Healthy Blue

# Medical Policy

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| **Subject:** | Electronic Home Visual Field Monitoring | | |
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## Description/Scope

This document addresses the use of electronic home visual field monitoring.

## Position Statement

**Investigational and Not Medically Necessary:**

The use of electronic home visual field monitoring is considered **investigational and not medically necessary** for all indications.

## Rationale

Age-related macular degeneration (AMD) is the leading cause of blindness in the elderly population. There are two major types: a "dry" form associated with slowly progressive vision loss and a "wet" form which can be associated with rapidly progressive vision loss. Vision loss in AMD is usually a result of choroidal neovascularization (CNV), abnormal vessels within or under the retina, which can be associated with rapid decline in vision.

Efforts to identify CNV and intervene have been the focus of care for individuals with AMD. The Amsler grid has been used for many years to assist individuals in recognizing new symptoms that can indicate the onset of CNV. Another method to monitor progression of AMD is preferential hyperacuity perimeter (PHP) testing which is performed in a clinical setting under supervision. During a PHP test, a series of dots are typically flashed in various locations of the visual field. The majority of the dots are aligned with each other, however, a few dots are misaligned which creates the perception of a wave or artificial distortion in what would otherwise be a straight line. The individual being tested marks the locations of the artificial distortions when perceived by pointing at the stimuli on a screen.

The 2015 American Academy of Ophthalmology Preferred Practice Pattern® for AMD encourages individuals with early AMD or a family history of AMD to monitor their own visual acuity (for example using an Amsler grid) between office visits. The 2014 Guidelines for the Management of Neovascular Age-Related Macular Degeneration published by the European Society of Retina Specialists (Schmidt-Erfurth) recommends individual "self-monitoring with regular Amsler grid testing is suggested between ophthalmological visits" and "those with intermediate AMD (large drusen in one or both eyes) could benefit from home monitoring with PHP, whenever the device is available." Home monitoring devices using PHP technology are now available however, they differ from the original devices in that they are unsupervised and the test is performed outside of a clinical setting. In addition, the

home device works somewhat differently and requires participants to use a mouse to mark the locations of perceived artificial distortions. These differences are substantial and evidence is required to demonstrate the the test provides the same net health benefit when done at home as when done under clinical supervision.

In 2010 Loewenstein and colleagues evaluated the sensitivity and specificity of a home device test performed while unsupervised. This study contained both a retrospective and a prospective part. Participants were included if there was evidence of intermediate AMD or a recent onset of CNV, greater than 50 years of age, and visual acuity with habitual correction of greater than 20/200 on Snellen charts. In the retrospective part, experience with a computer mouse was not a requirement, however the participants without any computer mouse experience were taught how to use the mouse and participation was conditioned on passing a tutorial. The retrospective portion was done using tests performed by participants with intermediate AMD and newly diagnosed CNV. There were 109 participants included. Of these, 14 (13%) had unreliable home device tests and 18 additional participants were not included because of geographic atrophy, early AMD, or poor-quality photographs. The device showed abnormal test results in 29 of 34 eyes with CNV and in 7 of 43 eyes with intermediate AMD with a sensitivity of 0.85 ± 0.12 (95% confidence interval [CI]), specificity of 0.84 ± 0.11 (95% CI) and accuracy of 0.85 ± .011 (95% CI). The accuracy of the device was then challenged with a prospective enrollment of participants (n=99). In the prospective part, all individuals had experience with a computer mouse. Of the 99 participants enrolled, 15 (15%) did not pass the home device tutorial and were excluded, 8 (8%) had unreliable home device tests, 22 individuals were not included because geographic atrophy, pattern dystrophy, or no or poor-quality photographs. The device identified abnormal test results in 27 of 32 eyes with CNV and in 3 of 22 eyes with intermediate AMD with a sensitivity of 0.84 ± 0.13 (95% CI), specificity of 0.86 ± 0.14 (95% CI), and accuracy of 0.85 ± 0.13 (95% CI). In addition to the evident technical challenges of using the home device, there was no mention of long-term monitoring or how treatment was changed based on results of the home monitoring.

