanna et al. (2018) conducted a prospective observational cohort study to investigate the role of CH as a risk factor for development of glaucoma. Two hundred and eighty-seven eyes of 199 individuals suspected of having glaucoma were observed for approximately 4 years. Participants underwent a comprehensive ophthalmologic examination including IOP measured using GAT, gonioscopy, stereoscopic optic disc examination, visual field testing, and central corneal thickness (CCT) measurements via ultrasound pachymetry and were assessed at baseline and every 6 months thereafter. A minimum follow-up period of 18 months and 4 separate visits were required. Development of glaucoma was defined as occurrence of 3 consecutive abnormal standard automated perimetry tests during the follow-up period. Fifty-four (19%) eyes developed repeatable visual field defects during follow-up. Each 1 mmHg lower CH measurement was associated with an increase of 21% in the risk of developing glaucoma during follow-up (95% confidence interval [CI]: 1.04–1.41; p=0.013]. After adjusting for age, intraocular pressure, central corneal thickness, PSD, and treatment, CH was still predictive of development of glaucoma (hazard ratio=1.20; 95% CI: 1.01–1.42; p=0.040). The authors concluded that the decrease in CH measurements represents a risk factor for developing glaucoma. Study limitations included but were not limited to study design , lack of information on participants lost to follow up, as well as uncontrolled confounding by unmeasured factors, such as family history of glaucoma.

Additionally, the study doesn't test whether the use of CH improves care. Future studies should be performed to further clarify the clinical utility of using CH as part of glaucoma management on patient outcomes.

A 2018 Hayes report 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 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.

Murphy et al. (2017) conducted a cross sectional study with 123 patients (one eye each) to determine if CH differs between patients with glaucoma, ocular hypertension (OHT) and glaucoma-like optic discs (GLD). The secondary aim was to investigate whether corneal resistance factor (CRF) and CCT differ between these patient groups. A One-way Analysis of Covariance (ANCOVA) was conducted to evaluate the mean difference in CH between the 3 diagnostic groups (glaucoma, OHT and GLD), correcting for potential confounding factors, IOP and age. Analysis was repeated for CRF and CCT. There was a significant difference in mean CH across the 3 groups. Mean CH was significantly higher for GLD compared to glaucoma, and significantly higher for OHT compared to glaucoma. Mean CH was slightly lower in patients with GLD than those with OHT, but this difference was not statistically significant. A similar pattern was seen when the analysis was repeated for CRF and CCT. The authors concluded that higher CH in GLD and OHT compared to glaucoma suggests increased viscoelasticity of ocular tissues may have a protective role against glaucoma. Additional studies are still needed to clarify the utility of CH in the risk, diagnosis and clinical management of glaucoma. This study was also included in the Hayes report (2018).

Zhang et al. (2016) conducted a cohort study to evaluate the relationship between CH and progressive retinal nerve fiber layer (RNFL) loss among patients with glaucoma. At baseline and at 6-month intervals thereafter, participants received a comprehensive ophthalmologic examination and several other imaging and functional tests. A total of 186 eyes (133 patients) with glaucoma were followed for an average of 3.8 ± 0.8 years (range: 2.0 to 5.2 years). The average baseline RNFL thickness was 76.4 ± 18.1 μm and average baseline CH 9.2 ± 1.8 mmHg. CH had a significant effect on rates of RNFL progression. In the univariable model, including only CH as a predictive factor along with time and their interaction, each 1 mmHg lower CH was associated with a 0.13 μm/year faster rate of RNFL decline (p=0.011). A similar relationship between low CH and faster rates of RNFL loss was found using a multivariable model accounting for age, race, average IOP and CCT (p=0.015). The authors concluded that lower CH was significantly associated with faster rates of RNFL loss over time. While this study provides evidence that CH is an important factor to be considered in the assessment of the risk of progression, there is no evidence that CH measurement will affect patient management; further research is still needed to prove the utility of CH measurement in the clinical setting. This study was also included in the Hayes report (2018).

