Anthem

Medical Policy

Subject: Remote Devices for Intermittent Monitoring of Intraocular Pressure
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Description/Scope

This document addresses remote devices for the intermittent monitoring of intraocular pressure (IOP). Measuring of IOP is an important part of the monitoring and treatment of individuals with glaucoma and other eye conditions, and is conventionally an in-office procedure. The use of a remote hand-held device (iCare HOME2) has been proposed as an alternative.

Note: This document does not address continuous monitoring of IOP. Please see the following related document for additional information on continuous or 24-hour monitoring of IOP:

- MED.00118 Continuous Monitoring of Intraocular Pressure

Position Statement

Investigational and Not Medically Necessary:

The use of remote devices for intermittent monitoring of IOP is considered**investigational and not medically necessary** for all indications.

Rationale

Elevated IOP is implicated in the development and progression of glaucoma, a group of diseases of the eye. A common issue in glaucoma is increased pressure in the eye that may result in optic nerve damage and vision loss. Measurement of IOP is important for diagnosis and management of glaucoma. The current gold standard method for measurement of IOP is Goldmann applanation tonometry (GAT). This tonometry method is performed only by trained staff within a clinic setting and requires specialized equipment and anesthetic drops to be administered to the eyes. GAT measures the force required to flatten the cornea which is proportional to the IOP. A newer method of measuring IOP is rebound tonometry. By this method, a thin, disposable wire probe with a round plastic tip is bounced off the cornea. The deceleration of the probe is measured, which is more rapid if the IOP is high and slower if the IOP is low. The device, iCare HOME2 tonometer (iCare, Raleigh, NC), converts the deceleration into an IOP measurement. No topical anesthetic is required because of the very small size of the tip. The device is hand-held, portable, and allows individuals to self-monitor their IOP anywhere and at any time of the day.

Several studies have compared IOP measurements from a rebound self-tonometer with those obtained by standard tonometry in a clinic setting. In some cases, the self-tonometer measurements were performed by trained clinicians and in other cases, by the individuals with glaucoma themselves. When performed by clinicians, IOP measurements tended to be lower than applanation tonometry but differences were within 3 mm Hg for most individual comparisons (Huang, 2020). Ye and colleagues (2022) also found reliable correlation between measurements taken by both methods with the self-tonometer tending to underestimate the IOP in individuals with a lower IOP (< 10 mm Hg). However, in another study (Takagi, 2017), self-tonometer measurements tended to overestimate IOP relative to GAT measurements. When measured by individuals with glaucoma themselves, two studies (Brown, 2018; Cvenkel, 2020) found that self-tonometry tended to provide slightly lower average readings than GAT. Thus, questions remain about the comparability of the two methods, even in a clinic setting.

Despite the hand-held tonometer device being meant for self-monitoring, few studies have examined remote usage by individuals without professional supervision in a clinic setting. In a study to assess whether trained individuals with glaucoma could accurately and reliably measure IOP at home, Ogle and colleagues (2021) compared IOP measurements obtained using the remote hand-held tonometer before and after a week of self-monitoring at home. GAT measurements obtained in the clinic by an experienced glaucoma nurse clinician were used as a reference standard. A total of 40 subjects were studied. Subjects were trained to use the remote tonometer and measured their IOP twice daily over a loan period of 7 days. Up to 80% of subjects were able to obtain IOP readings within 3 mm Hg of the glaucoma nurse clinician's readings at the preloan visit, and up to 90% at the end of the week. Correlation between readings of the individual with glaucoma and nurse clinician readings improved from moderate to good (right eye) and from good to excellent (left eye) over the 1-week period. This may indicate that there is a learning curve for subjects during the 1-week period of usage.

In a retrospective single-center study, McGlumphy and colleagues (2021) examined IOP as measured during remote tonometry vs. in-clinic tonometry by GAT. A total of 107 eyes from 61 subjects were analyzed. Individuals were instructed to obtain at least 4 daytime measurements daily over the course of a week. Remote tonometry identified significantly higher maximum IOP, lower minimum IOP, and greater IOP range than GAT in the clinic ($p<0.001$). However, the clinical meaning of these data is unclear, that is whether these IOP fluctuations are predictive of worsening disease. The authors concluded that “Further prospective studies are needed to confirm the validity of home tonometry to aid in glaucoma decision making by assessing whether home tonometry is independently predictive of future glaucoma disease worsening.”

In a single-center prospective trial, Scott and colleagues (2022) evaluated whether remote usage of a hand-held tonometer could detect therapy-related changes during self-monitoring of IOP. A total of 27 subjects (43 eyes) were studied. Subjects were grouped into control eyes managed on stable therapy (18 eyes) or therapy change eyes destined to undergo surgery or addition of medication (25 eyes). At the outset, subjects recorded IOP 4 times daily for 1 week using remote hand-held tonometry. Following initiation of therapy, an additional week of remote IOP measurements was recorded after 4-6 weeks. Control subjects also recorded an additional week of measurements after 6 weeks. GAT was performed at each clinic visit for comparison. Response to therapy was defined as an IOP reduction of greater than or equal to 20%. For eyes that showed a therapy response by GAT (11 eyes), remote tonometry detected a therapy response in 90.9% of eyes in at least one time period and 45.5% of eyes in all four time periods. For eyes without a therapy response by GAT (14 eyes), remote tonometry detected a response for 71.4% of eyes in at least one time period and for 7.1% of eyes in all four time periods. Control eyes showed no significant differences between study weeks. The authors concluded that additional studies with longer follow-up periods are needed to help understand the long-term clinical impact of IOP range fluctuation and to identify which time periods correlate closest with disease progression.

