Policy Number	**MED201.044**
Policy Effective Date	**06/15/2025**
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Home-Based Monitoring of Visual Field

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Home-based monitoring of the visual field (e.g., ForeseeHome®) **is considered experimental, investigational and/or unproven** for any indication, including but not limited to monitoring age related macular degeneration (AMD).

Policy Guidelines

None.

Description

The macula is an area that is located in the center of the back of the retina. The macula is made up of millions of light-sensing cells that provide sharp, central vision and is the most sensitive part of the retina. The retina converts light into electrical signals and then transmits these electrical signals through the optic nerve to the brain, where they are translated into images. When the macula is damaged, the central vision may appear blurry, distorted, or dark.

Age related macular degeneration (ARMD, or AMD) is a common eye condition and a primary cause of vision loss in individuals over the age of 55. ARMD is characterized in its earliest stages by absent visual impairment and the presence of medium sized drusen. Individuals with intermediate ARMD usually exhibit large drusen or pigment changes (or both) in the retina during an eye exam. The individual may or may not experience vision loss. Individuals with late ARMD present with drusen and vision loss due to macular damage. There are currently 2 distinctively different forms of late ARMD which include (1):

- Geographic atrophy or dry AMD: In dry AMD there is a slow progressive breakdown of light sensitive cells in the macula which provides visual information to the brain and supporting tissue beneath the macula causing vision loss. Dry AMD is the most common form of ARMD. (1, 2)
- Neovascular or wet AMD: This wet form of late ARMD is distinguished from the atrophic form by the development of subretinal choroidal neovascularization (CNV) which damages the macula. Risk of developing severe irreversible loss of vision is greatly increased by the presence of CNV. It is possible to have both geographic atrophy and neovascular AMD in the same eye. (1-3)

Individuals at risk for developing AMD should be monitored periodically by eye care professionals. Comprehensive eye exams may include a visual acuity test, pupil dilation, fluorescein angiography, optical coherence tomography, and the use of the Amsler grid. With the Amsler grid, the individual looks, with one eye at a time, at a small dot in the center of a grid of horizontal and vertical lines. With macular disease, the individual may indicate the lines are wavy or absent. (1, 2)

Another test is the ForeseeHome AMD monitor that uses preferential hyperacuity perimetry (PHP), a proprietary psychophysical home test to identify and quantify visual abnormalities such as metamorphopsia and scotoma. Hyperacuity, or vernier acuity is the human's ability to perceive small differences in the relative spatial localization of two objects in space. The patient starts the home test by inserting his/her head into the viewer. A pair of infrared sensors located within the walls of the viewer detects the position of the head relative to the hood to ensure that the test is not initiated until the head is correctly positioned. During the test, stimuli are presented on screen successively flashing in various locations of the visual field. A typical stimulus includes a series of dots, a few of which are misaligned, creating a perception of a wave or artificial distortion in an otherwise straight line. The patient task is to move the cursor to and click on the location where the distortion is perceived. Patients are instructed to test their prescribed eye(s) daily, and their responses are transmitted to the Notal Vision Data Monitoring Center (DMC) following each test. The wireless data is transmitted to the physician portal for evaluation. (4)

Regulatory Status
In 2009, the U.S. Food and Drug Administration (FDA) gave Notal Vision, Ltd approval to market the ForeseeHome®, which uses a technology known as preferential hyperacuity perimetry (PHP). This ophthalmic device is indicated for use in the detection and characterization of central and paracentral metamorphopsia (visual distortion) in patients with ARMD, 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 stabilization. FDA product code: HPT (5)

In 2015, myVisionTrack™ (Vital Art and Science Incorporated) was U.S. FDA approved as a predicate device under the 510(k) summary. This smartphone and tablet-based technology is intended for the detection and characterization of central 3 degrees metamorphopsia (visual distortion) in patients with maculopathy, including ARMD and diabetic retinopathy, and as an aid in monitoring progression of disease factors causing metamorphopsia. The FDA gave myVisionTrack™ (myVT) 510(k) clearance (K143211) based on its equivalence to the Amsler grid and ForeseeHome. The FDA states the myVisionTrack™ is not intended to diagnose; diagnosis is the responsibility of the prescribing eye-care professional. FDA product code HOQ (6)

