KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Continuous 24-hour monitoring of Intraocular Pressure

- SENSIMED Triggerfish® telemetric contact lens sensor (CLS; Sensimed AG, Lausanne, Switzerland)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **"**Continuous 24-hour monitoring of Intraocular Pressure**"** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Glaucoma is the second leading cause of blindness worldwide. It is a chronic optic neuropathy characterized by the loss of retinal ganglion cells and its axons. If left untreated, the condition progresses leading to reduction of the visual field and eventually loss of sight. Elevated intraocular pressure (IOP) is the only proven modifiable risk factor for the development and progression of glaucoma. Results of a pivotal glaucoma trial suggest that a 1 mmHg increase in IOP is associated with an 11% increase in the hazard ratio for the progression of glaucoma. Thus, the accurate measurement of IOP and its efficient control are essential in the management of glaucoma (De Smedt 2012, Freiberg 2012, Lorenz 2013, Mansouri 2012, 2013).

Some investigators reported that IOP fluctuates throughout the day (defined as nyctohemeral rhythm) in healthy and glaucomatous eyes and that understanding the IOP behavior over time is important for the management and treatment decisions. However, the role of IOP fluctuation as an independent predictive factor for glaucoma progression is still controversial. The current gold standard for measuring IOP is the Goldmann Applanation Tonometry (GAT), but it only provides a snapshot of IOP at a given moment and is normally used in the office by

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an ophthalmologist. The 24-hour IOP profiles are of increasing interest, and the repeated IOP measurements over 24-hour period may be performed using portable tonometry, but this can only provide multiple static and non-continuous snapshots for the IOP; up to one measurement per hour at the best. This also requires awakening the patient during the nocturnal sleep period which may potentially lead to stress-related artifacts and sleep disturbances. The 24-hour continuous use of GAT for assessing the IOP profile is only possible in specialized centers with a sleep laboratory (Mansouri 2013, Lorenz 2013, and Mottet 2013).

The SENSIMED Triggerfish® telemetric contact lens sensor (CLS; Sensimed AG, Lausanne, Switzerland) was recently developed to continuously monitor the IOP pattern in glaucoma in an ambulatory setting. The device does not directly measure IOP but is based on the assumption that there is a correlation between IOP and the corneal curvature. Its key element is a soft disposable silicone contact lens with an embedded microsensor that captures spontaneous circumferential changes at the corneoscleral area, allowing the measurement of changes in corneal curvature which are considered by investigators to be representative for IOP changes. The adhesive SENSIMED Triggerfish® Antenna, which is placed around the eye, wirelessly receives the information from the contact lens. Three hundred data points are acquired during a 30-second period every 5 minutes providing a total of 288 measurements over a 24-hour period. The data is transmitted through a thin flexible cable from the antenna to a portable recorder worn on the patient's waist. This stores the acquired data during the monitoring session. At the end of the recording period, the data is transferred via Bluetooth from the recorder to the software previously installed on the practitioner's computer for analysis. The CLS measurement is made automatically for a maximum of 24 hours (Frieberg 2012, Lorenz 2013, Mottet 2013, Hollo 2014, Manufacturer's webpage).
As indicated earlier, the CLS is based on an assumption that there is a correlation between IOP, and the corneal curvature and it can only provide indirect measurement of the IOP through changes in the corneal curvature. In addition, CLS does not display the output signal in mmHg, but in arbitrary units (au) that are proportional to the electric signal generated by the contact lens-embedded strain gauge. Calibration of the CLS output to mmHg is a challenge as the simultaneous use of CLS and tonometry on the same eye is not feasible. Another limitation is that CLS provides 288 IOP data points instead of a single one measurement (or 8 measurements typically obtained in a diurnal tension curve) which poses a challenge to the clinician. Since the output signal of the CLS is dependent on changes occurring at the corneoscleral junction, non-IOP-related changed in the corneal shape, hydration, or thickness may potentially affect the device output. It is also reported that information on the clinical meaning and practical value of the CLS curves is limited (Mansouri 2012, 2013, Mottet 2013, Hollo 2014).

The contact lens sensor (CLS) may lead to similar side effects caused by the classic vision correction contact lenses. Among the reported adverse effects were innocuous superficial corneal staining, corneal edema, superficial keratitis, and others (Mansouri 2012).

SENSIMED Triggerfish® was approved for use by the European regulatory authorities. It has not been approved by the US Food and Drug administration to date.

