Anthem

Medical Policy

Subject: Continuous Monitoring of Intraocular Pressure
Document #: MED.00118
Status: Reviewed

Publish Date: 04/10/2024
Last Review Date: 02/15/2024

Description/Scope

This document addresses the continuous monitoring of intraocular pressure (IOP).

Increased IOP is associated with a greater risk of developing glaucoma and disease progression, although glaucoma may occur with normal IOP. There are two major types of glaucoma, open-angle and closed-angle. Open-angle glaucoma (OAG) is a chronic condition that progresses slowly over a long period of time. It is the most common type of glaucoma. Closed-angle glaucoma quickly develops and can cause painful and immediate vision problems.

Changes in IOP occur normally over the course of a day, with peaks in pressure reached during the night. It has been postulated that fluctuations in intra-ocular pressure are associated with the progression of glaucoma. Measurement of IOP can help lead to a diagnosis of glaucoma. However, the most commonly used tests for glaucoma (tonometry, ophthalmoscopy, perimetry, and gonioscopy) are limited to single points in time. Researchers are exploring the use of 24-hour monitoring of IOP as a means to measure fluctuations in IOP in order to assess and monitor treatment for glaucoma.

Position Statement

Investigational and Not Medically Necessary:

The use of continuous monitoring of intraocular pressure is considered **investigational and not medically necessary** for all indications.

Rationale

SENSIMED Triggerfish®

Continuous, non-invasive measurement of IOP is being explored as a means to diagnose and manage elevated IOP. In a 2011 study by Mansouri and colleagues, the authors report on 15 participants with OAG who wore the SENSIMED Triggerfish® device, a disposable silicone contact lens with an embedded micro-electromechanical system, to measure continuous IOP. A total of 13 participants completed the 24-hour study monitoring period. Discontinuation of the device was due to device intolerance and technical device malfunction. Of the 13 participants who completed the monitoring period, 9 of them had the highest signals recorded during the nocturnal period. No serious side effects were reported.

Pajic and colleagues (2011) conducted a study using the Triggerfish device to measure continuous IOP in 5 individuals with chronic OAG and normal IOP. IOP measurements were obtained before and after treatment with an intraocular pressure-lowering drug. Continuous 24-hour IOP fluctuation monitoring was performed on two occasions separated by at least 6 weeks in each participant. In the control session, participants were untreated or previous IOP-lowering medication was washed-out for a minimum of 6 weeks. In the treatment session, participants received IOP-lowering medication for at least 6 weeks. The continuous IOP recordings were analyzed for differences between daytime and nighttime data and for repeatability over time. Additionally, profiles recorded for each participant in treated and non-treated conditions were compared. The authors reported that the data recorded during daytime portions of the recordings showed higher coefficients of variation than nighttime data. Positive and significant linear slopes for the transition period from wake time to sleep time were identified in all participants in the absence of anti-glaucomatous treatment, while 3 of the 5 participants had no significant slopes detected under treated conditions. The authors concluded that the continuous IOP fluctuation monitoring device is sensitive to individual IOP rhythms and to differences in such rhythms due to anti-glaucomatous drug therapy.

Mansouri and colleagues (2012) assessed the safety, tolerability, and reproducibility of IOP patterns during two continuous 24-hour IOP monitoring sessions, 1 week apart, with the Triggerfish device. A total of 40 participants suspected of having glaucoma (n=21) or with established glaucoma (n=19) were included in the study. There was moderate correlation between the two sessions, suggesting good reproducibility of the IOP recordings. With regard to tolerability, there was no difference in adverse events or survey scores between those with established glaucoma compared with those with suspected glaucoma. Main adverse events included blurred vision (82%), conjunctival hyperemia (80%), and superficial punctate keratitis (15%). The researchers concluded that repeated use of the Triggerfish device demonstrated good safety and tolerability and that data from continuous 24-hour IOP monitoring may be useful in the management of individuals with glaucoma. A limitation of this study is the absence of a control group within the cohort that was without glaucoma, which resulted in the study not addressing the reproducibility and accuracy of IOP measurements in populations with normal or near-normal IOP.

In a prospective, single-center, open, observational parallel study in 2013 by Lorenz and colleagues, the Triggerfish sensor was evaluated for safety and tolerability. A total of 20 control participants were compared to 20 participants with glaucoma. The device was placed in one eye for 24 hours. Tolerability was measured using a visual analog scale. The safety measures included best corrected visual acuity, pachymetry, epithelial defects, conjunctival erythema and corneal topography. Of the 20 participants in each of the control and observed groups, 19 of them completed the 24-hour wearing period. The early discontinuation was attributed to pain or inappropriate fitting of the sensor due to steep corneal radii. Mean tolerability in the control group was 21.8 and 26.8 in the glaucoma group. While both the control group and the glaucoma group had similar safety and tolerability, the population size in this study was small.

