

AMD Home Monitoring

The Notal Vision Diagnostic Clinic supports current and future paradigms in patient care

The advent of compact, patient-operated diagnostic devices and AI-based analytics of test data allows physicians to partner with remote diagnostic clinics and jointly manage patients with retinal disease. Patient engagement and education, as well as test compliance monitoring, are among the services remote diagnostic clinics provide to patients and prescribing physicians.



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In 2018, then president-elect of the American Academy of Ophthalmology George Williams presented his top priorities for 2019 and the future of the ophthalmic community: artificial intelligence (AI), clinical support, and patient-operated technology. AI is expected to give ophthalmologists new automated tools to support the diagnosis and treatment of ocular diseases. Patient-operated technologies, like remote diagnostic devices, are primed to provide better information to physicians making important clinical decisions about treatment. Computerized analytics are seen as the path toward more efficient and objective ways to interpret the abundance of images that these devices produce.

The wider medical community agrees that personalized medicine—the tailoring of medical treatment to the individual characteristics of each patient—is the way of the future. Medical institutions and pharmaceutical companies are

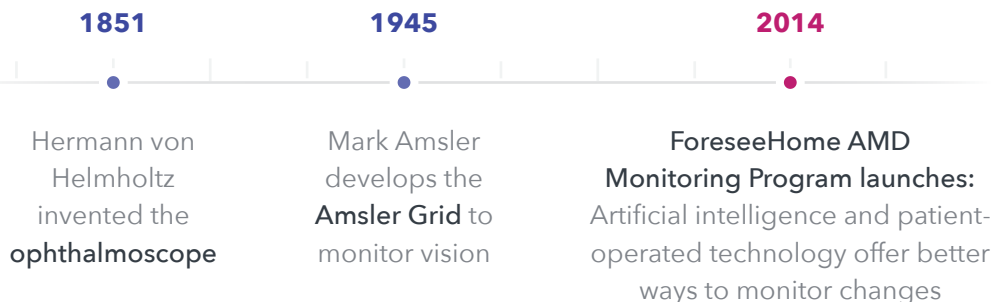
putting substantial resources into developing individualized medicine programs to tailor therapy with the best outcome and highest safety margin to ensure better patient care.

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Remote diagnostics enable patient monitoring at home, between physician office visits, and can play an important role in supporting personalized medicine. Unfortunately, they cannot provide a meaningful solution for physicians or patients unless they are part of a holistic program that provides clinical support, empowers the patient to take control of their care, and enforces compliance.

A BRIEF HISTORY of

Advancements in Remote Monitoring



The Remote Diagnostics Challenge

In ophthalmology, the management of retinal diseases like dry age-related Related macular degeneration (AMD) can significantly benefit from patient home monitoring between office visits. The Amsler grid has been the standard of care for decades but has limitations of perceptual completion and lack of patient compliance, which reduces its overall ability to detect the conversion from dry to wet AMD to less than 50%.^{1, 2, 3}

Remote technologies were introduced that used smart phone or tablet applications for visual acuity home monitoring. Testing results are managed in different ways depending on the application. One uses cloud-based algorithms to analyze for subtle vision changes, and results are sent to the physician. Another informs the patient if there is an anomaly in their scores so they can schedule a follow-up exam with their doctor themselves.

In addition to technology, more advanced solutions employ services to connect and partner with patients and physicians. Such solutions provide patient education, ongoing support, and a positive and empowering experience to ensure successful home monitoring and true clinical benefits.

Notal Vision has pioneered home diagnostic services in ophthalmology. At its onset, the company identified the unmet need to detect the conversion from dry to wet AMD as early as possible in order to improve therapeutic outcomes. It quickly became apparent that, in addition to innovative diagnostic testing equipment and automated data analytics, engagement solutions embracing prescribing practices and patient needs are critical factors to the success of a dependable home monitoring service.

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Physicians prescribing a home monitoring service need to trust the provider to whom they are referring their patients. The remote management of patients by the service provider must match the standards that physicians apply to their own in-office encounters. A reliable partnership between physician and the home monitoring provider is pivotal to successfully co-manage patients.

