Intraocular Pressure Measurement (for Louisiana Only)

Policy Number: CS026LA.~~K~~**L**
Effective Date: ~~January 1, 2023~~**TBD**

➲ Instructions for Use

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

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

- 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 federal, state, or contractual requirements 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

Codes labeled with an asterisk (*) are not on the state of Louisiana Fee Schedule and therefore not covered by the State of Louisiana Medicaid Program.

Description of Services

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

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.

In a single center cross-sectional observational study by Bayraktar et al. (2022), ocular blood flow (OBF) and choroidal thickness (CT) were evaluated as potential markers and/or risk factors that may measure the progression of OHT to glaucoma. The authors performed a detailed ophthalmological examination including visual acuity, slit-lamp biomicroscopy, gonioscopy, applanation tonometry and axial length (AL) measurement on 63 patients, of which 32 patients (60 eyes) had OHT and the remaining 31 were control patients (61 eyes). The authors used color Doppler imaging (CDI) of the ophthalmic artery (OA), central retinal artery (CRA), medial and lateral branches of short posterior ciliary arteries (MPCA, LPCA) to collect OBF data for peak systolic velocity (PSV), end-diastolic velocity (EDV), resistivity index (RI) and pulsatility index (PI). Retrobulbar blood flow velocities and calculated vascular resistive indices (RI) were measured by the same radiologist who was blinded as to whether each patient had OHT or was a control. Optical coherence tomography (OCT) was used to measure the retinal nerve fiber layer, ganglion cell complex, and central corneal thickness. The authors reported that when the blood flow values of the OA, CRA, MPCA, and LPCA arteries were compared in both groups, EDV of all arteries were significantly lower in the OHT group while the PI and RI values of all arteries were statistically significantly increased in the OHT group. Limitations of this study include the single center cross-sectional design, and the small sample size. The authors concluded that OBF decline, and choroidal thinning occurred in the OHT group compared with controls and that the use of CDI and OCT to monitor OBF and CT measurements may help to prevent and reduce potential optic nerve damage. They recommend larger long-term studies to evaluate OBF and CT with newer technological imaging methods. The study doesn't however address the clinical utility of OBF.

Wang et al (2022) completed a longitudinal, observational cohort study to determine the relationship between optical coherence tomography angiography (OCTA) measurements and visual field (VF) progression in patients with NTG. There were 335 eligible eyes from 179 patients with NTG at the baseline examination; however, 65 eyes were excluded due to image quality control, which left 270 eyes from 164 patients with NTG in the final analysis. The study participants were followed for at least two years (mean of 48.58 + 7.98 months). Each participant underwent comprehensive ophthalmic examinations at baseline and semiannually during follow-up, including measurements of best-corrected visual acuity, refractive error by an autorefractor, axial length, IOP by Goldmann applanation tonometry, CCT by a noncontact tonopachymeter, slit-lamp biomicroscopy examination of the optic disc and retina and dilated fundus examination. OCTA images were taken at the peripapillary region and the macular region to gather ocular blood flow metrics including circumpapillary vessel density (cpVD), vessel diameter index (VDI) and fractal dimension (FD) in the radial superficial capillary network and macular vessel density, foveal avascular zone (FAZ) area, FAZ circularity and macular FD in superficial capillary plexus (SCP) and deep capillary plexus (DCP) areas, respectively. The authors reported that 15.56% of the NTG eyes (n=42) developed VF deterioration and that baseline OCTA metrics revealed lower cpVD at superotemporal sectors in the peripapillary region in progressed NTG eyes compared with non-progressed eyes. They concluded that eyes with lower superotemporal cpVD at baseline were associated with a higher risk of glaucoma progression over time, independent of previously reported risk factors including age,

gender, and blood pressure. Limitations of the study included the small sample size, the limited OCTA metrics that were included, the inclusion of only eyes that had mild-to-moderate glaucoma at baseline, the relatively short follow-up period and the potential for bias due to the inclusion of both eyes in the same patient. The authors stated that the results of the study showed that the edition of cpVD measurement at baseline enhanced predictive discrimination on glaucoma progression and that their findings provided further evidence supporting the prognostic role of OCTA in the risk assessment of NTG progression. They recommended further studies to confirm their findings. The clinical utility of these measures is not addressed in this study.