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

In 2014, Chew et al. evaluated whether home monitoring using the ForeseeHome device detected ARMD-related choroidal neovascularization (CNV) earlier than standard of care

methods in a phase 3, unmasked, randomized clinical trial. (7) The main predictor of treatment outcome from anti-vascular endothelial growth factor (VEGF) agents was the visual acuity at the time of CNV treatment. The study was unmasked, controlled, and randomized. One thousand nine hundred and seventy participants (n=1970) from age 53 to 90 years who were at high risk of CNV were screened. Of these, 1520 participants with a mean age of 72.5 years were enrolled in the Home Monitoring of the Eye (HOME) study at 44 Age Related Eye Disease Study 2 (AREDS2) clinical centers. In the standard care and device arms, investigator-specific instructions were provided for self-monitoring vision at home followed by report of new symptoms to the clinic. In the device arm, the device was provided with recommendations for daily testing. The device monitoring center received test results and reported changes to the clinical centers, which contacted participants for examination. The main outcome measure was the difference in best-corrected visual acuity scores between baseline and detection of CNV. The event was determined by investigators based on clinical examination, color fundus photography, fluorescein angiography, and optical coherence tomography findings. Masked graders at a central reading center evaluated the images using standardized protocols. Seven hundred sixty-three participants were randomized to device monitoring and 757 participants were randomized to standard care and were followed up for a mean of 1.4 years between July 2010 and April 2013. At the prespecified interim analysis, 82 participants progressed to CNV, 51 in the device arm and 31 in the standard care arm. The primary analysis achieved statistical significance, with the participants in the device arm demonstrating a smaller decline in visual acuity with fewer letters lost from baseline to CNV detection (median, −4 letters; interquartile range [IQR], −11.0 to −1.0 letters) compared with standard care (median, −9 letters; IQR, −14.0 to −4.0 letters; P = 0.021), resulting in better visual acuity at CNV detection in the device arm. The Data and Safety Monitoring Committee recommended early study termination for efficacy. The study concluded that persons at high risk for developing CNV benefit from the home monitoring strategy for earlier detection, which increases the likelihood of better visual acuity results after intravitreal anti-VEGF therapy. Additionally, the participants in the standard care arm were able to use aids to check vision such as Amsler grids, but the study was not designed to compare the home device to another specific monitoring device. Without a head-to-head comparison of one device to another it is not possible to conclude the home device is as beneficial as established alternatives. With an approximate screen failure rate of 20% of the home device and no information provided how monitoring of the eyes with the use of the home device changed treatment management, it's difficult to determine how the home device was shown to improve health outcomes.

Chew et al. (2016) compared the rates of detecting incident neovascular AMD I prescheduled office visits versus (vs) office visits triggered by monitoring device or by symptom realization in a randomized trial evaluating home telemonitoring device plus standard care (device arm) vs standard care alone. (8) At prescheduled office visits, neovascular AMD was detected in 14/1927 visits (0.7%, 95% confidence interval [CI]: 0.4%-1.1%) and 14/1949 visits (0.7%, 95% CI: 0.3%-1.1%) in the device and standard care alone arms, respectively. Thirty-seven participants with neovascular AMD were detected in 318 office visits (11.6%, 95% CI: 8.1%-15.2%) triggered by device or symptom realization and 17 neovascular AMD in 65 office visits (26%, 95% CI: 15.5%-36.8%) triggered by symptom realization in the device and standard care alone arms,