In a small study by Mottet and colleagues (2013), researchers evaluated 24-hour IOP rhythm reproducibility during repeated continuous 24-hour IOP monitoring with the Triggerfish device and noncontact tonometry (NCT) in 12 healthy participants from a single institution. Participants received four 24-hour sessions of IOP measurements over a 6-month period. After initial randomized attribution, the IOP of the first eye was measured hourly using NCT and the contralateral eye was measured continuously using the Triggerfish device. Two sessions with NCT measurements in one eye and continuous contact lens measurements in the contralateral eye, one session with continuous contact lens sensor measurements in only one eye, and one session with NCT measurements in both eyes were conducted. The authors concluded that continuous IOP using the Triggerfish device is an accurate and reproducible

method to characterize the nyctohemeral IOP rhythm in healthy participants but does not allow for estimating the IOP value in millimeters of mercury corresponding to the relative variation of the electrical signal measured.

In 2014, Hollo and colleagues reported the results of a trial which evaluated 24-hour continuous IOP monitoring with the Triggerfish device to detect prostaglandin-induced IOP reduction. A total of 9 individuals with ocular hypertension and primary OAG were washed out from IOP-lowering medication for 6 weeks. One study eye per participant underwent 3 baseline 24-hour measurement curves 4 days apart: 2 curves employing continuous monitoring with a Triggerfish device and 1 curve using Goldmann applanation tonometry (GAT). Subsequently, the participants underwent travoprost monotherapy for a total of 3 months. Continuous IOP pressure monitoring using the Triggerfish device and GAT curves were repeated on the study eyes under treatment at the end of the third month. The 24-hour GAT IOP (mean ± SD) diminished from 22.91 ± 5.11 to 18.24 ± 2.49 mmHg ($p<0.001$). In contrast, the means of the 3 contact lens sensor curves demonstrated no significant difference (152.94, 142.35, and 132.98 au, $p=0.273$). The authors concluded that the continuous monitoring of IOP utilizing the Triggerfish device cannot be clinically used to monitor changes in IOP induced by topical medication in glaucoma, and has limited value in identification of transient IOP elevation periods.

DeMoraes (2018) conducted a study involving 445 participants with OAG who underwent 24-hour IOP measurements with the Triggerfish device and GAT, as well as repeat visual field testing. The goal of the study was to assess the association of a single prospective 24-hour measurement with the Triggerfish device with rates of retrospective visual field change progression. Using a multiple linear regression model, the authors reported that after adjusting for baseline visual field mean deviation change severity, age, and treatment, several Triggerfish variables were associated with fast visual field progression, including mean peak ratio while awake ($\beta=-0.021$), number of long peaks during sleep ($\beta=0.036$), night bursts ocular pulse frequency SD ($\beta=0.027$), and night bursts ocular pulse amplitude SD ($\beta=19.739$). Additionally, they stated that regression models including Triggerfish variables had better fit than Goldmann IOP when testing the association with rates of progression.

Marando and others reported on the tolerability of the Triggerfish device in 20 African American contact lens-naive participants with primary OAG over a 24-hour period. All participants wore the device for the entire 24-hour study period. Subject self-reported discomfort increased in the first 2 hours after implantation, but resolved and no significant mean discomfort from baseline was reported over the course of the 24-hour trial. Erythema of both the lid and conjunctiva were significantly increased at 24 hours after lens placement ($p=0.0018$ and $p<0.0001$), as well as 10 minutes post lens removal ($p=0.0004$ and $p<0.0001$), and 1 hour post lens removal ($p=0.0008$ and $p<0.0001$). However, gradual reduction was noted for both lid and conjunctival erythema from 10 minutes post removal to 1 hour post removal, indicating a return to baseline. A significant increase in visual impairment was reported, based on best corrected visual acuity (BCVA), with maximum impairment 15 minutes after lens placement ($p=0.0026$). This impairment persisted through the 24-hour trial and the 1-hour post lens removal. The authors noted that ad hoc assessment of subject charts indicated return to baseline at some unspecified time post lens removal. Additionally, tear film break-up time, corneal staining, and keratometry were not significantly changed from baseline at any recorded point post lens removal. One potential issue was a reported significant decrease in corneal thickness at both 10 minutes post lens removal ($p<0.0001$) and 1 hour post lens removal ($p=0.023$). However, they noted a trend towards normalization was seen at 1 hour post removal.