Carbonaro et al. (2014) conducted a cross-sectional study to determine whether corneal hysteresis and central corneal thickness are independent risk factors for glaucoma. Subjects were recruited from the Twins UK Adult Twin Registry at St Thomas' Hospital in London and invited to have an eye examination. The Ocular Response Analyzer (ORA) was used to measure CH, IOP, and CCT. Two measurements were performed on each eye; first and second tests were taken on 1 eye and then, on the other eye. If needed, a third reading was taken to ensure accuracy. Multivariable linear regression was performed to analyze corneal hysteresis with respect to other glaucoma-related endophenotypes including vertical cup-to-disc ratio, optic disc size, and optic cup areas. The final analytic sample included 1,645 individuals. CH was negatively associated with age (beta coefficient, -0.03; 95% CI, -0.03 to -0.02, p<0.0005) and IOP (beta coefficient, -0.06; 95% CI, -0.09 to -0.03; p=0.001). CH was also found to be associated with CCT (beta coefficient, 0.02; 95% CI, 0.021 to 0.025; p<0.0005). There was no significant association between corneal hysteresis and optic disc area (p=0.62), cup area (p=0.77), vertical cup-to-disc ratio (p=0.51), or spherical equivalent (p=0.07). The authors concluded that in this population of healthy British twins, CH is not independent risk factors for glaucoma.

Shin et al. (2014) conducted a cross-sectional study to evaluate the effects of corneal biomechanical properties on IOP measured with the ICare, and to compare IOP readings obtained with ICare, ORA, and GAT in normal-tension glaucoma (NTG) and normal subjects. IOP was measured with ICare, ORA, and GAT. All subjects had CH and CRF, which were measured with ORA; and CCT, axial length, spherical equivalent, and keratometry. This study enrolled 97 eyes of 97 NTG patients and 89 eyes of 89 normal subjects. CCT, CH, and CRF in NTG patients were significantly lower than those in normal subjects. CH and CRF

were significantly associated with IOP measurements with ICare in NTG and normal subjects (p<0.001). The greater difference between IOPcc and ICare in NTG patients was significantly influenced by the lower CH (p<0.001). The authors concluded that IOP measurements obtained with the ICare tonometer in NTG patients were significantly influenced by CH and corneal resistance factor but not CCT. While there were agreement and reproducibility between the ICare and other tonometers readings, variability with an individual's corneal biomechanical properties must be considered and interindividual differences in corneal biomechanics may cause the ICare to underestimate IOP in NTG patients.

Ogbuehi et al. (2014) conducted a validation study to assess the precision and reproducibility of the corneal biomechanical parameters, and their relationships with the intraocular pressure (IOP) measured with the Goldmann tonometer and a noncontact tonometer. Routine optometry patients, who were oculovisual normal and in good general health, were eligible for participation. Prior to inclusion in the study, each subject underwent a comprehensive ophthalmic examination. Each subject was required to visit the clinic for two separate measurement sessions separated by approximately one week. Readings for biomechanical properties and for IOP measured with the Goldmann and noncontact tonometers, were taken on one randomly selected eye of 106 normal subjects, on each one of the two measurement sessions. Measurements with the ocular response analyzer (ORA) and the noncontact tonometer were randomized, followed by the measurement of central corneal thickness and with the Goldmann tonometer. Repeatability coefficients for CCT, CH and corneal resistance factor (CRF) in Session 1 were ±0.01 μm, ±3.05 mmHg and ±2.62 mmHg, respectively. The mean CCT, CH, CRF, Goldmann and noncontact tonometry did not vary significantly between sessions. Reproducibility coefficients for CCT, CH and CRF were ±0.02 μm, ±2.19 mmHg and ±1.97 mmHg, respectively. Univariate regression analysis showed that CCT, CH and CRF significantly (p<0.0001) correlated with the IOP measured with the Goldmann and noncontact tonometers (and with the differences between tonometers) in Session 1. There were no significant correlations with the differences between tonometers in Session 2. Multivariate analysis revealed a minimal effect of CCT on Goldmann measurements but a significant effect on those of the noncontact tonometer. The authors concluded that measurement of the biomechanical properties of the cornea, using the ORA, are repeatable and reproducible, affect Goldmann tonometry less than noncontact tonometry, and have a small influence on the difference in measured intraocular pressure between tonometers. A limitation of this study is the non-inclusion of a wider variety of subjects i.e., restricting participation to oculovisual normal individuals who were in good health. Therefore, prospective, longitudinal studies with a wider variety of subjects are required to establish the association between the ORA biomechanical properties and IOP measured by tonometry. Furthermore, the study does not address whether measurement of CH improves patient care.