respectively. The home device strategy had a higher neovascular AMD detection rate than prescheduled office visits (relative risk = 16.0 [95% CI: 8.8-29.3]). Neovascular AMD detected at triggered visits were associated with less vision loss from baseline in the device arm versus standard care alone arm (-3 letters vs. -11.5 letters, respectively, p= 0.03). Authors concluded that the home monitoring device, particularly when used at least twice per week as recommended, as an adjunct to self-monitoring, could potentially allow a reduction in the number of pre-scheduled office visits for some patients at risk of AMD progression, reducing the burden on physicians, patients, families, and payers. The authors note that a cost-benefit analysis of the monitoring device strategy will be helpful to assess how this novel home management modality may best fit into the management of persons at high risk of AMD progression. In addition, the individuals who used the home monitoring device had 5.6 times as many false positive unscheduled office visits compared to those in the standard care arm. While the visual acuity loss at the time of detection of neovascular AMD compared to baseline was less in the home device monitoring arm, 27% of the neovascular AMD was detected at pre-scheduled office visits and were missed between the pre-scheduled visits despite the home device monitoring. Additional studies are necessary to determine if use of a home device and triggered office visits detects AMD better than established alternatives and whether earlier detection in this manner produces improved net health outcomes. A limitation is the exclusion of individuals with AMD who are not able to use the technology or establish reproducible baseline values for future comparisons. Also, for individuals who are monitored more frequently such as those receiving monthly intravitreal injections of anti-vascular endothelial growth factor, the utility of the home monitoring device is unknown. (8)

In 2014, Faes et al. (9) studied the diagnostic accuracy of the Amsler grid and preferential hyperacuity perimetry (PHP) in the screening of patients with wet ARMD. The systematic review and meta-analysis included 12 studies which enrolled 903 patients and allowed constructing 27 two-by-two tables. Twelve tables reported on the Amsler grid and its modifications, 12 tables reported on the PHP, one table assessed the macular computerized psychophysical test (MCPT), and two tables assessed the M-charts. All but 2 studies had a case-control design. The pooled sensitivity of studies assessing the Amsler grid was 0.78 (95% CI; 0.64-0.87), and the pooled specificity was 0.97 (95% CI; 0.91-0.99). The corresponding positive and negative likelihood ratios were 23.1 (95% CI; 8.4-64.0) and 0.23 (95% CI; 0.14-0.39), respectively. The pooled sensitivity of studies assessing the PHP was 0.85 (95% CI; 0.80-0.89), and specificity was 0.87 (95% CI; 0.82-0.91). The corresponding positive and negative likelihood ratios were 6.7 (95% CI; 4.6-9.8) and 0.17 (95% CI; 0.13-0.23). No pooling was possible for MCPT and M-charts. Results from these small preliminary studies show promising test performance characteristics both for the Amsler grid and PHP to rule out wet AMD in the screening setting. To what extent these findings can be transferred to a real practice still needs to be determined. However, most of the studies were so called diagnostic case–control studies, i.e., test results of patients with diagnosed wet AMD were compared with test results of healthy subjects or another sampled group of patients. Although this design may be appropriate in the early, proof of concept phase of evaluation, it must be noted that they are prone to exaggerate test performance. For MCPT and the M-chart, data were to scarce to perform a meta-analysis.

In 2021, Yu et al. (10) performed a retrospective study that reported on 448 participants (775 eyes) who were prescribed an electronic home visual field monitoring device. The purpose of the study was to report on compliance of usage of the device by frequency and length of use, determination of a baseline measurement, number of eyes that converted to neovascular ARMD, and the number of alerts. There were 126 eyes that never had use of the device after prescription. There were 478 eyes able to have established baseline measurement, while 171 eyes were unsuccessful at establishing baseline. Of the eyes which had established baseline, the mean frequency of use was 3.44 ± 1.86 tests per week. The device was used at least once by 649 eyes. In the group which established a baseline measurement, there were 126 eyes in which the test was used greater than or equal to 2 times per week and 250 eyes which did have use of the device for greater than or equal to 3 times per week. The device was discontinued most frequently within the first year. Over a mean period of 20.35 months, 106 eyes with an established baseline measurement had at least 1 alert with a total accumulation of 152 alerts. There were 125 test score change alerts and 27 unreliable pattern alerts. Conversion to neovascular ARMD was identified in 3, and 47 had false positives with the alerts. The retrospective nature of this study makes it difficult to ascertain how compliance with the device was encouraged. The lack of compliance and difficulty in establishing baseline measurements make it difficult to determine improvement in net health outcomes. Compliance using the device and ability to operate the device properly are necessary for accurate results. The authors noted that compared with the HOME study, the utility of the ForeseeHome device in the current analysis of clinical practice is limited since a meaningful proportion of individuals 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.

