NICE National Institute for Health and Care Excellence®

NICE guidance

Digital technologies to support home monitoring of vision changes for people with advanced dry age-related macular degeneration: early-use assessment

HealthTech guidance
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1 Recommendation

1.1 More research is needed on digital technologies to support home monitoring of vision changes for people with advanced dry age-related macular degeneration (AMD, also known as geographic atrophy) before they can be funded by the NHS. The technologies are:

- Alleye
- Digivis DVA
- OdySight
- OKKO for AMD.

What this means in practice

There is not enough evidence to support funding of digital technologies for home monitoring of vision changes for people with advanced dry AMD in the NHS.

Access to these technologies should be through company, research or non-core NHS funding, and clinical or financial risks should be managed appropriately.

What research is needed

More research for digital technologies to support home monitoring of vision changes for people with advanced dry AMD is needed on:

- diagnostic accuracy to detect progression to wet AMD (also known as neovascular AMD)
- optimal frequency of self-monitoring
- impact on resource use
- time to identification of development of wet AMD

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- patient-reported usability and acceptability
- clinician-reported acceptability
- long-term adherence
- changes in health-related quality of life
- changes in functional vision including visual acuity.

Research on the same outcomes in people with intermediate AMD would also be beneficial.

Why the committee made this recommendation

There is an unmet need for tools to help people with advanced dry AMD monitor their vision at home. There is currently no treatment for advanced dry AMD. If it progresses to wet AMD, that can be treated. The technologies could help address the need for monitoring tools if they can accurately detect vision changes that indicate development of wet AMD. It is important that progression to wet AMD is detected and treated quickly to help avoid permanent vision loss.

There is limited clinical-trial evidence for using the technologies in advanced dry AMD, so their clinical effectiveness is uncertain. The evidence may not reflect use of the technologies in the NHS because some studies were done outside the UK. Also, some of the studies are small or not restricted to people with advanced dry AMD. There is some evidence for the diagnostic performance of Alleye and OdySight. But this is limited because it does not specifically evaluate detection of wet AMD developing in people with advanced dry AMD. There is no relevant clinical-effectiveness evidence for Digivis DVA and OKKO for AMD.

People with advanced dry AMD have reduced contrast sensitivity, so the technologies may be difficult for them to use. Also, the technologies that measure visual acuity may not detect changes in contrast sensitivity.

Because of the limitations in the clinical evidence, the cost effectiveness of the technologies is uncertain. There is uncertainty about the assumptions used in the model because of the lack of evidence. So, more research is needed.

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2 Information about the technologies

2.1 Four digital technologies for monitoring vision changes were included in this evaluation: Alleye (Oculocare Medical Inc), Digivis DVA (Cambridge Medical Innovation Ltd), OdySight (Tilak Healthcare) and OKKO for AMD (OKKO Health). These are proposed to be used as an adjunct to standard care. An overview of the 4 technologies included in the guidance is shown in table 1. Further detail on the technologies is in table 3 of the external assessment group (EAG) report.

The technologies measure hyperacuity, visual acuity, distortion or a combination of these to detect changes that could indicate development of wet AMD (also known as neovascular AMD). The technologies are used on an app or web page. They have functionality to share the results with healthcare professionals and patients.

The committee agreed that Peek Acuity Pro, which was initially included, is out of scope for this evaluation because it is not intended for monitoring vision changes at home in people with advanced dry AMD (also known as geographic atrophy). The technology's intended use is for screening for vision problems in the community in developing countries.

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Table 1: Overview of technology features

Technology name (Company)	Intended use	Regulation	Platform	Functionality
Alleye (Oculocare Medical Inc)	Macular diseases including dry AMD, wet AMD, diabetic macular oedema and retinal vein occlusion	Class 1 CE mark	Smartphone app	• Hyperacuity test • Results submitted to clinician dashboard with alerts monitored by secondary care team, with alarm to prompt review
Digivis DVA (Cambridge Medical Innovation Ltd)	To allow users of ophthalmology services to perform a test of distance visual acuity without assistance from a healthcare professional	Class 1 CE mark	Web-based test, requiring 2 internet connected devices	• Distance visual acuity replicating Early Treatment Diabetic Retinopathy Study chart testing • Results reported to users and healthcare professionals