Gillman (2020) reported a study evaluating a Triggerfish data-based progression report (PR) compared to physician estimates based on clinical assessments. The study involved 30 participants with OAG who underwent 24-hour IOP monitoring from which a progression report was produced estimating the likelihood of glaucoma progression detected by at least three visual field tests over the course of 2 years. The progression report estimates were compared to clinical assessments by two separate masked physicians and the visual field test results. Overall visual field mean deviation progressed by an average of 0.9 ± 1.6 dB/y (Decibels per year), including 8 (26.7%) determined to be fast progressors (visual field mean deviation decrease by an average of 2.9 ± 1.9 dB/y). The average progression report risk score was 42%, vs. 39% and 25% for the two masked assessors. The average scores of both assessors resulted in a mean risk score of 32%. Correlations were good between the two assessors ($r=0.59$), and between progression report risk score and the first assessor ($r=0.64$), but only fair between progression report risk score and the second assessor ($r=0.43$). Correlation between the progression report risk scores and the averaged assessors' gradings was good, at 0.59. Correlation between the annual visual field mean deviation decrease progression rates and progression report risk score, Assessor 1 and Assessor 2's gradings were $r=0.57$, 0.31, and 0.43, respectively. The authors concluded that "PR provided comparable predictions of the risk of fast VF progression as did physician estimates based on all available clinical data." However, the results from this study are limited by low power and other methodological issues.

Shioya (2020) reported on a study involving 65 participants characterized by glaucomatous visual field defects and optic disc damage, open iridocorneal angle and the absence of secondary causes of glaucoma. All participants underwent 24-hour Triggerfish monitoring, and serial GAT measurements every 3 hours over a period of 15 hours. The authors combined the data for each GAT timepoint with the corresponding Triggerfish data to assess participants' potential for exceeding the threshold for diagnosis of normal tension glaucoma. The authors reported that sensitivity was at least 60% for four out of the six timepoints measured. Two specific timepoints (15:00 and 18:00) were highly sensitive, at 100% each. Negative predictive value was above 90% for all timepoints. The authors concluded that "Contact lens sensor information can be used in conjunction with a single tonometric reading to determine patients' potential of having IOP levels exceeding the diagnostic threshold within a 24-hr period, without the need to perform a 24-hr tonometric curve." These results indicate there is some potential role for use of the Triggerfish device in identifying individuals with glaucoma who may be missed with routine screening. However, the results of this trial should be validated in a larger trial with a more robust methodology.

Miki (2020) reported on the impact of Triggerfish device use on refractive error. The authors described a small study involving 14 participants with primary OAG who underwent 24-hour IOP measurements followed by automated refraction, keratometry, anterior segment optical coherence tomography 2 to 4 days post lens removal. Post-lens removal, slit-lamp examination revealed superficial punctate keratitis in 2 participants, severe conjunctival hyperemia in 1 subject (7.1%), and a mild Descemet membrane fold in 1 subject (7.1%). All these adverse events resolved without treatment at the second post lens-removal visit. The myopic spherical equivalent (SE) increased significantly from −5.1 ± 4.2 D to −6.0 ± 4.1 D after 24-hour monitoring ($p<0.001$), but had returned to the baseline levels by the second visit (−5.3 ± 4.4 D, $p=0.315$). The cylindrical refractive errors were not significantly different (−1.1 ± 0.8 D and −1.1 ± 0.6 D, respectively, $p=0.953$). The peripheral corneal thickness increased significantly (609.8 ± 27.6 to 625.3 ± 27.1 μm ($p<0.001$). No significant differences in any tomographic parameters were reported. The authors concluded that 24-hour measurement with the Triggerfish device resulted in significant increases in the myopic refractive error, corneal central steepening, and midperipheral flattening. However, they commented that these changes are transient and do not negate the clinical merits of the Triggerfish device.

Yang and colleagues (2020) described another study evaluating the correlation of 24-hour IOP measurement with visual field progression in 32 participants with primary OAG. All participants had a minimum of 2.5 years of follow-up and at least 3 measurements with comprehensive ophthalmologic examination including standard automated visual field tests (mean 9.9 ± 4.4 years). All participants underwent two or three 24-hour trials with the Triggerfish device. An average of 5.1 ± 3.1 visual field tests were acquired prior to Triggerfish recordings over a period of 3.1 ± 2.1 years. An average of 6.8 ± 4.2 visual field tests were acquired over 2.7 ± 1.2 years following Triggerfish recordings. The average rate of mean deviation progression was -0.2 ± 0.4 dB/year, with 26 eyes progressing less than -0.5 dB/year and 6 eyes progressing more than -0.5 dB/year. The average number of glaucoma medications

was 1.2 ± 1.0 and average number of laser trabeculoplasty procedures was 0.4 ± 0.7. During the follow-up period, 6 eyes underwent glaucoma surgery, and 11 eyes received cataract surgery. A multivariate analysis indicated that participants with larger nocturnal variability per 10 Units recorded by 24-hour IOP study were significantly more likely to have faster rate of progression (Coefficient -0.249, p=0.035). The authors concluded that 24-hour IOP recording of IOP-related ocular dimensional change was associated with faster visual field progression and may be useful to assess the risk of progression in individuals with OAG.