Kueten et al. (2021) investigated the relationship of ocular blood flow (via arteriovenous passage time, AVP) and contrast sensitivity (CS) in healthy **individuals** as well as **individuals with** ~~normal tension glaucoma (~~NTG~~) subjects~~ in a ~~mono~~**single**-center comparative prospective trial. Twenty-five patients with NTG but no medication and 25 healthy test participants were recruited. AVP as a measure of retinal blood flow was recorded via fluorescein angiography after CS measurement using digital image analysis. Association of AVP and CS at 4 spatial frequencies (3, 6, 12, and 18 cycles per degree, cpd) was explored with correlation analysis. Significant differences regarding AVP, visual field defect, intraocular pressure, and CS measurement were recorded in-between the control group and NTG patients. In NTG patients, AVP was significantly correlated to CS at all investigated cpd (3 cpd: $r = 0.432$, $p < 0.03$; 6 cpd: $r = 0.629$, $p < 0.0005$; 12 cpd: $r = 0.535$, $p < 0.005$; and 18 cpd: $r = 0.58$, $p < 0.001$), whereas no significant correlations were found in the control group. Visual acuity was significantly correlated to CS at 6, 12, and 18 cpd in NTG patients ($r = 0.68$, $p < 0.002$; $r = 0.54$, $p < .02$, and $r = 0.88$, $p < 0.0001$ respectively), however not in healthy control patients. Age, visual field defect MD, and PSD were not significantly correlated to CS in in the NTG group. MD and PSD were significantly correlated to CS at 3 cpd in healthy eyes ($r = 0.55$, $p < 0.02$; $r = 0.47$, $p < 0.03$). The authors concluded that retinal blood flow alterations show a relationship with contrast sensitivity loss in NTG patients which may reflect a disease-related link between retinal blood flow and visual function. This association was not recorded in healthy volunteers. According to the authors, further studies are necessary to verify that including CS testing as well as blood flow measurement is beneficial in the assessment and care of patients with glaucoma.

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 patients with glaucoma (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~~**) 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.

Clinical Practice Guidelines

American Academy of Ophthalmology (AAO)

The AAO ~~PPP~~ **Preferred Practice Pattern** for ~~POAG~~ **primary open-angle glaucoma** does not address measurement of ~~OBF~~ **ocular blood flow** for the evaluation and management of glaucoma (~~American Academy of Ophthalmology, 2020~~Gedde, 2021).

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.

In a retrospective, single-blind, single-center study to evaluate the precision of digital ~~intraocular pressure (~~IOP~~)~~ measurement in silicone oil (SO) filled eyes during vitrectomy, Xue et al. (2020) found that the use of digital IOP may be an acceptable technique for experienced surgeons. Their study included 131 patients with a mean age of 51.0 ± 16.1 years who underwent vitrectomy with SO injection for treatment of retinal detachment (RD). During the surgery performed by one of seven surgeons, the patient's IOP was digitally measured and then measured by a rebound tonometer. When the authors compared the digitally measured IOP with the rebound tonometer and calculated the absolute deviation in IOP (ΔIOP) between the two methods, they found that there was no

significant difference in IOPs between digital measurement and the rebound tonometer (15.6±4.3 mm Hg vs 15.7±5.1 mm Hg). Their results showed a mean ΔIOP of 2.0±1.9 mm Hg with 58 eyes (44.3%) having ΔIOP within 1 mm Hg, 98 eyes (74.8%) within 3 mm Hg, and 122 eyes (93.1%) within 5 mm Hg. A subgroup analysis of levels of surgeons' experience showed that the correlations were not as strong in cases performed by surgeons with less than 10 years of experience as it was in cases performed by more experienced surgeons. These weaker correlations were also shown to be the case for pseudophakic eyes in general, while refractive status and lens status were found to have no significant correlations with ΔIOP. The authors noted that the relatively smaller sample size of the most and least experienced surgeon groups may have brought bias to the study and that the small, retrospective, single-center design were limitations of their study. Furthermore, the study did not measure the impact of the technology on clinical outcomes of the surgery. They recommended future prospective, multi-center studies with larger sample sizes to confirm their findings.