In a phase 3, unmasked, randomized clinical trial by Chew and colleagues (Chew, 2014a) the authors evaluated the use of a home visual field monitoring device plus standard care to standard care alone for eyes at high risk of progression to CNV. The primary objective was to assess whether home monitoring reflected better visual acuity at the time of detection of CNV (the difference in best-corrected visual acuity scores between baseline and detection of CNV). There were 763 participants randomized to device monitoring and 757 participants to standard care. In the standard care arm, participants received instructions for self-monitoring at home to detect progression of AMD using aids such as the Amsler grid. In the device monitoring arm of the study, the participants received the same standard care instructions as the standard care arm, but also received a home monitoring device with instructions for installation and use with encouragement to use the device daily. At baseline, all participants had testing for best-corrected visual acuity and color fundus photos of three stereographic fields in both eyes. Participants were followed for a mean of 1.4 years. In the device arm, 728 participants used the device during part of the study period while 156 participants returned the device, stopped using it before CNV developed, study termination, or were lost to follow-up. For those who continued using the device during the study period, the average weekly usage was 4.4 times per week and in 70 participants was less than twice a week. Among those randomized to the device arm, 88 participants failed to establish baseline values during the initial home testing. This was due to visual field defects not identified during the office screening. Of these 88 participants, 17 did not establish baseline values in either study eye. There were 16 participants who continued in the study with 1 participant dropping out. Initially, participants in the device arm accumulated events at a higher rate with the standard care arm lagging behind,

however the events rate became virtually identical in each of the monitoring arms later in the study. At the pre-specified interim analysis, 51 participants progressed to CNV in the device arm with 31 participants progressing to CNV in the standard care arm. The primary analysis showed that at the time of CNV detection, the decrease in visual acuity score was at least 5 letters lower in the median decrease in best-corrected visual acuity in the device arm compared to the standard arm. In the device arm, 27 eyes maintained best-corrected visual acuity within 1 line of baseline visual acuity, 6 eyes lost 15 or more letters from baseline, and 1 eye had visual acuity of 20/200 or worse at the time of the CNV event. In the standard care arm,12 eyes maintained best-corrected visual acuity within 1 line of baseline visual acuity, 7 eyes lost 15 or more letters from baseline, and 1 eye had visual acuity of 20/200 or worse at the time of the CNV event. The proportions between groups for these secondary visual acuity outcomes generally favored the device arm, but did not meet statistical significance. The Data and Safety Monitoring Committee reviewed study results at a pre-planned interim and recommended stopping the trial early. 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 ascertain how the home device was shown to improve health outcomes.

In 2016 Chew and colleagues sought to determine the effectiveness of different monitoring modalities to identify new CNV associated with AMD. They compared vision outcomes at the time of detection of neovascular AMD at pre-scheduled office visits to office visits triggered by either participant recognition of new symptoms with or without Amsler grid testing. During the study period, more office visits occurred for those using the home device compared to the standard care arm (2.245 vs 2.014, respectively). This was felt to be due to the home device prompting visits. At the pre-scheduled office visits, neovascular AMD was found in 14/1927 visits in the device arm (0.7%; 95% CI, 0.4%-1.1%) and 14/1949 visits in the standard care arm (0.7%; 95% CI, 0.3%-1.1%). In the device arm, 37 participants with neovascular AMD were detected in 318 office visits (11.6%; 95% CI, 8.1%-15.2%) triggered by device or symptom realization with 17 participants with neovascular AMD in 65 office visits (26%; 95% CI, 15.5%-36.8%) in the standard care arm. Of the individuals in the device arm, the median vision change from baseline was -8.5 letters with a median visual acuity loss of -3.0 letters from baseline when the AMD was detected. For the individuals in the standard care arm, there was a median loss of -8.0 letters from baseline when AMD was diagnosed. The median change in vision was a loss of -11.5 letters from baseline. In comparing the percentage of individuals who maintained visual acuity of 20/40 or better by detection modality, there was no significant difference between those detected during pre-scheduled visits (75% vs. 62%), however for events found during triggered office visits the percentage was 91% in the device arm and 59% in the standard care arm. Without new symptoms, the optimal frequency for office visits to monitor for disease progression in unknown. The average exams for this study participants was twice per year. The authors note that 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. Further 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 clinical outcomes.