Gaboriau (2023) reported a prospective cross-sectional study evaluating the Triggerfish device's ability to compare 24-hour IOP-related fluctuation monitoring in 54 participants with OAG. The participants were stratified into two groups based upon different rates of visual field progression measured with standard automated perimetry, < -0.5 dB/year (Group 1) or ≥ -0.5 dB/year (Group 2). Monitoring was begun in the morning for all participants following Goldman applanation tonometry IOP measurement. The Triggerfish device was monitored 24 hours and then removed. At the end of the study period, the magnitude of monitoring curve (24hMagn) was significantly higher in group 1 (343.1 ± 62.3 mV) than in group 2 (274.0 ± 75.0 mV; p=0.0027), as was the absolute value of the area under the monitoring curve (24hArea; p=0.0251). The authors reported an overall accuracy of 77.7%, sensitivity of 81.3%, and specificity of 72.7%. They concluded that use of the Triggerfish device, in addition to other predictive factors, may allow earlier identification of disease progression and appropriate treatment adjustments.

In addition to these studies, there are a number of studies that describe the use of the Triggerfish device to characterize IOP patterns in different circumstances, including over 24 hours (Agnifili, 2015; Hoban, 2017; Muniesa, 2019; Wasilewicz, 2020) and nocturnally (Duby, 2020; Kim, 2020; Lee, 2015; Mansouri; 2015a and 2015b; Posarelli, 2018). The impact of various conditions and procedures on IOP, including sleep apnea (Carnero, 2020), surgical procedures (Cutolo, 2019; Lee, 2014; Rekas, 2016), and pseudoexfoliation syndrome (Tojo, 2016 and 2020) have also been studied using the Triggerfish device. These studies do not provide any useful information regarding the use of the Triggerfish device in the clinical setting, but do demonstrate its possible utility as a research tool.

Overall, continuous IOP monitoring with the Triggerfish device and standard tonometry for measurement of IOP are two methods that are not directly comparable and do not have the same objective. In contrast to tonometry, which indirectly measures the IOP by applying a force on the cornea, the Triggerfish device monitors IOP indirectly via the ocular volume at the corneoscleral area. The exact calibration of the Triggerfish device output to mmHg is complex and cannot easily be translated to the mmHg of pressure expressed in tonometry.

No clinical studies have been published comparing the rates of glaucoma progression in individuals who have undergone continuous monitoring of IOP compared to individuals who are monitored using current standard practice. Also, the peer-reviewed studies consist of small study populations and lack long-term follow-up.

Pressure Measuring Contact Lens

Gillman and colleagues (2021) reported on a proof-of-concept for a novel pressure-measuring contact lens (PMCL). The purpose of the study was to assess the reliability of the novel PMCL for IOP measurement against pneumatonometry, in healthy individuals and those with OAG exposed to tests and change in body position. There were 8 participants enrolled in the study, 4 healthy and 4 with OAG. The healthy participants were required to present without nonstructural or functional defect as confirmed with optical coherence tomography (OCT) imaging or biomicroscopic examination of the optic nerve and no previous ocular pathology. Glaucoma participants had to be either untreated or without glaucoma medication for at least 4 weeks prior to the first measures. All participants were required to be 18 years of age or older with a body mass index (BMI) 30 kg/m2, a central corneal radius (CCR) between 7.5 mm (45 D) and 7.9 mm (42.75 D), a central corneal thickness (CCT) between 500 µm and 600 µm in both eyes and a good IOP symmetry between eyes to enable inter-eye comparisons. The mean age was 52.9 ± 17.2 years, with the glaucoma group being older than the healthy participants (63.0 ± 18.2 vs. 42.7 ± 9.4 years respectively). All enrolled participants were fitted with the PMCL, and pneumatonometer measurements of IOP were repeated in the fellow eye (1) in sitting position, (2) supine position, (3) 30 minutes before and over 1 hour after a water drinking test (WDT) during which participants were asked to drink 1 liter of water within 5 minutes. Following the WDT, participants were to resume their daily activities and returned after 24 hours for removal of the PMCL. The authors concluded that the preliminary results confirmed that the PMCL was able to measure IOP continuously for up to 24 hours. Across all timepoints, 88.0% of PMCL measurements were within 5 mmHg of that made with a pneumatonometer on the fellow eyes. The ± 5 mmHg threshold being the generally accepted limit for testing new pneumatonometers, the authors suggested that the PMCL is capable of accurately measuring IOP variations. Gillman and colleagues concluded the results were encouraging, there was a fair accuracy in IOP values measurement compared to pneumatonometry, and a good sensitivity to subtle IOP variations over 24 hours. It was noted that the device still needed to be optimized to improve performance, safety and tolerability, and tested in larger cohorts.