Early Notal Vision market research found that a major challenge to successful home monitoring begins at diagnosis. During research conducted in 2018, dry AMD patients expressed concern about the overwhelming nature of a dry AMD diagnosis.⁴ According to the research, patients reported mixed emotions including fear, confusion, anger and lack of control.⁵ Without adequate education by their doctor, patients do not fully understand the disease's progression, and the loss of control is as frightening as the potential loss of vision.⁶ However, they felt empowered when they were given tools to do more, giving them some control over the disease.⁷

1 Fine AM, Elman MJ, Ebert JE, Prestia PA, Starr JS, File SL. Earliest symptoms cause neovascular membranes in the macula. Arch Ophthalmol. 1986; 104:513-514.

2 Schuchard RA. Validity and interpretation of Amsler grid reports. Arch Ophthalmol. 1993; 111:776-780.

3 Achard OA, Safran AB, Duret FC, Ragama E. Roles of the completion phenomenon in the evolution of Amsler grid results. Am J Ophthalmol. 1995; 120:322-329.

4,5,6,7 Data on file. Notal Vision, 2018

Prescribing physicians require that the home monitoring experience align with the service that patients expect and reflect positively on them and their practice. However, physicians often have limited time to fully explain a dry AMD diagnosis and why monitoring the disease from home between office visits is important. Even when offering their patients tools like the Amsler grid, there is often a lack of compliance unless the patient understands the importance of monitoring for disease progression from home. The patient needs a more controlled journey, and proactive messaging, consistently reinforced by a clinical partner who can help guide them through their AMD journey and make sure they are testing regularly.

The Notal Vision Diagnostic Clinic (NVDC) Solution

Imagine a world where AI, patient-operated remote diagnostics and clinical support are integrated: a “one-stop shop” for physicians to monitor patients at home using advanced but easy-to-use technology that provides timely information in the detection and treatment of retinal diseases, helping them determine the best course of action, all while empowering patients in their own care.

Notal Vision connects patients and physicians beyond the clinic to advance eye care using an ecosystem that is the foundation for supporting personalized medicine. With a proven approach to home-based patient-operated diagnostics and AI-enabled data analysis, we are helping to improve visual outcomes by preserving AMD patients’ vision.⁸

⁸ Chew EY, Clemons TE, Bressler SB, et al; AREDS2-HOME Study Research Group. Randomized trial of a home monitoring system for early detection of choroidal neovascularization home monitoring of the eye (HOME) study. *Ophthalmology*. 2014;121(2):535-544.

The Notal Vision Diagnostic Clinic (NVDC) engages patients and physicians throughout the home monitoring journey using an Independent Diagnostic Testing Facility (IDTF). IDTFs are utilized extensively across medicine, including in mammography and radiology, in blood laboratories, and for cardiac heart monitoring. An IDTF must have one or more supervising physicians who are responsible for the direct and ongoing oversight and quality of the testing performed, the proper operation and calibration of equipment used for testing, and oversight of the certified technicians who use the equipment.

As an IDTF, the NVDC is a full-service diagnostic clinic that provides holistic, beginning-to-end physician and patient education, training and support for dry AMD home monitoring. Directed by practicing ophthalmologists and supported by a team of certified ophthalmic technicians and patient engagement specialists, the NVDC is a medical provider and the epicenter for patient and physician engagement.

What is an Independent Diagnostic Testing Facility (IDTF)?

An IDTF does not solicit patients directly and only accepts patients referred by an attending physician who is providing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the patient’s specific medical problem. An IDTF is also required to maintain regulatory standards as stringent as other healthcare providers, ensuring that Health Insurance Portability and Accountability Act (HIPAA) guidelines are followed and a patient’s Protected Health Information (PHI) is secured at all times.

