Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 11/1/23**
(See policy history boxes for previous effective dates)

Title: Home Monitoring Device for Age-Related Macular Degeneration

Description/Background

Age-related macular degeneration (AMD) is a leading cause of blindness in individuals 50 years and older in the United States and Europe. Age-related macular degeneration severity typically is classified according to the Age-Related Eye Disease Study (AREDS) AMD categories 1 through 4. One of the 2 advanced forms of AMD (AREDS category 4) is neovascular AMD (nAMD), also referred to as “wet” macular degeneration. It is characterized by choroidal neovascularization (CNV), more recently termed macular neovascularization. Neovascular AMD occurs in 10% to 15% of all AMD patients and causes an estimated 80% of severe vision loss attributable to AMD. Typically, neovascular AMD is preceded by AREDS category 3 AMD, also referred to as intermediate dry AMD (iAMD). No known treatment exists for iAMD. When intermediate AMD converts to neovascular AMD the standard of care treatment includes intravitreal injections. Better visual acuity at the time treatment is initiated and decreased time between the onset of visual symptoms and treatment initiation have been shown to result in better long-term visual acuity.[1]

Monitoring of iAMD patients at risk of conversion to nAMD include regular in-office examinations in addition to patient reporting of changes in visual symptoms. For monitoring between office visits, patients are advised to use the Amsler grid, a validated test consisting of a pattern of lines which tests central vision. The limitations of the Amsler grid include the subjective nature of the test and patient noncompliance with monitoring protocols. However, more recent technology has been developed for home use in the monitoring of iAMD.[1]

The ForeseeHome™ age-related macular degeneration (AMD) monitor has been developed for home use. This device is used to perform macular visual field testing using preferential hyperacuity perimetry (PHP), and results of the testing are telemonitored to the provider. According to the manufacturer’s website, “Notal Vision, Ltd. designed a test with various amplitudes of artificial distortions that maximally distinguishes between dry AMD patients and newly diagnosed wet AMD. Numerous evaluations have demonstrated the technology’s keen

ability to provide early detection of changes occurring within a patient's vision, often before the patient is even aware."

Notal Vision has also developed a home optical coherence tomography (Home OCT) device for use in those diagnosed with wet AMD and receiving treatment for the condition. Home OCT is advertised as an artificial intelligence-enabled digital diagnostic tool. A patient completes a tutorial and a test; then a proprietary machine-learning algorithm, the Notal OCT Analyzer (NOATM), performs an automated analysis. If retinal fluid is detected, a report is generated and conveyed to the treating physician by the Notal Vision Diagnostic Clinic, with a goal of reducing the time from fluid onset to the next treatment. As of July 2022, the device has not yet been cleared by the U.S. Food and Drug Administration for clinical use.

Regulatory Status

In 2009 the FDA granted 510(k) premarket approval for the ForeseeHome™ device (Notal Vision Ltd.) (K091579).[2] The device is intended for use in the detection and characterization of central and paracentral metamorphopsia (visual distortion) in patients with age-related macular degeneration as an aid in monitoring progression of disease factors causing metamorphopsia including, but not limited to choroidal neovascularization (CNV). It is intended to be used at home for patients with stable fixation. Product code: HPT.

myVisionTrack (mVT) app (Vital Art and Science) is smartphone- and tablet-based technology. It is intended for the detection and characterization of central 3 degrees metamorphopsia (visual distortion) in patients with maculopathy, including age-related macular degeneration and diabetic retinopathy, and as an aid in monitoring progression of disease factors causing metamorphopsia. The FDA gave myVT 510(k) clearance in 2015 based on its equivalence to the Amsler grid and ForeseeHome (K143211).[3]

In December 2018 the FDA granted the Home OCT (Notal Vision Ltd.) Breakthrough Device status. The Breakthrough Devices Program supersedes the Expedited Access Pathway (EAP), which was launched in 2015. The device has not yet received clearance from the FDA.

Medical Policy Statement

Home monitoring devices using preferential hyperacuity perimetry (PHP) and telemonitoring of results for age-related macular degeneration are experimental/investigational. There is insufficient evidence in the peer-reviewed medical literature to demonstrate that these devices improve clinical outcomes over standard monitoring approaches.

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.):

0378T 0379T 0604T 0605T 0606T

Rationale

FORESEEHOME

The AREDS2-HOME Study Research Group (2014) reported results of a phase 3, unmasked, randomized clinical trial evaluating the role of home monitoring with the ForeseeHome device plus standard care compared with standard care alone for patients at high risk of progression to choroidal neovascularization (CNV).[4] The aim of the study was to determine if the addition of the device improves detection of CNV. One thousand five hundred and twenty participants with a mean age of 72.5 years were enrolled in the **HO**me **M**onitoring of the **E**ye (HOME) Study at 44 Age-Related Eye Disease Study2 clinical centers. Those randomized to the standard care only arm were instructed in self-monitoring at home to detect progression of AMD and included aids such as Amsler grid. If symptoms were noted, participants were instructed to call the clinical center immediately to schedule an appointment within 72 hours. The home monitoring device arm received the same instructions as those in the standard care arm, but in addition, they were given the home device and instructions for use. When the device testing detected a change compared with the baseline measurements, an alert was sent from the monitoring center to the clinical center. Clinical staff then contacted the patient to schedule an appointment within 72 hours. Of the 763 participants randomized to device monitoring, 607 continued to use the device throughout the study period. The follow up period occurred for a mean of 1.4 years between July 2010 and December 2013. At interim analysis, 82 participants progressed to CNV (51 in home device arm and 31 in standard care arm). Participants randomized to the device arm had significantly better visual acuity at the time of detection of incident CNV when compared to those randomized to standard care only: 87% of patients in the device arm had 20/40 or better, compared with 62% in the standard care arm.

