Supplementary Online Content

Thomas M, Wolfson Y, Zayit-Soudry S, Bressler SB, Bressler NM. Qualifying to use a home monitoring device for detection of neovascular age-related macular degeneration. *JAMA Ophthalmol*. Published online October 15, 2015. doi:10.1001/jamaophthalmol.2015.3684.

eAppendix. Qualification Test Methods

This supplementary material has been provided by the authors to give readers additional information about their work.

eAppendix. Qualification Test Methods

Reliability Test

The reliability score reflects the percentage of responses in which the patient indicates distortion is perceived and locates the distortion within a specific distance of the presented signal. Reliability scores of 70% or higher indicate the individual understands the task of recognizing and marking projected areas of artificial distortion.

Qualification Test

The qualification test score is generated by analyzing the distance between the patient's recorded location of the artificial distortions presented by the device and the actual location of the artificial distortions, weighted for the magnitude of the artificial distortions. In a proprietary study, the device developers previously established a test score threshold that differentiated patients with non-neovascular AMD from those with neovascular AMD and that a test score below this threshold (a score of 0.34 or lower) indicated a 90% probability that the participant would be able to establish a home baseline with the study eye. Only those participants that achieved a reliability test threshold of at least 70% and passed the qualification test with a score of 0.34 or lower in their study eye received the home device for subsequent AMD home monitoring.

Ability to Establish a Baseline

The home monitor was provided to each participant that achieved the qualification test score threshold hypothesized to be predictive of future successful usage of the home device. The device was provided with instructions for home set-up including completion of the tele-monitoring connections. A toll-free telephone support line was made available to participants to assist them with finalizing the initiation of the device. Participants were asked to test their study eye daily with the device, and they were reminded that the device was exclusively for their use and only could be used for the study eye.

Participants were asked to transmit test session results immediately after each test session via a telephone landline or a cellular modem (supplied by Notal Vision) to a web-based application viewed by a central monitoring site. Notal Vision staffed the monitoring center, viewed test scores daily, and notified ("alerted") the participant and the participant's ophthalmologist if test scores changed in a manner that was suspect for AMD progression. In the case of an alert triggered by home monitoring test sessions or if the participant recognized and reported a change in vision, the participant was asked to return to the clinic promptly to determine if CNV had developed. Participants also received one or more reminder phone calls from the Notal service center when the frequency of home device usage fell below an average of twice per week.

Each test session performed with the study eye during the home monitoring phase of this study resulted in a daily test score. These test scores were compared to a population normative database, and the test scores were normalized with scores ranging from 0 to 1.0. The first 5 study eye test sessions completed at home by the participant were used to calculate the patient's baseline value. The average of the first 5 test scores was compared to the established threshold that separated intermediate AMD from neovascular AMD in a previously tested cohort of patients with known non-neovascular or neovascular AMD. If the participant's mean test score fell below this threshold then the participant was categorized as establishing a baseline reference value for subsequent home monitoring. Participants with an average test score that greatly exceeded the threshold score or were associated with high variability between the 5 test sessions were categorized as failing to establish baseline, and these study eyes did not undergo further home device monitoring. Participants with an average test score that modestly exceeded the threshold score differentiating non-neovascular from neovascular AMD and associated with less variability were permitted to complete an additional 6 home test sessions. In this subgroup, the average of 11 home test sessions was compared to the threshold score and only those that then fell below the threshold were considered to establish their baseline value and continued further home device monitoring; the remainder of this subgroup was categorized as failing to establish baseline and did not continue to use the monitor.