Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 7/1/23**
(See policy history boxes for previous effective dates)

Title: Continuous Intraocular Pressure Monitoring

Description/Background

Glaucoma is a condition that causes progressive damage to the optic nerve. It is associated with a gradual increase of pressure inside the eye, although glaucoma may occur with normal intraocular pressure (IOP). Over time, glaucoma can lead to vision loss and may cause blindness. As glaucoma develops, the outer peripheral field of vision is typically affected first, and people with glaucoma often do not notice any symptoms in the early stages. Fluctuations in intraocular pressure usually occur during the night and may therefore not be identified with traditional monitoring methods. As a result, some researchers have proposed that 24-hour monitoring of intraocular pressure might be helpful in assessing and monitoring glaucoma. Current devices for 24-h IOP monitoring include Icare®, Icare Home®, Triggerfish® and EyeMate®.

Sensimed, a Swiss company, developed Triggerfish®, a non-invasive ocular device designed to measure fluctuations in intraocular pressure over a 24-hour period in adults with glaucoma. Triggerfish® uses a soft disposable silicone contact lens that contains a tiny sensor, a disposable, self-adhesive antenna placed around the eye, and a small recording device that is worn around the patient's neck. According to Sensimed, the sensor in the contact lens measures variations in intraocular pressure by detecting changes in the surface of the eye. This information is transmitted from the sensor in the contact lens to the recording device via the antenna. A graph is produced, from the 24 hour measurements, which accurately portrays the intraocular pressure fluctuation over time. The recording device then sends the information to the physician's computer for evaluation.

Goldmann Applanation Tonometry is currently considered to be the Gold Standard method of measuring intraocular pressure (IOP). This method indirectly measures the pressure by gauging how much force it takes to flatten the cornea.

Regulatory Status:

The Sensimed Triggerfish® continuous intraocular pressure monitoring device received a CE mark (signify that products sold in the European Economic Area have been assessed to meet high safety, health and environmental protection requirements) in May 2009 and was launched in the United Kingdom in 2012. Triggerfish is also available commercially in Canada and Australia. In 2016 the U.S. FDA classified SENSIMED Triggerfish® as a Class II device and marketing approval was granted. Product code PLZ

Medical Policy Statement

The use of continuous intraocular pressure monitoring devices is experimental/investigational. There is insufficient evidence to permit conclusions on health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0329T

Rationale

There are no published clinical studies comparing the rate of glaucoma progression in patients who are monitored with IOP devices, such as Sensimed Triggerfish®, with individuals who are monitored using current standard practices. Further research is needed to evaluate the relationship between fluctuations in intraocular pressure and the progression of glaucoma. Additionally, studies are needed to assess the accuracy and reproducibility of the proposed intraocular pressure monitoring systems measurements in large populations of individuals.

Government Regulations

National:

There is no National Coverage Determination on this topic.

Local:

There is no Local Coverage Determination on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Corneal Hysteresis
Ophthalmologic Techniques for Evaluating Glaucoma

References

1. Hollo, G. et al., "Evaluation of continuous 24-hour intraocular pressure monitoring for assessment of prostaglandin-induced pressure reduction in glaucoma," *J Glaucoma*, Jan 2014, Volume 23, Issue 1, e6-12. doi: 10.1097/IJG.0b013e31829e5635.
2. Ittoop, S. et al., "Systematic Review of Current Devices for 24-h Intraocular Pressure Monitoring," *Adv Ther*, 2016, Volume 33 pp. 1679-90.
3. Liu, John H. K. et al., "Twenty-four–Hour Intraocular Pressure Pattern Associated with Early Glaucomatous Changes," *Investigative Ophthalmology & Visual Science*, April 2003, Vol. 44, No. 4, pp. 1586-90.
4. Lorenz, K., et al., "Tolerability of 24-hour intraocular pressure monitoring of a pressure-sensitive contact lens," *J Glaucoma*, Apr-May 2013, Volume 22, Issue 4, pp. 311-16. doi: 10.1097/IJG.0b013e318241b874.
5. Mansouri, K. et al., "Analysis of Continuous 24-h Intraocular Pressure Patterns in Glaucoma," *Invest. Ophthalmol. Vis. Sci.,* Published online before print. November 8, 2012.
6. Mansouri, K. et al., "A Minimally Invasive Device for the Monitoring of 24-hour Intraocular Pressure Patterns," *US Ophthalmic Review*, 2013;6(1):10–4.
7. Mansouri, K. et al., "Continuous 24-Hour Monitoring of Intraocular Pressure Patterns With a Contact Lens Sensor - Safety, Tolerability, and Reproducibility in Patients With Glaucoma," *Arch Ophthalmol*. Published online August 13, 2012.
8. Mottet, B. et al., "24-hour intraocular pressure rhythm in young healthy subjects evaluated with continuous monitoring using a contact lens sensor," *JAMA Ophthalmol*, 2013, Volume 131, Issue 12, pp. 1507-16. doi:10.1001/jamaophthalmol.2013.5297.
9. Richardson, D., A New Intraocular Pressure Monitoring Device, Glaucoma Healthub, 2014; http://new-glaucoma-treatments.com/the-sensimed-triggerfish-sensor-device/. Accessed February 22, 2023.

10. United States Food and Drug Administration, “DEN140017: SENSIMED Triggerfish®.” (2016). https://www.accessdata.fda.gov/cdrh_docs/pdf14/DEN140017.pdf. Accessed February 22, 2023.
11. Vetrugno, M. et al., “Continuous Intraocular Pressure Monitoring by Means of the Sensimed Triggerfish® System, *European Ophthalmic Review*, 2011;5(1);43-5.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 2/22/23, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/13	8/20/13	9/10/13	Joint policy established
3/1/15	12/12/14	12/29/14	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
7/1/17	4/18/17	4/18/17	• Routine maintenance • Added FDA approval to market
7/1/18	4/17/18	4/17/18	Routine maintenance
7/1/19	4/16/19		Routine maintenance
7/1/20	4/14/20		Routine maintenance
7/1/21	4/20/21		Routine maintenance
7/1/22	4/19/22		Routine maintenance
7/1/23	4/18/23		Routine maintenance (slp) Vendor managed: N/A

Next Review Date: 2nd Qtr, 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: CONTINUOUS INTRAOCULAR PRESSURE MONITORING

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.