In 2021, Ho et al. (11) evaluated the performance of an at-home monitoring system in combination with standard care in an industry sponsored retrospective review. Participants with intermediate AMD who converted to neovascular AMD while using the at-home monitoring device were reviewed. Inclusion criteria was diagnosis of intermediate dry AMD along with best corrected visual acuity of 20/60 or better. All participants received a home testing device along with training on the device. All participants also established a baseline visual acuity. Out of 8991 enrolled participants, 306 eyes were reported to have converted from intermediate AMD to neovascular AMD during the study period. Of the 306 eyes with confirmed progression of disease, 211 (69%) were identified via the at-home device and 95 eyes (31%) were identified during a routine office visit or symptom-driven visit. Mean weekly frequency of testing per eye was 3.7 ± 1.9 and mean weekly frequency of testing per participant was 5.6 ± 3.2. The main limitation of this study is the retrospective design. Not all visual acuities were available at baseline or at conversion. Some of the visual acuity values were reported telephonically which may have led to some bias. In addition, the authors reported they did not collect information about the outcomes from alerts issued by the at-home monitoring device that didn't lead to immediate identification of conversion to neovascular AMD. While this study suggests that consistent use of an at-home monitoring system may increase the early detection of neovascular AMD with good vision, lack of consistent baseline visual acuity values and lack of information about improved net health outcomes make it difficult to ascertain if use of the

device is more effective than established alternatives. Prospective, randomized trials are necessary.

The Ho et al. study (11) and the Yu et al. study (10) differs in that Ho et al. evaluated a patient population that had a device with a valid baseline up to and including the time of conversion. Yu et al. evaluated all patients who were prescribed the device, and they cite a large number of patients who did not or could not establish or re-establish a baseline, as well as a considerable number of patients who discontinued use of the device.

In 2022, Mathai et al. (12) reported on a retrospective review of records from 2123 participants from 5 retina clinics. The primary outcome was to assess the change in visual acuity from the initial office visit to the most recent office visit for those who converted to neovascular AMD while using an electronic home visual field monitoring device. The hypothesis was that for those who converted to neovascular AMD while using an electronic home visual field monitoring device, they would consistently maintain good functional and anatomic status with continued management. The mean follow-up was 3.1 years. Frequency of use of the electronic home monitoring device was a mean of 5.2 times per week. Baseline visual acuity needs to be established for each eye before monitoring can be initiated. There were 82.9% of eyes which established a baseline. While using the electronic home visual field monitoring device, 285 eyes converted to neovascular AMD at an annual rate of 2.72%. They were treated with a mean of 17.3 injections over a mean of 2.7 years. For the eyes that did convert to neovascular AMD during the study period, median baseline visual acuity was 20/30, median visual acuity at conversion was 20/39, and median visual acuity at final follow-up was 20/32. For the eyes which did not convert to neovascular AMD, the median baseline visual acuity was 20/27 and the median final visual acuity was 20/34. For the eyes which did not convert to neovascular AMD, visual acuity data was only available for 30% to 40% of the eyes. Of the eyes which converted to neovascular AMD, 52% of the conversions were detected in an office visit prompted by a system alert on the home monitoring, while 48% were detected during an office visit triggered by standard care means. Due to the retrospective nature of this industry-sponsored study, there was no information available about the medications used for treatment, and visual acuity measurements were taken by Snellen acuity charts instead of the strict study methodology used for clinical trials. Well-designed prospective randomized clinical trials demonstrating improved outcomes using an electronic home visual field monitoring device in allowing earlier detection and intervention for dry-to-wet AMD conversions are necessary.

