NICE National Institute for Health and Care Excellence

HealthTech Programme

Medical Technologies Advisory Committee

Digital technologies to support monitoring of vision change at home for people with age-related macular degeneration – 1st meeting

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The following documents are made available to the Committee:

1. Cover sheet
2. Final Scope [noCON]
3. External assessment report overview (ARO) [noCON]
4. Professional group submission
   4a. The Royal College of Ophthalmologists [noACIC]
5. Professional expert questionnaires [noCON]
6. EAR clean [ACIC] redacted dated 6 May 2026 including some EAG changes in response to companies' factual accuracy comments
7. Company comments and EAG responses on the External Assessment Report (EAR) [CIC] redacted
8. Register of interests [noCON]

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

Digital technologies to support monitoring of vision change at home for people with age-related macular degeneration

Final scope

1. Introduction

The technologies included in this NICE HealthTech evaluation are technologies to support monitoring of vision change at home for people with age-related macular degeneration.

The technologies are proposed to be assessed for early use. Early-use assessment considers HealthTech products that could address a national NHS unmet need. It rapidly assesses products that are early in the lifecycle (but that have appropriate regulatory approval for use in the UK) or that have limited use in the NHS and need further evidence to support wider use. Technologies considered for early use can be conditionally recommended for use while further evidence is generated during the evidence generation period. This enables early access to promising new technologies for patients. Conditional recommendations are for a fixed period of time and the technologies will be reassessed for routine use using the evidence generated.

This scope document describes the context and the scope of the assessment. Questions for the scoping workshop are in appendix A. The methods and process for the assessment follow the NICE HealthTech programme manual.

2. The condition

Macular disease refers to conditions that affect the macula, an area of the retina at the back of the eye that is responsible for central vision, fine details and most of colour vision. When a person has macular disease, the macula becomes damaged, causing the vision to become blurred or distorted. Macular disease is the biggest cause of sight loss in the UK and affects nearly 1.5 million people. Several eye conditions can cause macular disease. The most common cause of macular disease is age-related macular degeneration (AMD).

2.1 Age-related macular degeneration

AMD is a progressive macular disease which usually affects people over 55. Risk factors include:

- older age
- presence of AMD in the other eye
- family history of AMD
- smoking
- hypertension
- BMI of 30 kg/m^2 or higher
- diet
- lack of exercise.

The Macular Society reports that AMD is the leading cause of sight loss in the UK, affecting more than 700,000 people. AMD is commonly described according to the following classification, as described by The Royal College of Ophthalmology (Royal College of Ophthalmologists commissioning guidance – age-related macular degeneration services, 2024):

- Early AMD or age-related maculopathy
- Intermediate AMD
- Neovascular AMD or wet AMD
- Advanced dry AMD or geographic atrophy

- Advanced wet AMD/disciform scar.

The terms wet AMD and neovascular AMD are used interchangeably, and in the scope will be referred to as “neovascular (wet) AMD” throughout the scope. Similarly, the terms advanced dry AMD and geographic atrophy are used interchangeably, and will be referred to as “advanced dry AMD (geographic atrophy)” throughout the scope.

Classification group depends on damage to the macula. Around 75% of people with AMD have early AMD with no symptoms. For people with early AMD, their AMD can be stable for years, but the condition can progress and sight loss may become more noticeable. Advanced dry AMD (geographic atrophy) is caused by deterioration of the macula, where cells die off but are not renewed. Neovascular (wet) AMD develops when abnormal blood vessels grow into the macula. In advanced wet AMD or disciform scar, abnormal blood vessels are present but are not currently leaking blood or fluid. In neovascular (wet) AMD, the abnormal blood vessels leak blood or fluid, leading to scarring of the macula and rapid loss of central vision. As the condition progresses, symptoms include:

- blurry central vision
- straight lines appearing distorted
- difficulty recognising faces
- difficulty seeing in low light
- dark or empty spots in the centre of vision
- difficulty reading, driving or doing close up work.