Mansouri et al. (2012a) conducted a cross-sectional study to investigate the association between corneal biomechanical parameters using the Ocular Response Analyzer (ORA) and glaucoma severity. Each participant underwent a complete ophthalmologic examination, including visual acuity assessment, slit-lamp biomicroscopy, gonioscopy, dilated fundoscopic examination using 78-diopter (D) lens, stereoscopic disc photography, and standard automated perimetry using the 24-2 Swedish Interactive Threshold Algorithm. CCT was measured using an ultrasound pachymeter over an undilated pupil and the mean of 3 readings was recorded. To study the influence of corneal biomechanical parameters as measured by the ORA on the visual field and RNFL thickness, eyes suspected of having the disease as well as those with confirmed glaucoma were included. A total 299 eyes of 191 participants (151 suspect and 148 glaucoma eyes) with a mean age of 68.1 years (SD: 11.0 years; range 30–91 years) participated in the study. CH and CRF were both positively associated with mean defect (MD) (R2=0.03; p<0.01 and R2=0.10; p<0.01, respectively). In multivariable analysis, the association between CRF and MD remained significant while CH to MD did not (p<0.01 and p=0.77). In the GDx ECC subgroup (204 eyes), there was a weak association between CH and CRF and average RNFL thickness (R2=0.07; p<0.01 and R2=0.05; p<0.01, respectively), which was not observed in the SD-OCT subgroup (146 eyes) (R2=0.01; p=0.30 and R2=0.01; p=0.21). After adjusting for central corneal thickness, age, and axial length, the relationship of CH and CRF to RNFL thickness no longer reached statistical significance. The authors concluded that they found only a weak relationship between corneal biomechanical parameters and measures of structural and functional damage in glaucoma. Additional studies are needed to investigate the relationship between corneal biomechanics and long-term risk of glaucoma progression. This study was also included in the Hayes report (2018).

Professional Societies

American Academy of Ophthalmology (AAO)

The AAO Preferred Practice Pattern (PPP) for POAG states that CH, which is a measure of the viscoelastic dampening of the cornea, has been shown to be associated with the risk of glaucoma progression. In addition, it states that low CH is associated with glaucoma progression (Prum et al., 2016).

Measurement of Ocular Blood Flow by Intraocular Pressure Sampling

There is insufficient clinical evidence that measuring ocular blood flow by interocular pressure sampling will impact treatment decisions and demonstrate improved health outcomes. Further studies are needed to determine the clinical utility of this test.

Barbosa-Breda et al. (2019) conducted a cohort analysis to determine vascular factors that better describe patients with NTG compared to those with primary open-angle glaucoma (POAG). A total of 384 glaucoma patients (202 POAG and 182 NTG) from the Leuven Eye Study (LES) database were included. Four different devices were used to assess ocular pulse amplitude, ocular blood flow, retinal oximetry and choroidal thickness. Three multivariate logistic regression models were developed: a conventional model (conventional parameters only, including vascular-related self-reported phenomena, such as migraine or peripheral vasospasm); an advanced vascular model (advanced vascular parameters only: ocular blood flow, retinal oximetry, ocular pulse amplitude and choroidal thickness); and a global model, in which both types of parameters were allowed. Receiver operating characteristic (ROC) curves and corresponding areas under the curve (AUC) were calculated and compared between models. Patients with NTG had a higher resistive index and lower early systolic acceleration (ESA) in their retrobulbar vessels and a smaller arteriovenous retinal oxygen saturation difference. The global model (AUC 0.743) showed a significantly better discriminative ability when compared to either the conventional (AUC 0.687, p=0.049) or the advanced vascular (AUC 0.677, p=0.005) models. Also, the conventional and the advanced vascular models showed a similar discriminative ability (p=0.823). The authors concluded that patients who have NTG have more signs of vascular dysfunction. And, that the conventional parameters, such as asking simple vascular-related questions, combined with advanced vascular examinations provide information to better understand the value that non-IOP-related factors contribute to NTG. However, future studies are needed to validate these results and to clarify whether advanced vascular examinations are relevant to predict disease progression or provide benefit for the management of patients with NTG or POAG.