In a 2014 systematic review and meta-analysis by Faes and colleagues, the authors reported on the screening potential of the Amsler grid and PHP in detecting or ruling out AMD. There were 12 studies (903 subjects) included in the analysis. Diagnostic accuracy of the Amsler grid (or modification) or PHP were addressed in 7 studies with 2 studies evaluating the M-Charts and 1 study evaluating the Macular Computerized Psychophysical Test (MCPT). All but two studies were designed as case–control. The 12 studies allowed constructing 27 two-by-two tables. For methodological reasons (one table assessing the MCPT and two tables assessing the M-charts) meta-analysis was not feasible for the studies that included M-charts and MCPT. Twelve tables reported on the Amsler grid and its modifications and twelve tables reported on the PHP. For the 12 studies that included the Amsler grid, sensitivity ranged from 0.34 to 1.0 with specificity ranging from 0.85 to 1.0. In the twelve studies that included PHP, sensitivity ranged from 0.68 to 1.0 with specificity ranging from 0.71 to 0.97. For the studies assessing the Amsler grid, pooled sensitivity was 0.78 (95% CI; 0.64-0.87), pooled specificity was 0.97 (95% CI; 0.91-0.99), positive likelihood ratios were 23.1 (95% CI; 8.4-64.0), and negative likelihood ratios were 0.23 (95% CI; 0.14-0.39). For the studies which assessed PHP, the pooled sensitivity was 0.85 (95% CI; 0.80-0.89), specificity was 0.87 (95% CI; 0.82-0.91), positive likelihood ratios were 6.7 (95% CI; 4.6-9.8), and negative likelihood ratios were 0.17 (95% CI; 0.13-0.23). A limitation of the systematic review and meta-analysis is that the included studies used different reference tests. Results of studies are promising in the diagnostic work-up of AMD, however differing study designs (for example, case-control versus prospective design), and differing reference tests make it difficult to draw firm conclusions of one type of test versus another. Education on proper instruction for using home testing is necessary to assist with accuracy.

One limitation of the home monitoring device 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. Further studies are necessary to assess these individuals to determine an improvement in health outcome.

Another key limitation of 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 at home. A study by Thomas and colleagues (2015) 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 had visual acuity of 20/63 or better. There were 91 participants who had a reliable test score and achieved a score at or below the threshold to qualify to initiate monitoring using the home device (69.5%; 95% CI, 61.6%-77.4%) and 40 participants who had unreliable test results, did not qualify for home monitoring, or who failed to establish a baseline value. 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 two 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 look into 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. Compliance using the device and ability to operate the device properly are necessary for accurate results.

## Background/Overview

AMD is the leading cause of irreversible blindness in people over 50 years of age in the developed world. AMD is broadly classified into two types: nonexudative (dry) and exudative (wet). Dry (nonexudative). AMD occurs when the light-sensitive cells in the macula gradually break down, resulting in blurred vision and and gradual loss of central vision in the affected eye(s). Wet AMD arises from abnormal blood vessels behind the retina which start to grow under the macula (the light sensitive part of the retina). These new blood vessels have a tendency to be very fragile and often leak fluid and blood. The blood and fluid cause the macula to move from its normal position at the back of the eye. Loss of central vision (needed for seeing objects clearly and for activities such as reading and driving), can occur rapidly.

AMD is becoming increasingly prevalent and has no effective cure (Jager, 2008). According to the American Academy of Ophthalmology, approximately 2.1 million Americans 50 years of age or older have late AMD.

The visual field is how wide of an area the eye can see when focused on a central point. Testing of the visual field measures how much vision can be seen in the eyes and how much vision loss has occurred over time. Visual field testing is one way to assess for AMD. Visual field tests are typically done in a physician's office. With emerging technology, some visual field testing devices are now being offered in the home setting. One such device is the ForeseeHOME™ device (Notal Vision™, Manassas, VA). This is a home-based monitoring device used to reportedly detect wet AMD early. In 2009 the ForeseeHOME received 510(k) clearance from the United States Food and Drug Administration (FDA). Using technology known as Preferential Hyperacuity Perimetry (PHP), the device is intended to be used as an aid in detecting, monitoring progression of disease, and characterizing visual distortion in individuals with AMD.

## Definitions

Age related macular degeneration (AMD): A disease blurring the sharp, central vision needed for "straight-ahead" activities such as reading, sewing, and driving. AMD affects the macula, the part of the eye used for fine detail. In some cases, AMD advances so slowly that people notice little change in their vision and in others, the disease progresses faster and may lead to a loss of vision in both eyes.

Amsler grid: A type of visual field test for central vision. It is a pattern of straight lines that makes a grid of many equal squares. Individuals look at a dot in the middle of the grid and describe any areas that may appear wavy, blurry or blank.