Chew et al (2016) reported on a study evaluating the effectiveness of different monitoring modalities to detect incident neovascularization associated with AMD.[5] The research found that tele-monitoring may alter the management of patients with AMD and improve vision outcomes. However, the authors stated that a key limitation of the home monitoring device is the exclusion of persons with AMD who were not able to use the technology or to establish the crucial reproducible baseline values for future comparisons. The utility of the device is not known for those individuals who are monitored more frequently such as patients receiving monthly intra-vitreal injections of anti-VEGF.

Yu et al (2020) evaluated the real world utility of the ForeseeHome monitoring device for the detection and conversion from intermediate AMD to neovascular AMD.[1] This was a retrospective analysis of electronic health records, across 4 retinal practices in the United States. Seven hundred seventy-five eyes of 448 patients were prescribed use of the ForeseeHome device. Six hundred forty-nine eyes (83.7%) used the device at least once;

among this population, 478 (73.7%) established a baseline measurement. Patients who established a baseline measurement were significantly younger than those who did not (*P*< 0.001). Among eyes that established a baseline measurement, 126 (26.4%) had an overall inadequate frequency of use (>2 tests per week), and 250 (52.3%) did not use the device as frequently as instructed by the manufacturer (>3 tests per week); 24.7% of eyes discontinued use within 1 year. Of the 136 eyes [among the 211 eyes that were prescribed the device] that established a baseline measurement at 1 clinical site, 52 alerts were recorded; 3 (6.8%) correctly identified conversion to nAMD and 47 (93.2%) represented false-positive alerts. The authors concluded that in comparison with the prospective HOME study, the utility of the ForeseeHome device in the analysis of clinical practice application was limited. A meaningful proportion of eyes never used the device or could not establish a baseline measurement. Overall frequency of use was low, and continuous use of the device decreased over time.

myVisionTrack (mVT)
There is no Level I evidence from a large randomized controlled clinical trial comparing visual outcomes with mVT monitoring to outcomes achieved with standard care.

SUPPLEMENTAL INFORMATION

American Academy of Ophthalmology

The American Academy of Ophthalmology's Age-Related Macular Degeneration Preferred Practice Pattern (2019), for Monitoring and Early Detection, states:

> "Patients with early AMD and/or a family history of AMD should be encouraged to assess their own VA using monocular vision testing (ie, Amsler grid or electronic home monitoring) and have scheduled dilated eye examinations for detecting the intermediate stage of AMD."[6]

Government Regulations
National:
There is no national coverage determination on this topic.

Local:
There is no local coverage determination on this topic.

Wisconsin Physicians Service Insurance Corporation, Local Coverage Article: Billing and Coding: Category III Codes (A56902)
Original Effective Date: 08/29/2019
Revision Effective Date: 04/27/23

Codes 0378T, 0379T, 0604T, 0605T and 0606T are not listed as reasonable and medically necessary codes.

There are no fees in the CMS 2023 Physician Fee Schedule for codes 0378T, 0379T, 0604T, 0605T or 0606T.

(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

- Genetic Testing for Macular Degeneration
- Implantable Miniature Telescope for the Treatment of End-Stage Age-Related Wet Macular Degeneration (AMD) (Retired)
- Intraocular Radiation Therapy for Age-Related Macular Degeneration
- Intravitreal Injections for Retinal Conditions (P&T policy)
- Photocoagulation of Macular Drusen (Retired)

References

1. Yu HJ, Kiernan DF, Eichenbaum D, et al. Home monitoring of age-related degeneration: utility of the ForeseeHome device for detection of neovascularization. Ophthalmol Retina. 2021 Apr;5(4):348-356. PMID 32810682
2. U.S. Food and Drug Administration. ForeseeHome, (K091579) https://www.accessdata.fda.gov/cdrh_docs/pdf9/K091579.pdf Accessed 7/11/23
3. U.S. Food and Drug Administration. myVisionTrack. (K143211) https://www.accessdata.fda.gov/cdrh_docs/pdf14/K143211.pdf Accessed 7/11/23
4. AREDS2-HOME Study Research Group, et al. Randomized trial of a home monitoring system for early detection of choroidal neovascularization home monitoring of the Eye (HOME) study. Ophthalmology. 2014 Feb; 121(2): 535–544.
5. Chew EY, Clemons TE, Harrington M. et al. Effectiveness of different monitoring modalities in the detection of neovascular age-related macular degeneration. Retina. 2016;36(8):1542-1547.
6. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related Macular Degeneration PPP 2019. https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp Accessed 7/11/23.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 7/11/23, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/16	2/16/16	3/16/16	Joint policy established
5/1/17	2/21/17	2/21/17	Routine maintenance
1/1/18	10/19/17	10/19/17	Routine maintenance
1/1/19	10/16/18	10/16/18	Routine maintenance
1/1/20	10/15/19		Routine maintenance
1/1/21	10/20/20		Routine maintenance Codes 0604T-0606T added
1/1/22	10/19/21		Routine maintenance Ref 1 added
1/1/23	10/18/22		Routine maintenance (ls)
11/1/23	8/15/23		Routine maintenance (jf) Vendor Managed: NA

Next Review Date: 3rd Qtr, 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: HOME MONITORING DEVICE FOR AGE-RELATED MACULAR DEGENERATION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See Governmental Regulations Section.
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.