Janulevičiene et al. (2011) conducted a single-center, randomized, double-masked intervention study with an observational component to evaluate hemodynamic parameters as possible predictors for glaucoma progression. Patients with OAG and characteristic glaucomatous visual field loss, optic nerve head damage, and IOP not adequately controlled with timolol maleate (BID) were eligible for participation. After a timolol baseline examination, patients were randomly assigned to double-masked fixed combination treatment: dorzolamide/timolol (DTFC) or and latanoprost/timolol (LTFC). Examinations were carried out in both eyes and the study eye was chosen randomly. The examinations were conducted at baseline and at months 1, 6, 12, and 18 of treatment. The examinations included a full ophthalmic examination, visual acuity, Goldmann IOP, central corneal thickness (CCT) Humphrey visual field examination (24-2 SITA Standard), and scanning laser polarimetry. A total of 30 OAG patients (15 patients in each study group) with a mean age of 58.13 (SD 8.6) participated in the study. There were no statistically significant differences between baseline parameters of either treatment group. The DTFC and LTFC groups had similar IOP lowering effect over 18 months of observation (p=0.653). Six patients in DTFC and 7 in LTFC group met glaucoma progression criteria. Patients with progressing glaucoma had higher nerve fiber index, lower systolic BP, OPP, DPP, higher ophthalmic and central retinal artery vascular resistance, and lower pulse volume (p<0.05). The authors concluded that structural changes consistent with glaucoma progression correlate with non-IOP-dependent risk factors. And, stated that larger group studies with longer follow-up, standardization of measurement techniques for glaucoma progression, and OBF parameters are required to elicit a clear understanding of vascular risk factors in glaucoma progression. The study however does not address the clinical utility of adding measurement of ocular blood flow by intraocular pressure sampling to improve patient care.

Professional Societies

American Academy of Ophthalmology (AAO)

The AAO PPP for POAG does not address measurement of OBF for the evaluation and management of glaucoma (Prum et al., 2016).

Monitoring of Intraocular Pressure during Vitrectomy

There is limited evidence to support that intraoperative IOP monitoring will improve health outcomes in patients undergoing vitrectomy. Additional clinical trials are necessary to determine its benefit.

Yang et al. (2017) conducted a prospective case series analysis to evaluate IOP during in vivo routine vitrectomy. IOP flucuations during vitrectomy can adversely effect retinal and optic nerve function as well as future visual acuity therefore, close monitoring IOP is often an integral part of the procedure. In this study, the primary aim was to compare IOP measurements between two vitrectomy machines with integrated IOP monioring devices. A total of 61 eyes of 61 consecutive patients were

assigned to one of two types of microincisional vitrectomy systems: Accurus system (n=32, group 1) and Constellation system (n=29, group 2). Prior to vitrectomy, the mean IOP in group 1 was 20.3±2.4 mmHg using conventional vented gas forced infusion system and 20.0±0.0 mmHg in group 2 using active IOP control at 20 mmHg (p=0.532). During core vitrectomy, the mean IOP change was -8.6 ± 4.3 mmHg in group 1 and -0.8 ± 1.1 mmHg in group 2 (p<0.001). Maximum IOP was significantly decreased in group 1 compared with group 2 (-17.0±2.6 mmHg and -4.1±2.2 mmHg, respectively; p<0.001). During vitrectomy, partial ocular collapse was only observed in group 1 (78.1%). Peak IOP significantly increased during scleral compression and gas and fluid injection but was not significantly different between the groups (all p≥0.147). The IOP fluctuation range was 50-70 mmHg in both groups. The authors concluded that IOP fluctuated significantly during routine vitrectomy using both systems. Hypotony and partial ocular collapse were more frequently observed with the Accurus system than with the Constellation system, and both systems were vulnerable to IOP surge during indentation and intravitreal injection. While this study suggest usefulness of intraocular pressure monitoring during vitrectomy in the research setting, its benefit in routine clinical practice remains to be established.

In a prospective, interventional, consecutive case series, Sugiura et al. (2011) measured ophthalmodynamometric 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, 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 case series of 10 patients to directly measure dynamic 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. The authors report that no “patients had adverse effects such as cataract, vitreous hemorrhage, or retinal tear as a result of this study.” According to the authors, the physiologic significance of these findings requires further study.