The Royal College of Ophthalmologists classification does not represent a linear progression between each class of AMD. Advanced dry AMD (geographic atrophy) does not necessarily develop before neovascular (wet) AMD. Either pathway may develop independently, and some patients progress directly from intermediate AMD to neovascular (wet) AMD without passing through advanced dry AMD (geographic atrophy).

3. Current practice

In the NHS, the referral, diagnosis and treatment of AMD follow the:

- NICE Age-related macular degeneration guideline (NG82)
- Getting it right first time pathway for age-related macular degeneration
- The Royal College of Ophthalmologists commissioning guidance – Age related macular degeneration services

3.1 Diagnosis and referral

NICE's guideline for age-related macular degeneration recommends offering fundus examination as part of an eye examination to people presenting with changes in vision or visual disturbances. This is typically done in a primary or community care setting by an optometrist. Early AMD and advanced dry AMD (geographic atrophy) are usually diagnosed using optical coherence tomography (OCT). People with asymptomatic early AMD should not be referred to hospital eye services for further tests, and people with advanced dry AMD (geographic atrophy) should be referred only:

- for certification of sight impairment **or**
- if this is how people access low-vision services in the local pathway **or**
- if they develop new visual symptoms that may suggest neovascular (wet) AMD **or**
- if it would help them to participate in research into new treatments for advanced dry AMD (geographic atrophy).

An urgent referral to hospital eye services (within 1 working day) should be made for people with suspected neovascular (wet) AMD. People with suspected neovascular (wet) AMD should be offered OCT. Fundus fluorescein angiography should only be offered to confirm a diagnosis of neovascular (wet) AMD if OCT does not exclude neovascular disease. People with

confirmed neovascular (wet) AMD should be offered treatment as soon as possible, within 14 days of referral to the macular service.

Clinical experts stated that diagnosis and referral pathways may vary depending on local set up.

3.2 Treatment

There are currently no treatment options for early AMD, advanced dry AMD (geographic atrophy) or advanced wet AMD/ disciform scar. People with these conditions are typically given lifestyle advice, information and support. Most people with neovascular (wet) AMD can be offered treatment with intravitreal anti-vascular endothelial growth factor (VEGF) injections to stop abnormal blood vessel growth.

3.3 Monitoring

NICE's guideline for age-related macular degeneration recommends that people with early AMD or advanced dry AMD (geographic atrophy) should not be routinely monitored through hospital eye services. People with advanced dry AMD (geographic atrophy) or people with AMD that have been discharged from hospital services are advised to self-monitor their AMD, continue with routine sight-tests with their community optometrist and to consult an eye-care professional as soon as possible if their vision changes. People are given advice on how to detect vision changes at home. A paper copy of the Amsler grid or ambient references with a grid pattern, for example kitchen or bathroom tiles, can be used to support self-monitoring. Lines on the Amsler grid or ambient reference that appear wavy or distorted can indicate vision changes.

The Royal College of Ophthalmologists commissioning guidance for age-related macular degeneration services states that OCT is the most sensitive monitoring tool. It also says that, for community provision, OCT should be used to monitor people at high risk of new neovascular (wet) AMD. In practice, there is likely to be variation in whether people with advanced dry AMD (geographic atrophy) can access OCT as part of routine monitoring. Some

people with advanced dry AMD (geographic atrophy) may be able to access OCT by paying for it at their optometrist. People who are registered as partially sighted can access free routine eye tests, which may include OCT.

4. Unmet need

The cost of sight impairment and sight loss to the UK economy is estimated at £25 billion annually and is predicted to rise to £33.5 billion by 2050. With the growing ageing population in the UK and an increasing prevalence of diabetes, the cost of managing macular disease to the NHS is predicted to rise. Ophthalmology is the busiest outpatient speciality in the NHS carrying out more than 7.5 million outpatient appointments in England between 2022 and 2023 (Fight for Sight, 2021).

The UK prevalence of advanced AMD, including late dry AMD (geographic atrophy) and neovascular (wet) AMD, has been estimated at 513,000 individuals (based on 2007-2009 data) and was projected to rise to 679,000 by 2020. Geographic atrophy is estimated to affect 1.3% of people aged 50 and over, between 2.6-2.9% of people aged 65 and over, and 6.7% of people aged 80 and over (Owen et al, 2021).