Medical Technology Assessment Committee (MTAC)

Continuous 24-hour monitoring of Intraocular Pressure

6/16/2014: MTAC REVIEW

Evidence Conclusion: The role of IOP fluctuation as an independent predictive factored for glaucoma progression is still controversial and has not been proved in large, well-designed prospective studies, to date. Also, the assumption that there is a correlation between IOP, and the corneal curvature is not universally accepted. The SENSIMED Triggerfish® telemetric contact lens sensor was not validated in humans, only in ex vivo in enucleated porcine eyes. The largest published study on continuous 24-hour monitoring of IOP patterns with contact lens sensor was conducted by Mansouri and colleagues (2012). They examined the safety, tolerability, and reproducibility of the device among 40 patients with established (n = 19) or suspected (n = 21) glaucoma in 2 study sessions conducted approximately 1 week apart. After a baseline ophthalmic examination, the patients were fitted with the CLS and re-examined after a 24-hour monitoring session. All participants underwent a second 24-hour monitoring session approximately 1 week later. Complete ophthalmic examinations were performed after each monitoring session, and any change from the baseline ophthalmic examination was reported as an adverse event (AE). Complete data recording was obtained from 37 patients in the first session and 39 patients in the second session. Data were not available for 4 patients' due poor battery or disconnection of the device or other unknown reason. The calculated Pearson correlation was ($r = 0.59$, $P = .12$) indicating fair to good agreement between the 2 sessions. Patient comfort level was assessed by visual analog scale, which showed moderate to good tolerability of the device (mean score 27.2 + 18.5mm in the first monitoring session and 23.8 + 18.7mm in the second session). 49 device-related adverse events occurred among 38 study participants (Table). All AEs were transient and resolved within 24 hours of CLS removal. Adverse events (AEs) in patients undergoing 24-hour intraocular monitoring with CLS

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Adverse events	No. of even	No. (%) of patients with AEs
Mild		32 (80)
Blurred vision	58	30 (75)
Conjunctival hyperemia	52	13 (32)
Eye complications associate	17	5 (12)
with device	5	3 (8)
Superficial punctate keratitis	3	3 (8)
Eye irritation	3	1 (2)
Eye pruritus	2	1 (2)
Ocular discomfort	1	1 (2)
Conjunctival edema	1	1 (2)
Device intolerance		
Moderate		
Superficial punctate keratitis	1	1 (2)
Blurred vision	1	1 (2)
Severe		
Conjunctival edema.	5	2 (5)

A more recent very small study (Hollo 2014) evaluated 24-hour continuous intraocular pressure (IOP) monitoring with a CLS to detect prostaglandin-induced IOP reduction. The study included nine ocular hypertensive and primary open-angle glaucoma patients. After a washed-out from IOP-lowering medication for 6 weeks, one study eye per patient underwent 3 baseline 24-hour measurement curves 4 days apart: 2 curves with Sensimed Triggerfish CLS and 1 curve with standard tonometry (GAT). The patients then received travoprost monotherapy for 3 months. The 24-hour CLS and tonometry curves were repeated on the study eyes after 3 months. The results showed that a significant decrease in IOP measured by the 24-hour GAT, but no significant difference was observed in the means of the 3 CLS curves. There was a high correlation between the 3 CLS curves but no correlation was seen between the CLS and GAT values either at baseline or under treatment. The authors concluded that these results suggest that the current CLS technique cannot be clinically used to monitor IOP decrease induced by topical medication in glaucoma and has limited value in identification of transient IOP elevation periods. Impact on management was studied in a small case series (Mansouri 2011) with 15 glaucoma patients with worsening disease despite the controlled IOP values as measured by office GAT. The 24-hour monitoring with CLS found that 9/13 (69%) of the patients who completed the 24-hour monitoring had the highest IOP during sleep. Based on the CLS findings, the management plan was changed in 11 (73%) patients.
There is a lack of published literature on 24-hour IOP monitoring using contact lens sensors.
Articles: The literature search did not reveal any validation study of the CLS or any other study that compared its accuracy with the gold standard of 24-hour GA, or trial that evaluated its clinical utility in managing patients with glaucoma. There was only a limited number of very small observational nonrandomized studies or case series that examined the safety and tolerability of the CLS. The population sizes varied between 5-15 subjects with only one study involving 40 individuals. The published studies were mainly conducted in Europe, particularly in Switzerland, mostly by the same group of authors, and sponsored by the SENSIMED the manufacturer of the SENSIMED Triggerfish® telemetric contact lens sensor.

The use of Continuous 24-hour monitoring of intraocular pressure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	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

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

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Date Created	Date Reviewed	Date Last Revised
07/01/2014	07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 10/02/2018[MPC], 10/01/2019 [MPC], 10/06/2020[MPC], 10/05/2021[MPC], 10/04/2022[MPC]	07/01/2014

[MPC] Medical Policy Committee

Revision History	Description

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