Monitoring of Intraocular Pressure for 24 Hours or Longer

There is insufficient clinical evidence demonstrating the safety and/or efficacy of monitoring of intraocular pressure for 24 hours or longer.

Mansouri et al. (2015) conducted a prospective clinical trial to evaluate the performance of a contact lens sensor (CLS, (Triggerfish, Sensimed, Switzerland) for 24-hour monitoring of IOP-related short-term patterns compared with IOP obtained by pneumatonometry. Thirty-one healthy volunteers and 2 glaucoma patients stayed in a sleep laboratory for 24 hours. One randomly selected eye was fitted with the CLS, which measures changes in ocular circumference. In the contralateral eye, IOP measurements were taken using a pneumatonometer every two hours with subjects in the habitual body positions. Heart rate (HR) was measured 3 times during the night for periods of 6 minutes separated by 2 hours. Performance of the CLS was defined in two ways: 1) recording the known pattern of IOP increase going from awake (sitting position) to sleep (recumbent), defined as the wake/sleep (W/S) slope and 2) accuracy of the ocular pulse frequency (OPF) concurrent to that of the HR interval. Strength of association between overall CLS and pneumatonometer curves was assessed using coefficients of determination (R2). The W/S slope was statistically significantly positive in both eyes of each subject (CLS, 57.0 ± 40.5 mVeq/h, p<0.001 and 1.6 ± 0.9 mmHg/h, p<0.05 in the contralateral eye). A total of 87 CLS plots concurrent to the HR interval were evaluated. Graders agreed on evaluability for OPF in 83.9% of CLS plots. Accuracy of the CLS to detect the OPF was 86.5%. Coefficient of correlation between CLS and pneumatonometer for the mean 24-h curve was R2 = 0.914. The authors concluded that CLS measurements were comparable to the pneumatonometer and may be of practical use for detection of sleep-induced IOP changes. Additional studies with larger sample sizes are needed to accurately confirm these findings. Furthermore, the clinical utility of this approach to manage patients with glaucoma remains to be demonstrated.

Mansouri et al. (2012b) examined the safety, tolerability, and reproducibility of IOP patterns during repeated continuous 24-hour IOP monitoring with the Triggerfish CLS. 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. However, this study did not address how this approach can be used to improve physician decision-making and patient care.

In a prospective, observational cohort of 15 patients, Mansouri and Shaarawy (2011) reported their initial clinical results with the Sensimed Triggerfish for continuous 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 device 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 and insufficient data regarding the benefit of this approach on patient outcomes.

There are multiple clinical trials evaluating the Sensimed Triggerfish System. Additional information is available at: www.clinicaltrials.gov. (Accessed April 11, 2020)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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. More information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf3/K032799.pdf. (Accessed April 11, 2020)

On October 21, 2002, the Blood Flow Analyzer (BFA) received FDA marketing clearance. More information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf2/k023245.pdf. (Accessed April 11, 2020)

On March 4, 2016, the Triggerfish® contact lens sensor (CLS) received FDA marketing clearance. More information is available at: https://www.accessdata.fda.gov/cdrh_docs/reviews/den140017.pdf. (Accessed April 11, 2020)

Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for measurement of corneal hysteresis. Local Coverage Determinations (LCDs) exist; see the LCDs for Noncovered Services, Category III CPT Codes and Corneal Hysteresis.

Medicare does not have an NCD for measurement of ocular blood flow by using a tonometer. LCDs exist; see the LCDs for Noncovered Services, Services That Are Not Reasonable and Necessary and Category III CPT Codes.

Medicare does not have an NCD for monitoring of intraocular pressure during vitrectomy. LCDs do not exist at this time.

Medicare does not have an NCD for continuous monitoring of intraocular pressure for 24 hours or longer. LCDs exist; see the LCDs for Noncovered Services , Services That Are Not Reasonable and Necessary and Category III CPT Codes. (Accessed April 13, 2020)

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Policy History/Revision Information

Date	Summary of Changes
08/01/2020	Template Update • Reformatted policy; transferred content to new template
07/01/2020	Supporting Information • Updated *Clinical Evidence*, *CMS*, and *References* sections to reflect the most current information • Archived previous policy version 2019T0133U

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Policies 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.