People with advanced dry AMD (geographic atrophy) are at risk of their AMD progressing to neovascular (wet) AMD requiring treatment. The Age-related eye disease study (AREDS) severity score can be used to estimate the risk of progression. It is important that progression to neovascular (wet) AMD is detected quickly. This is because treatment should be offered as soon as possible to reduce leakage from blood vessels and prevent new blood vessel growth, which reduces fluid in the eye and helps to avoid permanent vision loss. People with advanced dry AMD (geographic atrophy) are not usually routinely monitored in hospital. After diagnosis, people with advanced dry AMD (geographic atrophy) 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 eye care professional (usually an

optometrist) if they notice changes in vision. The NICE guideline does not recommend any specific tools for self-monitoring of advanced dry AMD (geographic atrophy) at home. Many people are advised to use the Amsler grid, which is freely available but has some limitations. The Amsler grid is not standardised, has poor reproducibility, and only measures distortion. The EDNA study found that the Amsler grid has low sensitivity and moderate specificity for detecting onset of neovascular (wet) AMD.

Given the lack of routine monitoring appointments, limitations of the Amsler grid and the risk associated with not detecting neovascular (wet) AMD in a timely manner, there is a need for tools that detect vision changes and identify when a person needs to have their vision clinically assessed for onset of neovascular (wet) AMD. Technologies that support self-monitoring of vision could help address the unmet by detecting changes in vision and sharing information with eye care professionals to prompt an urgent referral for assessment if required, leading to timely diagnosis and treatment and improved patient outcomes. The technologies could also help patients to feel empowered by helping them take an active role in managing their condition.

5. The technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts, and publicly available information. NICE has not carried out an independent evaluation of these descriptions.

The purpose of the technologies is to monitor changes in vision and detect changes which indicate that the person needs to have their vision assessed by hospital eye services or offered treatment. Structural changes in the eye must be detected and treated quickly to avoid permanent vision loss. So, timely and accurate detection of vision changes is an essential feature for these technologies.

For this proposed early use assessment, NICE will consider technologies that:

- are intended for use by adults who have been diagnosed with advanced dry AMD (geographic atrophy) and are at risk of developing neovascular (wet) AMD
- provide monitoring of vision changes for use at home
- have a CE or UKCA mark, or expect to have one by the time of final guidance publication
- are available for use in the NHS, or will be by the time of final guidance publication.

For this proposed early use assessment, NICE will not consider technologies that:

- are used for diagnosing eye conditions
- use AI to review imaging alone, for example images from fundus photography or OCT
- are used in settings other than the home, for example technologies used only in hospitals or community settings.

Sections 5.1 to 5.6 describe the 6 included technologies. All the included technologies were available to the NHS at the time of writing this scope or were expected to become available during the assessment period.

5.1 Alleye (Oculocare Medical Inc)

Alleye is a smartphone app that measures visual function (visual acuity/hyperacuity) using a dot-alignment Vernier task, performed monocularly. It allows users to self-monitor changes in their vision at home. The test takes 2 to 3 minutes per eye and should be repeated several times per week. Alleye informs users when their vision has changed and when they should contact an eye professional. Alleye tracks treatments, eye health over time, and upcoming appointments. The technology can trigger alarms for the clinical team to contact the user for a review. Alleye is intended for the detection and characterisation of central and paracentral visual distortion in

people with retinal disease. It can be used for self-monitoring at home by people with late AMD (dry) who are advised to self-monitor at home.

Alleye is a CE marked (class 1) medical device. It is compliant with DTAC. It is available in the UK and not currently in widespread NHS use. To date, it has been used at Moorfields Eye Hospital NHS Foundation Trust as part of a remote monitoring pathway for macular disease.