Implandata eyemate® System

Another device, the eyemate® system, consists of a permanent implantable and biocompatible micro sensor, responsible for intraocular pressure measurements. Three hundred data points are acquired during a 30-second measurement period, which is repeated every 5 minutes. The micro sensor is powered and read by an external device.

Koutsonas (2018) reported the use of the eyemate system in a single subject with OAG in whom the system was implanted during cataract surgery. In this feasibility study the subject wore a sleep mask at night and eyepatch during the day, both of which had imbedded antennae to receive data from the implant. They were monitored for 3 consecutive days involving 24-hour IOP measurements. The device was well tolerated with no impairment or sleep disturbances reported. No mention of adverse events was made.

Enders (2019) conducted a study to evaluate IOP in 12 participants undergoing implantation of Boston keratoprosthesis. The eyemate system was implanted at the same time as the keratoprosthesis and was monitored for 12 months. IOP measurements were compared to finger palpation at each post-operative visit. The authors reported that Kruskal-Wallis test results indicated a statistically significant difference between telemetric IOP measurements and finger palpation categories (p<0.001), but the clinical significance of this finding is unclear. No adverse events were reported.

Choritz (2019) conducted a safety and performance trial of the eyemate system in 22 participants with primary OAG undergoing cataract surgery. The eyemate device was implanted at the same time as the artificial lens. Participants were followed for 12 months and comparison of the eyemate IOP data to GAT was made at each visit. Surgical complications related to the eyemate device occurred in 5 participants and included iris prolapse/floppy iris and pigment dispersion. All complications occurred early in the study and were avoided after re-evaluation of the surgical procedure and retraining of the surgeons. Serious adverse events were reported in 4 participants and included 2 cases of fibrin reaction in the anterior chamber, 1 case of temporary corneal decompensation, and 1 case of intractable IOP increase requiring glaucoma surgery. The fibrin reactions resolved with intensive anti-inflammatory therapy. Additionally, 70 nonserious adverse events possibly related to the medical device were reported in 18 participants. These included increased IOP, (22 times in 14 participants), anterior chamber inflammation with increased anterior chamber cells and Tyndall flare (11 times in 9 participants), mild to moderate pigment dispersion in 8 participants and 1 case of persistent cystoid macular edema. There was a slight decrease in anterior chamber angle from median Shaffer grade 3 at screening to a median Schaffer grade 2 at the

end of study. An increase in median pigmentation from mild to moderate over the course of the study was also reported. Mild to moderate iris transillumination defects were seen in 8 participants and mild pigment deposits in the anterior chamber in 6 participants at the end of the study. A total of 434 comparisons of IOP measurements from the eyemate system and GAT revealed good concordance (Cronbach alpha of 0.882 and an intraclass correlation coefficient of 0.783). The authors noted that on average eyemate measurements were higher than GAT measurements with a mean difference of 3.2 mm Hg, and that this difference was consistent throughout the study period. Throughout the study, participants were asked to check IOP data from the eyemate device 4 times a day at times of their choosing, and data indicated high utilization with an average of 7.9 checks per day over the study period. There were no permanent device malfunctions reported, and those that were reported were related to a shift in IOP measurements that was resolved with recalibration.

Szurman (2022) reported the results of a prospective, open-label, single-arm study investigating the 1-year safety, performance, and accuracy of the eyemate-SC in 24 participants with primary OAG undergoing simultaneous nonpenetrating glaucoma surgery (n=15 canaloplasty and n=9 deep sclerectomy). A total of 536 eyemate measurements were pairwise compared to GAT measurements. During the first 3 months postoperatively, the eyemate measurements were significantly higher than GAT measurements, with a maximum difference of 2.5 mmHg at day 10. Subsequent to the 3-month time point, the overall difference between the two measurement methods declined significantly, reaching a stable agreement through the end of the study (mean overall difference -0.3 mmHg at day 360). No device migration, dislocation, or serious device-related complications were recorded. The most frequent postoperative complication was spontaneously resolving hyphema (n=9). Additionally, the following were also reported: superficial punctate keratitis of 3 weeks duration (n=2), early postoperative leakage (n=1), choroidal detachment and hypotony for 3 weeks (n=1), postoperative photopsia of 5 weeks duration (n=1), touch sensitivity (n=3), operative site pain (n=2), and intermittent headaches (n=1). The results of this underpowered, unblinded study need to be confirmed by a more methodologically robust trial.

As with the Triggerfish device, the eyemate system has been used to help characterize daily and seasonal fluctuations in IOP (Mansouri 2020a and 200b). An additional study investigated the use of the eyemate device with simultaneous steady state pattern electroretinogram during IOP manipulation (Al-Nosairy, 2020).

Overall, the clinical utility of these results has not been elucidated to date, and additional investigation is warranted.