Yang et al. (2017) conducted a prospective case series analysis to evaluate IOP during in vivo routine vitrectomy. In this study, the primary aim was to compare IOP measurements between two vitrectomy machines with integrated IOP monitoring devices. A total of 61 eyes of 61 consecutive patients were assigned to one of two types of micro-incisional 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 $p \geq 0.147$). 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 suggests 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~~**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.

In a single-center test validation study assessing the safety and tolerability of a contact lens sensor (CLS) tonometer system for continuous three- and 24-hour IOP monitoring, Zhang et al (2022) recruited 25 subjects with a mean age of 24.1 + 3.4 years for a 3-hour IOP measurement by CLS test. One eye in each participant was fitted with the CLS who then wore it for three hours. Once it was removed, they underwent corneal fluorescein staining (CFS) which revealed an increase from 0.6 + 0.7 to 2.4 +1.5. Following the 3-hour IOP measurement arm of the study, the authors recruited 30 more participants with a mean age of 30.9 + 9.8 years (10 control subjects and 20 patients with open-angle glaucoma) for the 24-hour IOP monitoring phase of the study. In this group, again, each participant was fitted with a CLS in only one eye. Each participant was evaluated using ocular surface disease index (OSDI) before and one day after measurement, the contact lens dry eye questionnaire-8 was assessed immediately after measurement, visual analog scale (VAS) of discomfort was measured before, immediately after, and one day after measurement, best-corrected visual acuity (BCVA), tear break-up time (TBUT), and CFS were assessed before, immediately after, and 1 day after measurement. The authors reported that the OSDI increased from 9.1±9.7 to 18.0±12.4, the CLDEQ-8 score was 11.6±5.8 while the VAS increased from 11.1±14.2 to 35.2±21.8 after measurement then decreased to 26.7±18.4 one day later and the BCVA decreased from 1.0±0.01 to 0.8±0.1 and returned to 0.9±0.1 after one day. Other results included a decrease in TBUT from 5.1±3.9 to 2.6±1.5 s which then returned to 4.8±2.5 s and the CFS increased from 0.7±0.9 to 4.3±0.8 then dropped to 0.8±0.7 at 1 day after measurement. No significant difference was found for all variations of indicators between normal subjects and glaucoma patients. Limitations include the relatively young age of the participants, the short (1 day) follow up period, the small sample size and the single-center design. The authors concluded that the CLS showed great potential for safe and tolerable 24-hour IOP monitoring in patients with and without glaucoma; however, they also noted that worsening clinical signs and symptoms after CLS wear require attention. Further study was recommended to further assess the worsening signs and symptoms after measurement.

Shioya et al. (2020) evaluated the use of a contact lens sensor (CLS) to record a 24-hour ocular dimensional profile on 65 patients in a prospective open-label, single-center evaluation of Japanese patients previously diagnosed with ~~normal tension glaucoma (~~NTG~~)~~ to determine the potential for misclassifying patients with ~~primary open-angle glaucoma (~~POAG~~)~~ with NTG. All patients had been characterized by glaucomatous visual field defects and optic disc damage, open iridocorneal angle and the absence of secondary causes of glaucoma and all had undergone a complete ophthalmic examination that ~~included central corneal thickness (~~CCT~~)~~ measurements and standard automated visual field testing. To be considered for enrollment in the study, the patients had discontinued any glaucoma medication at least 4 weeks prior to the first procedures and had not undergone any ocular surgery. Each patient underwent ~~intraocular pressure (~~IOP~~)~~ measurement with tonometry on one eye every 3 hours from 9 am to midnight on day 1 of the study then had a 24-hour CLS profile recorded on the same eye the next day. Following the two days of IOP measurements, patients were reclassified as NTG when their IOP was consistently below 20 mmHg or with POAG when their IOP was ≥ 20mmHg in at least 1 of the time-points in the study The authors reported that five patients (7.7%) were reclassified as POAG following the diurnal measurement and that two of the classifiers (15:00 CLS and 18:00 CLS) showed

high sensitivity and negative predictive value (100%) that identified all of the POAG patients. Limitations noted by the authors included the fact that the tests could not be done simultaneously as no tonometry measurement can be performed when the CLS is placed on the patient's eye, and the inclusion of only Japanese subjects from a single center. They recommend additional studies to include other ethnicities. The authors concluded that CLS information can be used in conjunction with a single tonometric reading to determine a patient's potential of having IOP levels exceeding the diagnostic threshold within a 24-hour period, without the need to conduct a 24-hour tonometric curve.