5.2 DigiVis DVA (Cambridge Medical Innovation Ltd.)

Digivis DVA is a web application which allows people with eye conditions to test their own vision by providing an automated medical test of distance visual acuity. Digivis DVA can be used for any eye condition requiring assessment of distance visual acuity, including AMD. Digivis DVA standard is intended for home or low volume testing environments. The technology requires two internet connected devices. One device displays a letter chart; the other device accepts user input for interacting with the test. Users can keep a record of their results and clinicians can access them through electronic patient record or the Digivis Portal.

Digivis DVA is a UKCA class 1 medical device and is available on the UK market. It is currently in NHS use at Cambridge University Hospital Foundation Trust and the Royal Berkshire Hospital, and due to be launched for use at Manchester Eye Hospital.

5.3 Odysight (Tilak Healthcare)

Odysight is a smartphone app for people with AMD combined with a dashboard for the eye care professional. It is prescribed by an ophthalmologist with the aim of improving the monitoring of eye disease and its progression. It offers2 vision tests: a visual acuity test (Tumbling E) and a digital Amsler grid. Users are advised to test once a week and the test takes less than 1 minute to complete. Based on the visual acuity test, an algorithm detects the change in vision and alerts both the user and the eye care professional to trigger a call or appointment. The app includes a gaming incentive (puzzle games designed by optometrists) to help with user

adherence. Odysight has a class 1 CE mark. It is not currently used in the NHS.

5.4 OKKO for AMD (OKKO Health)

OKKO is an app which uses simple puzzle games to detect changes in visual acuity and distortion and can be accessed from a smartphone or tablet. It offers home monitoring of vision for people with AMD to monitor their vision between clinic visits. Results can be collected and shared with eye care professionals. OKKO for AMD has a class 1 CE mark and has been piloted in the NHS.

5.5 Peek Acuity (Peek Vision)

Peek Vision is a smartphone app that detects vision change by testing visual acuity. Assistance from a second person, who does not need to be a healthcare professional, is required to use the app. It can be used in a range of community settings, including at home. It has been designed as a screening tool and could be used to monitor vision changes in people with macular disease. It has a class 1 CE mark and has been tested in the NHS.

5.6 The place of technologies in the care pathway

The technologies can potentially be used at several points in the care pathway as an adjunct to usual care. This assessment will look at technologies used to monitor changes in a person's vision at home to support healthcare professionals to detect progression of advanced dry AMD (geographic atrophy) to neovascular (wet) AMD. This includes technologies that:

- Detect changes in visual distortion, visual acuity or both.
- Trigger a person to contact eye services if vision has changed enough to warrant further assessment.
- Alert eye services of people whose vision has changed enough to warrant further assessment.

This assessment will focus on monitoring for progression of advanced dry AMD (geographic atrophy) to neovascular (wet) AMD following diagnosis of

advanced dry AMD (geographic atrophy). People with advanced dry AMD (geographic atrophy) who do not have neovascular (wet) AMD in the fellow eye are discharged from hospital eye services once the diagnosis of advanced dry AMD (geographic atrophy) has been made and advised to monitor vision changes at home. There is a risk of advanced dry AMD (geographic atrophy) progressing to neovascular (wet) AMD. The progression to neovascular (wet) AMD needs to be identified quickly so that treatment can be given quickly to reduce the risk of vision loss. If the technologies are sensitive at detecting progression to neovascular (wet) AMD, this could lead to an increased demand on hospital eye services.

Other potential use cases for the technologies include monitoring of neovascular (wet) AMD that is being treated to determine timing of treatment, and monitoring of neovascular (wet) AMD after completion of treatment. These use cases are outside of the scope for this assessment.

5.7 Innovative aspects

These technologies may:

- Allow for more timely detection of vision change at home
- Allow for detection of neovascular (wet) AMD
- Share information about changes in a person's vision with the clinical eye team and inform timing of assessment
- Support and empower patients to actively manage their eye condition.

6. Comparator

The comparator is usual care for monitoring vision changes in people who have advanced dry AMD (geographic atrophy), in line with section 3.3. The technologies would be used as an adjunct to standard care. The comparator is:

- Self-monitoring of AMD at home, with or without an Amsler grid

- Routine sight tests with community optometrist (usually once every 12 months), with or without OCT.