Background/Overview

In healthy individuals, IOP is generally between 10 and 20 mmHg. Small changes in the IOP during the course of the day and from one season to another are normal. IOP varies with changes in respiration or heart rate, and may also be affected by fluid intake and exercise. Temporary changes in IOP may also be caused by coughing, vomiting, or straining to lift heavy objects. Significant and/or persistent changes in IOP may be caused by anatomical problems (such as excessive production or drainage of aqueous fluid), inflammation in the eye following trauma or infection, medication use and genetic factors. A significant change in IOP that is sustained and goes untreated may eventually cause vision problems and lead to eye disease.

Glaucoma is a grouping of diseases that can damage the optic nerve and result in vision loss and blindness. Older adults have the greatest risk for developing glaucoma. Glaucoma may occur when the normal pressure of the fluid inside the eye slowly rises. However, it can also occur in individuals who do not have a rise in eye pressure.

There are two major types of glaucoma; open-angle and closed-angle. OAG is a chronic condition that progresses slowly over a long period of time. It is the most common type of glaucoma, affecting approximately 3 million Americans and is a leading cause of blindness according to the Centers for Disease Control (CDC). Closed-angle glaucoma quickly develops and can cause painful and immediate vision problems. Closed-angle glaucoma is less common than OAG.

Measurement of IOP can help lead to a diagnosis of and manage treatment for glaucoma. The use of 24-hour monitoring of IOP is being explored as a means to continuously measure variations in the IOP.

One device proposed for continuous IOP measurement is the SENSIMED Triggerfish device. According to the manufacturer's website, the Triggerfish device consists of a disposable soft silicone contact lens which contains a sensor, a flexible disposable self-adhesive antenna placed around the eye and a pocket-sized recorder. The recorder sends the collected information to a doctor's computer via Bluetooth. The Triggerfish device measures small changes in the curvature of the cornea which are purported to reflect changes in the IOP.

In March 2016, the SENSIMED Triggerfish device received FDA marketing clearance for the following use:

> To detect the peak patterns of variation in intraocular pressure over a maximum period of 24 hours to identify the window of time to measure intraocular pressure by conventional clinical methods. The SENSIMED Triggerfish® is indicated for patients 22 years of age and older (FDA, 2017).

Unlike the Triggerfish device which is removable, another device, the Implandata eyemate® system, is a permanently implantable micro sensor. The eyemate system is implanted into the eye to detect intraocular pressure and sends measurements to an external hand-held device. The eyemate system has not been cleared or approved by the FDA.

Although the Triggerfish and Eyemate system are commercially available to provide clinicians with information on an individual's real-life IOP fluctuations, the novel contact lens sensor device, (PMCL, Sensimed, Lausanne, Switzerland) was developed to monitor 24-hour IOP in ambulatory conditions, regardless of an individual's positions or activities, including sleep periods. The system is composed of a PMCL that transmits its measurements wirelessly to a periorbital patched adhesive antenna and a recorder. At the end of the recording period, individuals return to the clinic for removal of the PMCL, and analysis of the 24-hour IOP measurements stored on the recorder. (Gilman, 2021).

Definitions

Glaucoma: A group of diseases that can damage the optic nerve and result in vision loss and blindness.

Intraocular: Located within or administered through the eye.

Intraocular pressure (IOP): The tissue pressure within the eye; a measurement of the balance between the production and drainage of aqueous humor.

Optic nerve: A collection of more than 1 million nerve fibers which connects the retina to the brain.

Retina: The light-sensitive tissue at the rear of the eye.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure code, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