A PATIENT'S AMD JOURNEY



AMD
Diagnosis



ForeseeHome™
Intermediate
Dry AMD

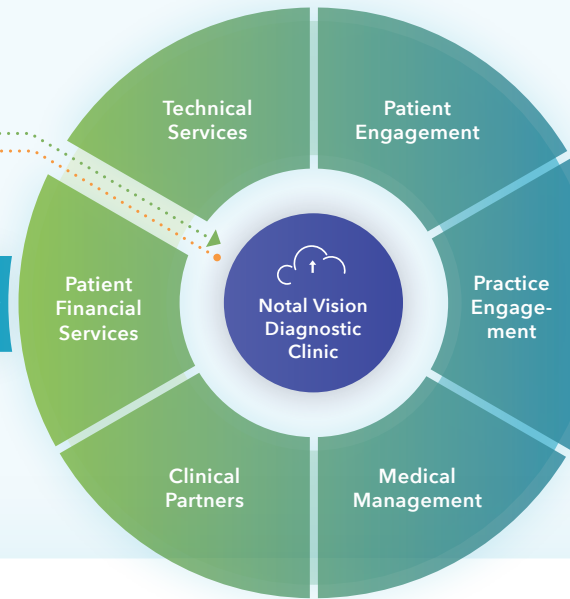


ALERT



Pipeline
Technologies

Wet AMD



Patients receive ongoing support from qualified clinical professionals as well as empowering tools for success with home monitoring. And physicians are confident knowing that the home monitoring experience reflects positively on them and their practice.

A Practice's Partner in Patient Care

Dedicated clinical account managers and NVDC practice specialists provide practices with the tools needed to order a Notal Vision home diagnostic service, like the ForeseeHome® AMD Monitoring Program.

The NVDC offers a host of in-office and take-home AMD and device education handouts, as well as resources to help set the practice apart as an AMD remote diagnostics leader. The NVDC also helps the practice implement a simple process to identify and educate patients and incorporate the referral process into

clinic flow. After receiving a referral, the NVDC provides a consistent feedback loop to the practice's designated contacts, including 24/7 access to patients' testing data, alert management support, and monthly patient summary reports via the Eye Care Professional (ECP) Portal.

The NVDC Feedback Loop

- 24/7 Access to Patients' Testing Data
- Alert Management Support
- Monthly Patient Summary Reports

The NVDC medical management team manages the alert process when there's a statistically significant change from a patient's test compared to the baseline, indicative of significant changes in metamorphopsia or scotoma. The NVDC is alerted to review the patient report. An email notification with a direct link to the patient report is sent by the NVDC to the practice, which is the practice's cue to contact the patient to schedule a follow-up exam.



The Notal Vision Diagnostic Clinic offers true end-to-end patient support

Helping Patients Take Control of Their AMD

Once a physician refers a patient to the NVDC, an introductory call is scheduled. Detailed materials encourage patients to call the NDVC as soon as possible, but they will be contacted within two business days if they don't contact the NVDC first.

During the first call, a dedicated NVDC clinical partner takes as much time as the patient needs to understand the disease and the importance of home monitoring to preserve their vision. The clinical partner reviews how the device and testing works, and then introduces a patient financial specialist to verify benefits and eligibility, as well as any prior authorization support needed (see sidebar for more information on costs and insurance coverage).

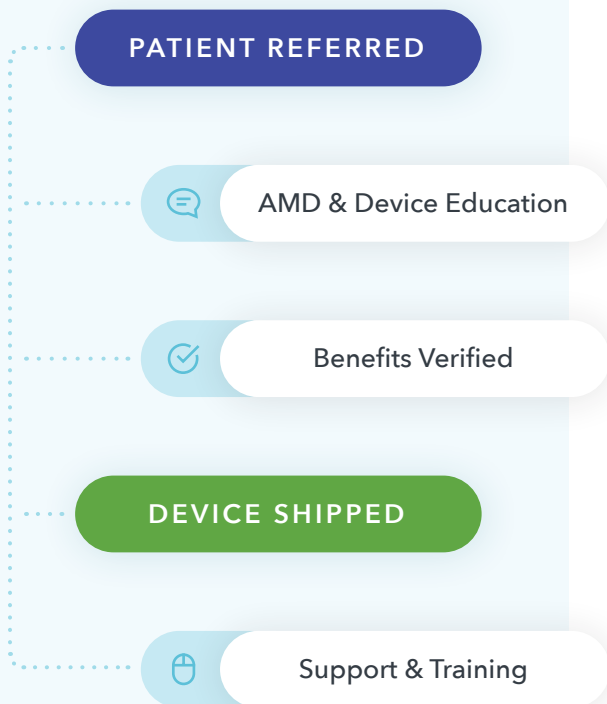
The device is then shipped to the patient's home. During a pre-scheduled call, the clinical partner walks them through unboxing and setting up the device. It is explained how to connect the device to either a Wi-Fi or cellular connection (cellular modem provided), and then the patient is guided through a tutorial session using the device.