In a cross-sectional controlled study, Kim et al. (2020) investigated 24-hour nyctohemeral ~~intraocular pressure (~~IOP~~)~~-related patterns with contact lens sensors (CLSs) in eyes with POAG with normal baseline IOP (i.e., normal-tension glaucoma [NTG]) and healthy controls. Thirty eyes of 30 patients with NTG, who had had a wash-out period for their IOP-lowering treatment, and 20 eyes of 20 healthy volunteer subjects were included in the study. Patients and subjects were hospitalized for the purposes of 24-hour CLS (SENSIMED Triggerfish; Sensimed AG, Lausanne, Switzerland) measurement. The IOP-related patterns during wake and sleep times over the course of the 24 hours were compared between the 2 groups. The 24-hour ambulatory blood pressure and posture were monitored simultaneously. A generalized linear model was used to find the factors associated with NTG. The main outcome measures included the IOP-related patterns, including mean and standard deviation (SD) of measurements, amplitude of cosine-fit curve, acrophase (signal peak), and bathyphase (signal trough) values (millivolt equivalents [mVEq]). The SDs of the 24-hour CLS measurements were significantly greater in NTG eyes than in healthy controls (112.51±26.90 vs. 85.18±29.61 mVEq, p = 0.002). The amplitudes of cosine-fit curve (141.88±39.96 vs. 106.08±41.49 mVEq, p = 0.004) and acrophase values (277.74±129.80 vs. 190.58±127.88 mVEq, p = 0.024), mostly measured during nocturnal period, were significantly greater in NTG eyes than in healthy controls. The NTG subjects slept longer in the lateral decubitus posture than the healthy controls (199.1±137.8 vs. 113.2±86.2 minutes, p = 0.009). In the multivariable generalized linear model, the greater amplitude of cosine-fit curve (β = 0.218, p = 0.012) and greater time of decubitus posture during sleep (β = 0.180, p = 0.004) were found to be significantly associated with NTG. The authors concluded that continuous monitoring of 24-hour IOP-related values with CLS can be useful for assessment of glaucoma risk, especially for patients with NTG whose IOP appears to be in the normal range. Fluctuation of 24-hour IOP-related values and posture during sleep time might be associated with NTG. According to the authors a study limitation was that although the false discovery rate was controlled for using the Benjaminie-Hochberg method, multiple hypotheses were tested against a relatively small number of subjects to support the main outcome of the study. Therefore, further validation for those variables with borderline significance or broad range of confidence interval is needed. The study did not address the utility of the data for clinical management of glaucoma.

Mansouri et al. (2015) conducted a 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 patients with glaucoma 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.

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: **https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K081756.** ~~http://www.accessdata.fda.gov/cdrh_docs/pdf3/K032799.pdf.~~ (Accessed ~~April 18, 2022~~**February 13, 2023**)

Information on other similar ocular tonograph devices can be found using Product Code HKX at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed ~~April 18, 2022~~**February 13, 2023**)

On October 21, 2002, the Blood Flow Analyzer (BFA) received FDA marketing clearance. More information is available at: **https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K023245.** ~~http://www.accessdata.fda.gov/cdrh_docs/pdf2/k023245.pdf.~~ (Accessed ~~April 18, 2022~~**February 13, 2023**)

Information on other similar ocular blood flow tonometer devices can be found using Product Code NJJ at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (~~Accessed April 18, 2022~~**February 13, 2023**)

On March 4, 2016, the Triggerfish® contact lens sensor (CLS) received FDA marketing clearance. More information is available at: **https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN140017.** ~~https://www.accessdata.fda.gov/cdrh_docs/reviews/den140017.pdf.~~ (~~Accessed April 18, 2022~~**February 13, 2023**)

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Policy History/Revision Information

Date	Action/Description
TBD	**Supporting Information** • **Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information** • **Archived previous policy version CS026LA.K**

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, check the federal, state or contractual requirements for benefit plan coverage. 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.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The 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.