0329T	Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

1. Agnifili L, Mastropasqua R, Frezzotti P, et al. Circadian intraocular pressure patterns in healthy subjects, primary open angle and normal tension glaucoma patients with a contact lens sensor. Acta Ophthalmol. 2015; 93(1):e14-e21.
2. Al-Nosairy KO, van den Bosch JJON, Pennisi V, et al. Use of a novel telemetric sensor to study interactions of intraocular pressure and ganglion-cell function in glaucoma. Br J Ophthalmol. 2021; 105(5):661-668.
3. Carnero E, Bragard J, Urrestarazu E, et al. Continuous intraocular pressure monitoring in patients with obstructive sleep apnea syndrome using a contact lens sensor. PLoS One. 2020; 5(3):e0229856.
4. Choritz L, Mansouri K, van den Bosch J, et al. ARGOS study group. Telemetric measurement of intraocular pressure via an implantable pressure sensor-12-month results from the ARGOS-02 trial. Am J Ophthalmol. 2020; 209:187-196.
5. Cutolo CA, De Moraes CG, Liebmann JM, et al.; Triggerfish Consortium. The effect of therapeutic IOP-lowering interventions on the 24-hour ocular dimensional profile recorded with a sensing contact lens. J Glaucoma. 2019; 28(3):252-257.
6. De Moraes CG, Mansouri K, Liebmann JM, Ritch R; Triggerfish Consortium. Association between 24-hour intraocular pressure monitored with contact lens sensor and visual field progression in older adults with glaucoma. JAMA Ophthalmol. 2018; 136(7):779-785.
7. Dubey S, Mittal D, Mukherjee S, et al. Relationship between nocturnal intraocular pressure-related peak recorded by contact lens sensor and disease progression in treated glaucomatous eyes. Indian J Ophthalmol. 2020; 68(11):2427-2433.
8. Enders P, Hall J, Bornhauser M, et al. Telemetric intraocular pressure monitoring after Boston keratoprosthesis surgery using the Eyemate-IO sensor: dynamics in the first year. Am J Ophthalmol. 2019; 206:256-263.
9. Gaboriau T, Dubois R, Foucque B, et al. 24-Hour monitoring of intraocular pressure fluctuations using a contact lens sensor: diagnostic performance for glaucoma progression. Invest Ophthalmol Vis Sci. 2023; 64(3):3.
10. Gillmann K, Young CC, Stanley J, et al. Relationship between contact lens sensor output parameters and visual field progression in open-angle glaucoma: assessment of a practical tool to guide clinical risk-assessment. J Glaucoma. 2020; 29(6):461-466.
11. Gillmann K, Wasilewicz R, Hoskens K, et al. Continuous 24-hour measurement of intraocular pressure in millimeters of mercury (mmHg) using a novel contact lens sensor: comparison with pneumatonometry. PLoS One. 2021; 23:16(3):e0248211.
12. Hoban K, Peden R, Megaw R, et al. 24-hour contact lens sensor monitoring of intraocular pressure-related profiles in normal-tension glaucoma and rates of disease progression. Ophthalmic Res. 2017; 57(4):208-215.
13. Hollo G, Kothy P, Vargha P. Evaluation of continuous 24-hour intraocular pressure monitoring for assessment of prostaglandin-induced pressure reduction in glaucoma. J Glaucoma. 2014; 23(1):e6-e12.
14. Koutsonas A, Walter P, Kuerten D, Plange N. Automated, noncontact intraocular pressure home monitoring after implantation of a novel telemetric intraocular pressure sensor in patients with glaucoma: a feasibility study. Biomed Res Int. 2018; 2018:4024198.
15. Lee JW, Fu L, Chan JC, et al. Twenty-four-hour intraocular pressure related changes following adjuvant selective laser trabeculoplasty for normal tension glaucoma. Medicine (Baltimore). 2014; 93(27):e238.
16. Lee JW, Fu L, Shum JW, et al. Continuous 24-hour ocular dimensional profile recording in medically treated normal-tension glaucoma. Clin Ophthalmol. 2015; 9:197-202.
17. Lorenz K, Korb C, Herzog N, et al. Tolerability of 24-hour intraocular pressure monitoring of a pressure-sensitive contact lens. J Glaucoma. 2013; 22(4):311-316.
18. Mansouri K, Gillmann K, Rao HL, Weinreb RN; ARGOS–2 Study Group. Weekly and seasonal changes of intraocular pressure measured with an implanted intraocular telemetry sensor. Br J Ophthalmol. 2021; 105(3):387-391.
19. Mansouri K, Medeiros FA, Tafreshi A, Weinreb RN. Continuous 24-hour monitoring of intraocular pressure patterns with a contact lens sensor: safety, tolerability, and reproducibility in patients with glaucoma. Arch Ophthalmol. 2012; 130(12):1534-1539.
20. Mansouri K, Medeiros FA, Weinreb RN. Effect of glaucoma medications on 24-hour intraocular pressure-related patterns using a contact lens sensor. Clin Exp Ophthalmol. 2015a; 43(9):787-795.
21. Mansouri K, Rao HL, Weinreb RN; ARGOS-02 Study Group. Short-term and long-term variability of intraocular pressure measured with an intraocular telemetry sensor in patients with glaucoma. Ophthalmology. 2020b; S0161-6420(20)30678-3.
22. Mansouri K, Shaarawy T. Continuous intraocular pressure monitoring with a wireless ocular telemetry sensor: initial clinical experience in patients with open angle glaucoma. Br J Ophthalmol. 2011; 95(5):627-629.
23. Mansouri K, Weinreb RN, Liu JH. Efficacy of a contact lens sensor for monitoring 24-h intraocular pressure related patterns. PLoS One. 2015b; 10(5):e0125530.
24. Marando CM, Mansouri K, Kahook MY, Seibold LK. Tolerability and functionality of a wireless 24-hour ocular telemetry sensor in African American glaucoma patients. J Glaucoma. 2019; 28(2):119-124.
25. Miki A, Kumoi M, Maeda N, et al. Transient changes in refractive error and corneal tomography after 24-h continuous monitoring of intraocular pressure patterns with a contact lens sensor. Jpn J Ophthalmol. 2020; 64(2):127-133.
26. Mottet B, Aptel F, Romanet JP, et al. 24-hour intraocular pressure rhythm in young healthy subjects evaluated with continuous monitoring using a contact lens sensor. JAMA Ophthalmol. 2013; 131(12):1507-1516.
27. Muniesa MJ, Ezpeleta J, Benítez I. Fluctuations of the intraocular pressure in medically versus surgically treated glaucoma patients by a contact lens sensor. Am J Ophthalmol. 2019; 203:1-11.
28. Pajic B, Pajic-Eggspuchler B, Haefliger I, et al. Continuous IOP fluctuation recording in normal tension glaucoma patients. Current Eye Research 2011; 36(12):1129-1138.
29. Posarelli C, Ortenzio P, Ferreras A, et al. Twenty-four-hour contact lens sensor monitoring of aqueous humor dynamics in surgically or medically treated glaucoma patients. J Ophthalmol. 2019; 2019:9890831.