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Technology name (Company)	Intended use	Regulation	Platform	Functionality
OdySight (Tilak Healthcare)	Adults with chronic macular diseases complicated by choroidal neovascularisation or macular oedema requiring treatment or at risk of developing choroidal neovascularisation or macular oedema	Class 1 CE mark	Smartphone app	• Visual acuity and Amsler grid • Results reported to users and healthcare professionals
OKKO for AMD (OKKO Health)	People with AMD	Class 1 CE mark	Smartphone app	• Puzzle games to detect changes in visual acuity or distortion • Results reported to users and healthcare professionals

Sustainability

2.2 For information, Carbon Reduction Plans for UK carbon emissions, or a commitment to reducing greenhouse gas emissions and achieving net zero, are published here for each company:

- Oculocare has stated a commitment to transition to net zero greenhouse gas emissions by 2050 and the ongoing development of a carbon reduction framework: Oculocare net zero commitment.
- Cambridge Medical Innovation Ltd, Tilak Healthcare and OKKO Health did not provide Carbon Reduction Plans for UK carbon emissions or a net zero commitment.

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3 Committee discussion

The medical technologies advisory committee considered evidence on digital technologies to support monitoring of vision change at home for people with advanced dry age-related macular degeneration (AMD) from several sources. This included evidence submitted by Cambridge Medical Innovation, Oculocare and Tilak Healthcare, a review of clinical and cost evidence by the external assessment group (EAG), and responses from stakeholders. Full details are available in the project documents for this guidance.

The condition

3.1 AMD is a progressive condition, typically affecting people aged over 55, in which the macula becomes damaged, causing the vision to become blurred or distorted.

It was estimated that in 2020 in the UK, 340,000 people had advanced dry AMD (also known as geographic atrophy), and 339,000 people had wet AMD (also known as neovascular AMD). By 2050, there is expected to be 720,000 people with advanced dry AMD and 683,000 people with wet AMD in the UK (NICE's clinical knowledge summary, 2025).

Current practice

3.2 AMD diagnosis and management in the NHS follows NICE's guideline on age-related macular degeneration, Getting It Right First Time pathway, and Royal College of Ophthalmologists guidance. Initial assessment is usually in community optometry, using fundus examination and optical coherence tomography (OCT).

Early AMD and advanced dry AMD are generally not referred to hospital eye services unless specific criteria are met. There are currently no active treatments for early or dry AMD.

People with advanced dry AMD are at risk of their AMD progressing to wet AMD, which requires timely treatment. Active wet AMD is treated with intravitreal

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anti-VEGF injections, ideally within 14 days of referral. It is important that progression to wet AMD is detected quickly because treatment should be offered as soon as possible. This is to reduce leakage from blood vessels and prevent new abnormal blood vessel growth, which reduces fluid in the eye and helps avoid permanent vision loss.

Routine hospital monitoring is limited. Instead, people diagnosed with advanced dry AMD are advised to look out for changes to their vision such as blurred or grey patches, distortion or objects appearing smaller than normal. People are advised to report to their eyecare professional (usually an optometrist) if they notice changes in vision. The clinical experts advised that access to OCT in the community varies according to location and can require payment. NICE's guideline on age-related macular degeneration does not recommend any specific tools for self-monitoring of advanced dry AMD at home. Many people are advised to use the Amsler grid, a printed square with evenly spaced horizontal and vertical lines and a dot in the centre. If any lines on the grid appear wavy, distorted, blurry or have gaps, the person should contact an eyecare professional for clinical assessment. The Amsler grid is freely available but has limitations including that it is not standardised, has poor reproducibility and only measures distortion.

Unmet need

3.3 The clinical experts explained that the demand for ophthalmology services is high and growing. Ophthalmology is the busiest outpatient speciality in the NHS, with more than 9.7 million outpatient appointments in England between 2024 and 2025 (NHS England Hospital Outpatient Activity 2024 to 2025). With the growing ageing population and an increasing prevalence of diabetes (which can cause eyesight problems), there is a significant system need.

There is limited provision of routine monitoring appointments, and the Amsler grid has recognised limitations. Together, these factors increase the risk of delayed detection of wet AMD. So, there is an unmet need for tools that support timely identification of vision changes and prompt referral for clinical assessment. The technologies are intended to support vision self-monitoring, which could help address this unmet need. They work by detecting changes in vision and sharing

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this information with eyecare professionals. This may prompt urgent referrals when needed, enabling earlier diagnosis and treatment and improving outcomes. The tools may also empower people to take an active role in managing their condition.