Another limitation of home PHP technology is the potential inability of individuals to use the device properly in their home monitoring regimen. The manufacturers of the device designed an in-office qualification test to identify which individuals are most likely to successfully be able to use the device in the home environment. A study by Thomas et al. (13) evaluated the utility of the in-office qualification test. A total of 131 participants completed the in-office qualification test and 129 participants had a reliable test score (98.5%; 95% CI, 96.4%-99.9%). The study participants were age 55 years or older, had at least one study eye that was determined to have intermediate AMD and a visual acuity of 20/63 or better. Ninety-one participants had a reliable test score and achieved a score at or below the threshold to qualify

for home monitoring (69.5%; 95% CI, 61.6%-77.4%). Forty participants who had unreliable test results or who failed to establish a baseline value were excluded. Of the 91 study participants who received the home device, 89 completed the setup of the device (5 withdrew after setting up the device and 1 more withdrew after 2 home sessions). Of the remaining 83 participants, 74 participants established a baseline with 5 in-home tests, 1 did not establish a baseline with 5 tests, and 8 were permitted to perform 6 additional in-home baseline tests. Of the 8 participants who performed the 11 tests, 6 participants established baseline and 2 participants did not. A retrospective chart review of the 40 participants who had unreliable tests revealed 4 individuals who were subsequently diagnosed with CNV. The in-office qualification test may be a useful screening tool to identify individuals who might benefit from the home device. However, the in-home visual field testing requires an individual to place one's head on the device hood to view the screen and use a standard computer mouse. This requirement of advanced hand-eye coordination and balance often deteriorates with age leading to inaccurate test results. Movement disorders can also affect an individual's ability to look into a device for a specified period of time and properly use a computer mouse.

UpToDate

A 2025 UpToDate review on age-related macular degeneration (14) states that once AMD is detected, weekly self-monitoring at home with an Amsler grid is one of the best ways to detect, at the earliest phase, conversion from dry to wet AMD. This review does not mention the use of the ForeseeHome device and/or electronic home monitoring.

Professional Guidelines and Position Statements

American Academy of Ophthalmology (AAO)

In 2024, the AAO published their updated preferred practice pattern on ARMD that states (15):

- "Patients with early AMD and/or family history of AMD should be encouraged to assess their own visual acuity using monocular vision testing (i.e., Amsler grid or electric home monitoring) and have scheduled dilated eye exams for detecting the intermediate stage of AMD."
- "Electronic monitoring devices are now available to aid in the detection of neovascularization at an early stage. Such devices use hyperacuity perimetry (or vernier acuity) to create a quantified central visual map of metamorphopia. Further studies of a variety of such devices are ongoing."

Summary of Evidence

A search of published literature and professional guidelines did not yield sufficient evidence to support coverage for the use of home-based monitoring of visual fields. Additional long term well-designed studies are needed to confirm the impact on health outcomes in relation to office based ocular management for age related macular degeneration (ARMD) monitoring.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0378T, 0379T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
06/15/2025	Document updated with literature review. Coverage unchanged. Added reference 14; others updated.
04/01/2024	Reviewed. No changes.
05/01/2023	Document updated with literature review. Coverage unchanged. Added references 2, 3, 11-13; others updated and/or removed.
12/01/2022	Reviewed. No changes.
11/01/2021	Document updated with literature review. Coverage unchanged. Added references 8, 9; others updated.
09/01/2020	Reviewed. No changes.
04/15/2019	Document updated with literature review. Coverage unchanged. Reference 7 added.
03/15/2018	Reviewed. No changes.
04/01/2017	Document updated with Literature review. Coverage unchanged.
03/01/2016	Reviewed. No changes.

01/01/2015	New medical document. Home-based monitoring of the visual field (e.g., ForeseeHome) is considered experimental, investigational and/or unproven for any indication, including but not limited to monitoring age related macular degeneration (AMD).