30. Shioya S, Higashide T, Tsuchiya S, et al. Using 24-hr ocular dimensional profile recorded with a sensing contact lens to identify primary open-angle glaucoma patients with intraocular pressure constantly below the diagnostic threshold. Acta Ophthalmol. 2020; 98(8):e1017-e1023.
31. Szurman P, Gillmann K, Seuthe AM, et al.; EYEMATE-SC Study Group. EYEMATE-SC trial: twelve-month safety, performance, and accuracy of a suprachoroidal sensor for telemetric measurement of intraocular pressure. Ophthalmology. 2023a; 130(3):304-312.
32. Tojo N, Abe S, Ishida M, et al. The fluctuation of intraocular pressure measured by a contact lens sensor in normal-tension glaucoma patients and nonglaucoma subjects. J Glaucoma. 2017; 26(3):195-200.
33. Tojo N, Hayashi A. Can a contact lens sensor predict the success of trabectome surgery? Graefes Arch Clin Exp Ophthalmol. 2020; 258(4):843-850.
34. Tojo N, Hayashi A, Otsuka M, Miyakoshi A. Fluctuations of the intraocular pressure in pseudoexfoliation syndrome and normal eyes measured by a contact lens sensor. J Glaucoma. 2016; 25(5):e463-468.
35. Wasilewicz R, Varidel T, Simon-Zoula S, et al. First-in-human continuous 24-hour measurement of intraocular pressure and ocular pulsation using a novel contact lens sensor. Br J Ophthalmol. 2020; 104(11):1519-1523.
36. Yang Z, Mansouri K, Moghimi S, Weinreb RN. Nocturnal variability of intraocular pressure monitored with contact lens sensor is associated with visual field loss in glaucoma. J Glaucoma. 2021; 30(3):e56-e60.

Government Agency, Medical Society, and Other Authoritative Publications:

1. U.S Food and Drug Administration. De Novo Classification Request for Sensimed Triggerfish®. February 2017. Available at: http://www.accessdata.fda.gov/cdrh_docs/reviews/den140017.pdf. Accessed on February 1, 2024.

Websites for Additional Information

1. American Optometric Association. Glaucoma. Available at: http://www.aoa.org/patients-and-public/eye-and-vision-problems/glossary-of-eye-and-vision-conditions/glaucoma?sso=y. Accessed on February 1, 2024.
2. Centers for Disease Control and Prevention. Vision Health Initiative (VHI). Don't let glaucoma steal your sight! Last updated November 24, 2020. Available at: https://www.cdc.gov/visionhealth/resources/features/glaucoma-awareness.html#:~:text=Open%2Dangle%20glaucoma%2C%20the%20most,vision%20and%20prevent%20vision%20loss. Accessed on February 1, 2024.
3. National Eye Institute. Types of Glaucoma. Last reviewed: September 10, 2021. Available at:https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/glaucoma/types-glaucoma. Accessed on February 1, 2024.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Description, Rationale, Background, References and Websites sections.
Reviewed	02/16/2023	MPTAC review. Updated Rationale, Background, References and Websites sections.
Reviewed	02/17/2022	MPTAC review. Updated Rationale, Background, References and Websites sections.
Reviewed	02/11/2021	MPTAC review. Updated Description, References, Background, Websites, and Index sections.
Reviewed	02/20/2020	MPTAC review. Updated References and Websites for Additional Information sections.
Reviewed	03/21/2019	MPTAC review. Updated References and Websites for Additional Information sections.
Reviewed	05/03/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated References and Websites for Additional Information sections.
Reviewed	05/04/2017	MPTAC review. Updated Rationale, Background/Overview and References sections.
Reviewed	05/05/2016	MPTAC review. Updated Rationale and References sections. Removed ICD-9 codes from Coding section.
New	05/07/2015	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.