Patient considerations

3.4 The lived-experience experts explained that for people with advanced AMD, much of their sight loss is because of reduced contrast sensitivity rather than other aspects of vision. Reduced contrast sensitivity makes it difficult to see the faces of family members and friends. It also makes it difficult to distinguish the edge of a kerb, for example, which can lead to falls and accidents. The lived-experience experts explained they may need a companion when outdoors, to help keep them safe. They advised that the technologies would be unsuitable for many people with advanced AMD, because of:

- exhaustion caused by concentrating on a screen
- glare from a smartphone screen
- the small size of a smartphone screen
- existing sight loss (reduced contrast sensitivity), making it difficult to see the content on screen.

The lived-experience experts stated these barriers to using the technologies could not be overcome by provision of training and support.

The lived-experience experts stated that other modalities for monitoring vision change are preferred. They felt that if OCT provision could be more widely available in the community this could meet the needs of most people with advanced AMD. The committee noted that the availability of OCT has increased since NICE's guideline on age-related macular degeneration was published in 2018. The lived-experience experts stated that many people with AMD are not aware of the Amsler grid and do not use it. So, many people use straight edges in their home, such as kitchen tiles or window frames, to monitor vision changes.

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The committee recognised the potential for the technologies to cause anxiety in people using them. Anxiety could be caused by receiving an alert and waiting for an appointment for assessment to determine whether the alert was a true positive. If frequent use of an app is needed, this could also cause anxiety, because this requires the person to think about their condition regularly.

Clinical effectiveness

Evidence base

3.5 Four relevant studies were identified: 3 studies on Alleye (1 cross-sectional study, 1 qualitative study and 1 observational study) and 1 retrospective study on OdySight. The EAG assessed the studies as being good or moderate quality. Outcomes reported by the studies included diagnostic performance measures, acceptability, usability and user adherence. The population in the evidence base was broader than the population in the scope. Some studies included people with wet AMD and other eye conditions. Some studies had a small sample size. Study locations were in the UK, France, Singapore and Switzerland. No evidence was identified that met the population and use case in the scope for Digivis DVA or OKKO for AMD.

The committee discussed the generalisability of the evidence base to the NHS. Studies done outside the UK are not fully generalisable to the NHS because of differences in reimbursement of healthcare and in populations. Also, 1 of the studies was done in a university and does not reflect a healthcare setting. Some studies were done in mixed populations. For these reasons, the committee agreed that the generalisability of the evidence base to the NHS was limited.

Acceptability and adherence

3.6 One qualitative study evaluated the acceptability and usability of technologies for home monitoring, including Alleye. The study reported that home monitoring was

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generally rated positively by participants. Study participants recognised the potential benefits of home monitoring including earlier detection of disease progression, greater involvement in managing their eye condition, and reassurance between clinic visits. Concerns raised by participants included potential anxiety associated with interpreting test results and a possible reduction in face-to-face contact with healthcare professionals. Barriers to home monitoring included level of digital literacy and training and support needs. One observational study evaluated adherence to using Alleye in people with dry AMD. The study reported a 42% uptake of using Alleye. Of those who started using Alleye, 59% were still using it at 1.5 months. The committee concluded that further data on acceptability and adherence collected over at least 12 months would be useful.

Diagnostic performance

3.7 One study evaluated the diagnostic performance of OdySight in the prevention of progression to wet AMD for people diagnosed with dry AMD, and the prevention of recurrence of wet AMD for people who previously had treatment for wet AMD. This study reported that the specificity of OdySight was 94.3% and the sensitivity was 14.3% in the population who had previous treatment for wet AMD. Diagnostic performance for detection of progression from dry to wet AMD could not be calculated because there were no true positives in this group. One study reported the ability of Alleye to discriminate between wet and dry AMD when used in conjunction with a regression model. The area under the receiver operating characteristic curve is 0.66, indicating moderate ability to discriminate. The study does not provide any evidence of the ability of Alleye to detect differences specifically between advanced dry AMD and wet AMD, or its ability to detect the conversion of advanced dry AMD to wet AMD.

Patient safety

3.8 If the sensitivity of a technology is low, false-negative results will be high. The clinical and lived-experience experts expressed concerns about false-negative results, meaning that a diagnosis of wet AMD is missed. This could lead to delayed treatment and consequently an increased risk of permanent vision loss.