After the patient is given step-by-step device setup instructions and training, they will begin testing to establish a baseline. A baseline is a patient's normative pattern and is used in combination with an AMD population normative pattern to monitor subsequent tests for any changes. If a patient is unable to establish a baseline, the NVDC receives a notification and reviews the patient's report. After review, the patient and practice are notified via telephone and email to explain the findings if the decision is to discontinue the home monitoring service.

Patients are encouraged to use the device every day. Those who are close to falling below the minimum eight tests per 30-day cycle required for Medicare reimbursement will be notified to continue testing. If tests are not received for a period of one week, a clinical partner will contact the patient to encourage compliance or check and troubleshoot any data transmission issues. If a transmission problem cannot be fixed, the NVDC will send a new device to the patient.

The NVDC continues to engage the patient throughout their AMD journey with monthly testing summary reports and a monthly newsletter, curated by the NVDC's medical directors. The communication provides helpful tips and tricks for using the device, as well as interesting articles about AMD and patient success stories.

What Happens After a Referral?



Device is loaned to patient and the patient is charged a monthly monitoring fee. The fee is covered by Medicare and most private insurance.

Financial assistance available for qualified patients.

Visit foreseehome.com/HCP
or call 1-855-600-3112 to
learn more.

The Future of Remote Monitoring and Precision Medicine

Notal Vision remote diagnostic services, powered by innovative devices, AI-enabled data analysis and patient engagement solutions, are helping to preserve AMD patients' vision.

The future of precision medicine through remote diagnostic services is here, but it requires the support of a holistic solution to be effective. Beyond advanced technology, the Notal Vision Diagnostic Clinic is what drives the success of home monitoring for patients and their doctors.

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In addition to being an extension of a practice by providing a complete solution for eye care professionals and their patients, the NVDC wants to partner with practices that understand the importance of remote monitoring and the role it will play in the future of medicine. The NVDC can help differentiate a practice as an innovator and remote diagnostics leader in the community.



A PATIENT STORY

When Mrs. Eloine Vieira walked into her retina specialist's office, she was holding her husband's hand, not knowing what to expect.

Her doctor, Jeffrey Heier, MD of the Ophthalmic Consultants of Boston, had previously referred her to the ForeseeHome AMD Monitoring Program to monitor the dry age-related macular degeneration (AMD) that presented in both her eyes. Mrs. Vieira was testing with the device almost daily when she received a call from Dr. Heier's office asking her to come in for a follow-up examination.

"When I walked into his office," recalls Mrs. Vieira, "Dr. Heier put his arms out and said 'ForeseeHome did exactly what it was supposed to do. We caught this, and you are not going blind.' I teared up." Mrs. Vieira is a retired college professor and relies heavily on her eyesight because she is hard of hearing. She says "I read lips. If I did not have ForeseeHome, [I believe] not only would I be blind, but I would be deaf."

"Patients are terrified of developing wet macular degeneration," says Dr. Heier. "[They] are

desperately looking for ways to help detect it earlier, to help make sure they don't lose vision. Mrs. Vieira's case is an ideal example of what ForeseeHome can do." He explains how the Notal Vision Diagnostic Clinic alerted him to Mrs. Vieira's potential wet AMD conversion.

"The [alert] came into me... she had in fact developed wet AMD before she was even symptomatic."

– DR. JEFFREY HEIER

"The [alert] came into me, we called Mrs. Vieira, and she came in totally asymptomatic, [our] diagnostic imaging picked up that she had in fact developed wet AMD before she was even symptomatic. We were able to initiate treatment immediately. She began with good vision and continues to this day to have good vision."