Choroidal neovascularization: A condition characterized by the development of new blood vessels across the back portion of the eye, which may interfere with vision.

Drusen: Pale whitish-yellow deposits of extracellular material formed in a layer of the retina.

Dry AMD: Occurs when light-sensitive cells in the macula slowly break down, gradually blurring central vision in the affected eye. It generally affects both eyes, but vision can be lost in one eye while the other eye seems unaffected. Dry AMD has three stages, all of which may occur in one or both eyes.

Preferential hyperacuity perimetry: A method of monitoring the progression of AMD using hyperacuity; which is the ability to perceive differences in the spatial localization of two or more visual stimuli.

Wet AMD: Occurs when abnormal blood vessels behind the retina start to grow under the macula. These new blood vessels tend to be very fragile and often leak blood and fluid. The blood and fluid raise the macula from its normal place at the back of the eye and damage to the macula occurs rapidly; loss of central vision can occur quickly. Wet AMD is considered to be advanced AMD and is more severe than the dry form.

## 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 codes, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

**CPT**

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| 0378T | Visual field assessment, with concurrent real time data analysis and accessible data storage with patient initiated data transmitted to a remote surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional |
| 0379T | Visual field assessment, with concurrent real time data analysis and accessible data storage with patient initiated data transmitted to a remote surveillance center for up to 30 days; technical support and patient instructions, surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional |

**ICD-10 Diagnosis**

All diagnoses

## References

**Peer Reviewed Publications:**

1. Chew EY, Clemons TE, Bressler SB, et al. Randomized trial of a home monitoring system for early detection of choroidal neovascularization home monitoring of the Eye (HOME) study. Ophthalmology. 2014a; 121(2):535-544.
2. Chew EY, Clemons TE, Bressler SB, e al. Randomized trial of the ForeseeHome monitoring device for early detection of neovascular age-related macular degeneration. The HOme Monitoring of the Eye (HOME) study design -- HOME Study report number 1. Contemporary Clinical Trials. 2014b; 37:294-300.
3. Chew EY, Clemons TE, Harrington M, et al; the AREDS2-Home Study Research Group. Effectiveness of different monitoring modalities in the detection of neovascular age-related macular degeneration. The Home Study, Report Number 3. Retina. 2016; 36(8):1542-1547.
4. Faes L, Bodmer NS, Bachmann LM, et al. Diagnostic accuracy of the Amsler grid and the preferential hyperacuity perimetry in the screening of patients with age-related macular degeneration: systematic review and meta-analysis. Eye (Lond). 2014; 28(7):788-796.
5. Jager RD, Mieler WF, Miller JW. Age-related macular degeneration. N Engl J Med. 2008; 358(24):2606-2617.
6. Loewenstein A, Ferencz JR, Lang Y, et al. Toward earlier detection of choroidal neovascularization secondary to age-related macular degeneration: multicenter evaluation of a preferential hyperacuity perimeter designed as a home device. Retina. 2010;30(7):1058-1064.
7. Thomas M, Wolfson Y, Zayit-Soudry S, et al. Qualifying to use a home monitoring device for detection of neovascular age-related macular degeneration. JAMA Ophthalmol. 2015; 133(12):1425-1430.

**Government Agency, Medical Society, and Other Authoritative Publications:**

1. American Academy of Ophthalmology (AAO). Preferred Practice Pattern Age-Related Macular Degeneration. 2015. For additional information visit the AAO website: http://www.aao.org/ppp. Accessed on April 24, 2020.
2. Schmidt-Erfurth U, Chong V, Loewenstein A, et al.; European Society of Retina Specialists. Guidelines for the management of neovascular age-related macular degeneration by the European Society of Retina Specialists (EURETINA). Br J Ophthalmol. 2014;98(9):1144-1167.
3. U.S. Food and Drug Administration (FDA) 510(k) Premarket Notification Database. Summary of Safety and Effectiveness. Rockville, MD: FDA. Foresee Home. K091579. December 23, 2009. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf9/K091579.pdf. Accessed on April 24, 2020.

## Websites for Additional Information

1. American Academy of Ophthalmology. For additional information visit the AAO website: www.aao.org/. Accesssed on April 24, 2020.

## Index

ForeseeHome
Visual Fields

**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 |
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| New | 05/14/2020 | Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development. |