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A clinical expert explained that in wet AMD, when the abnormal blood vessels result in a large bleed there can be an immediate impact on visual acuity. But if the blood vessels are leaking slowly, away from the very centre of the eye, the impact on visual acuity is usually delayed. So, structural changes in the eye can sometimes be detected by OCT before changes in vision can be detected by tests for vision such as the digital technologies and the Amsler grid. The committee accepted that the technologies cannot detect structural changes directly and are unlikely to be as accurate as OCT for detecting development of wet AMD. But the technologies could still add value to the treatment pathway if they are better than the Amsler grid at detecting vision changes.

Other outcomes

3.9 There was no outcome data on how the technologies impact time to treatment, visual outcomes and health-related quality of life in people with advanced dry AMD. The committee concluded that the clinical effectiveness of the technologies is uncertain because of the limited evidence available.

Cost effectiveness

Exploratory model

3.10 The EAG developed a simple Markov model based on a generic technology because of the lack of clinical evidence and the challenges of modelling the diagnostic process for AMD. The generic technology was assumed to have better uptake, adherence, sensitivity and specificity than the Amsler grid. The model considered events only up to the point of diagnosis and did not capture costs or benefits after diagnosis. The EAG was unable to calculate a cost per quality-adjusted life year, only a cost per early diagnosis.

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Model results

3.11 The base case resulted in an incremental cost per early diagnosis of £9,228. The EAG used scenario analysis to investigate the impact of uncertainties in the base case. In the best-case scenario, the technology was assumed to have 100% uptake, adherence and accuracy. It also assumed the lowest technology cost. This resulted in an incremental cost per early diagnosis of £2,352.

Another scenario explored the impact of using the technologies for monitoring intermediate AMD instead of advanced dry AMD. The incremental cost per early diagnosis in this scenario was £4,432. The committee noted that the incremental cost per early diagnosis in the scenario analysis for intermediate AMD was lower than the base case, and noted that even the best-case scenario was cost-incurring. This is expected because the impact of earlier diagnosis is not captured in the model.

Impact on the healthcare system

3.12 The committee discussed the impact of implementing the technologies on the healthcare system. The clinical experts explained there is a need for staffing to monitor the alert system, and the staff members would need training. People using the technology would also need training on how to use them, and some people may require ongoing support. Provision of training and ongoing support for people using the technologies would need to be resourced.

The committee noted that if the technologies resulted in more false-positive results compared with current practice, this would lead to increased resource use in hospital eye services. This is because everyone with a positive result would need to have their eye assessed by hospital eye services. The committee concluded that further research on resource use is needed.

Value for money

3.13 The committee noted a lack of evidence to inform the model inputs, so the modelling used many assumptions. The committee concluded that value for

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money is uncertain.

Intermediate AMD

3.14 The clinical expert advised that the technologies may be better suited to people with intermediate AMD because they typically have less sight loss than people with advanced AMD. Also, people with intermediate AMD are more likely to develop wet AMD than people with advanced dry AMD. The committee agreed that evidence in people with intermediate AMD would be helpful to understand whether use of the technologies in this group could be beneficial.

Equality considerations

3.15 AMD can cause visual impairment, which can be considered a disability under the Equality Act. Some people may be unable to use the technologies, including people with a greater degree of visual impairment. And people who cannot read English may need additional support to use the technologies.

The technologies have been designed to work with smartphones that have a basic specification, and are compatible with 90% of smartphones on the market. But the committee noted that not all people have smartphones or access to the internet, which could result in digital exclusion.

A clinical expert explained that OCT is free for people who have their eye condition managed in secondary care. People with advanced dry AMD usually have their condition managed in the community and for most people there is no free provision of OCT. Many optometrists offer OCT that is paid for privately by the individual. But availability of community optometry varies according to geographical location, with more deprived areas generally having fewer optometry practices than less deprived areas. So, OCT may not be accessible when cost or local availability is a barrier.

The committee agreed that future studies should collect information about the characteristics of participants. Studies should aim to include a diverse range of

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people and have an equality impact assessment.

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4 Committee members and NICE project team

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chairs

Jacob Brown and Neil Hawkins
Medical technologies advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Nancy Pursey
Technical lead

Frances Nixon and Rebecca Owens
Technical advisers

Bruce Smith
Project manager

Rebecca Albrow
Associate director

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