The body of evidence regarding the analytical validity, clinical validity, and clinical utility of remote intermittent monitoring of IOP is conflicting and sparse. There are few prospective studies that have evaluated the clinical utility of this technology. No published clinical studies are available which compare the rates of glaucoma progression in individuals who underwent remote intermittent monitoring of IOP with individuals who were monitored using current standard practice. Use of remote intermittent monitoring of IOP has not been proven to improve net health outcomes.

Background/Overview

According to the Centers for Disease Control and Prevention (CDC), about 3 million Americans (or about 0.9% of the population) have glaucoma. The prevalence of glaucoma rises with advancing age and in 2010, glaucoma affected about 1.9% of people in the U.S. age 40 and older (National Eye Institute). Glaucoma is the second leading cause of blindness worldwide. There are two major types of glaucoma; open-angle and closed-angle. Open-angle glaucoma is the most common type and is a chronic condition that progresses slowly over a long period of time. In open-angle glaucoma, fluid in the eye passes too slowly through a spongy meshwork which causes the intraocular fluid to accumulate. As the fluid builds up, the pressure inside the eye rises to a level that may damage the optic nerve. Closed-angle glaucoma develops quickly and can cause painful and immediate vision problems. In both cases, when the optic nerve is damaged from increased pressure, vision loss may result.

Intraocular pressure (IOP) is currently the only modifiable risk factor for development and progression of optic nerve damage and vision loss characteristic of glaucoma (Rosenfeld, 2021). In healthy individuals, IOP is generally between 10 and 20 mm Hg. However, IOP is a continuous and dynamic parameter, with a circadian rhythm. 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.

Measurement of IOP can help lead to a diagnosis of glaucoma and aid in treatment management. It has been postulated that fluctuations in IOP are associated with the progression of glaucoma. Monitoring IOP during different hours of the day may provide clinical information to aid in the management of an individual with glaucoma. However, the most commonly used tests for glaucoma (tonometry, ophthalmoscopy, perimetry, and gonioscopy) are performed by trained staff in an office setting and limited to single points in time. There is interest in remote monitoring of IOP as a strategy to obtain additional IOP measurements outside of a clinic setting.

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 fluid 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.

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.

HCPCS	
E1399	Durable medical equipment, miscellaneous [when specified as a home tonometer, such as iCare HOME2]
ICD-10 Diagnosis	
	All diagnoses, including but not limited to
H40.001-H40.9	Glaucoma
H42	Glaucoma in diseases classified elsewhere
P15.3	Birth injury to eye (includes traumatic glaucoma due to birth injury)
Q15.0	Congenital glaucoma

References

Peer Reviewed Publications:

1. Brown L, Foulsham W, Pronin S, Tatham AJ. The influence of corneal biomechanical properties on intraocular pressure measurements using a rebound self-tonometer. J Glaucoma. 2018; 27(6):511-518.
2. Cvenkel B, Velkovska MA, Jordanova VD. Self-measurement with Icare HOME tonometer, patients' feasibility and acceptability. Eur J Ophthalmol. 2020; 30(2):258-263.
3. Huang J, Phu J, Kalloniatis M, Zangerl B. Determining significant elevation of intraocular pressure using self-tonometry. Optom Vis Sci. 2020; 97(2):86-93.
4. McGlumphy EJ, Mihailovic A, Ramulu PY, Johnson TV. Home Self-tonometry trials compared with clinic tonometry in patients with glaucoma. Ophthalmol Glaucoma. 2021; 4(6):569-580.
5. Ogle JJ, Soo Hoo WC, Chua CH, Yip LWL. Accuracy and reliability of self-measured intraocular pressure in glaucoma patients using the iCare HOME tonometer. J Glaucoma. 2021; 30(12):1027-1032.
6. Rosenfeld E, Rabina G, Barequet D et al. Role of home monitoring with iCare ONE rebound tonometer in glaucoma patients management. Int J Ophthalmol. 2021; 14(3):405-408.
7. Scott AT, Kanaster K, Kaizer AM et al. The utility of iCare HOME tonometry for detection of therapy-related intraocular pressure changes in glaucoma and ocular hypertension. Ophthalmol Glaucoma. 2022; 5(1):85-93.

8. Takagi D, Sawada A, Yamamoto T. Evaluation of a new rebound self-tonometer, Icare HOME: comparison with Goldmann applanation tonometer. J Glaucoma. 2017; 26(7):613-618.
9. Ye Y, Yang F, Ding L et al. Comparison of Icare HOME and non-contact tonometer in intraocular pressure measurement in the early stage after ICL V4c implantation. Eur J Ophthalmol. 2022; 32(6):3303-3311.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Centers for Disease Control and Prevention. Don't let glaucoma steal your sight! Available at: https://www.cdc.gov/visionhealth/resources/features/glaucoma-awareness.html. Accessed on May 16, 2023.
2. National Eye Institute. Glaucoma tables. Available at: https://www.nei.nih.gov/learn-about-eye-health/eye-health-data-and-statistics/glaucoma-data-and-statistics/glaucoma-tables. Accessed on May 16, 2023.

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 May 16, 2023.

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iCare HOME2 tonometer

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	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References and Websites for Additional Information sections.
New	08/11/2022	MPTAC review. Initial document development.