The reference standard for diagnostic accuracy outcomes is based on OCT.

7. Patient issues and preferences

Users would need to be able to use the technologies as directed by their healthcare professional and in accordance with manufacturer instructions. Education would be needed to ensure that the technologies are used correctly, including how to respond to alerts and when to contact a healthcare professional. If worsening vision is not detected and treated quickly, permanent vision loss could occur. For users already monitoring their vision at home, for example using an Amsler grid, adding or changing to using the technologies would be a change they would need to adapt to. Users may require ongoing support from healthcare professionals to be able to use the technologies. A user's adherence to the home monitoring protocol may depend on how easy they consider the technology to use and their experience of using it.

The technologies are applications that are available via smartphone apps, tablets and websites. To access the technologies, users will need to have access to one or more internet enabled devices. Some people may prefer not to use digital technologies. People who are less comfortable or skilled at using digital technologies may prefer an alternative approach to monitoring vision change or additional support and resources may be needed.

8. Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

Macular disease can cause visual impairment, which can be considered a disability under the Equality Act.

The likelihood of developing AMD increases with age. AMD is more common in white ethnic groups compared to people from other ethnic groups.

People with a learning disability may experience potential barriers to care that could lead to the delayed detection and treatment of AMD. These may include:

- not being aware of the importance of eye screening
- difficulties understanding and processing information
- memory of previous poor experiences
- needing to interact with strangers.

Reports suggest that people with a learning disability are 10 times more likely to experience serious sight loss than other people in the general population.

People with pre-existing reduced vision or vision loss in 1 eye, hearing difficulties, cognitive impairment, problems with manual dexterity, a learning disability, people who are unable to read or understand health-related information (including people who cannot read English) or neurodivergent people may need additional support to use digital technologies.

There is a risk of widening inequalities if technologies require personal device ownership, digital literacy or English fluency. Older people with AMD, those with cognitive impairment, and those with severe vision loss are less likely to benefit from the technologies and may require alternative pathways.

Age, disability, race, pregnancy and maternity are protected characteristics under the Equality Act 2010.

9. Guidance type

Technologies to support home monitoring of vision change for people with macular disease are proposed to be assessed for early use. This approach to guidance development is proposed because:

- the assessed technologies have limited or no current use in the NHS
- limited evidence is available for all technologies
- the technologies have the potential to address a high unmet need in the NHS
- the technologies have recent, ongoing or upcoming appropriate regulatory approval for use in the UK

10. Decision problem

The key decision questions for this assessment are:

- Does offering technologies to support monitoring of vision change at home for people with advanced dry AMD (geographic atrophy), have the potential to be a clinically and cost-effective use of NHS resources?
- Are there gaps in the evidence base and what are the key gaps?
- If there are gaps in the evidence base, are the technologies safe to use while further evidence is collected?

Table 1: Decision problem

Proposed type of assessment	Early use
Population	Adults who have advanced dry AMD (geographic atrophy) in one or two eyes that is at risk of progression to neovascular (wet) AMD. Subgroups: • AMD diagnosed before 50 years • People with an additional eye condition that is associated with the risk of developing subretinal neovascularisation

	• Advanced dry AMD (geographic atrophy) at high risk of progression as defined by: – Age-related eye disease study (AREDS) scale – Clinical factors including large drusen, pigmentary change, advanced dry AMD (geographic atrophy) with previous neovascular (wet) AMD in the fellow eye and specific OCT features.
Interventions	• Alleye • DigiVis DVA • Odysight • OKKO • Peek Vision
Comparator	Standard care for monitoring advanced dry AMD (geographic atrophy), including: • Self-monitoring using the Amsler grid or other ambient references that can detect distortion • Self-monitoring without the use of tools • Routine sight test with community optometrist with or without OCT
Setting	The technologies are for use in the home setting under the supervision of community optometry or primary care
Outcomes and costs (may include but are not limited to)	Intermediate outcomes: • Diagnostic accuracy for detecting progression to neovascular (wet) AMD compared to OCT as the reference standard • Time to identify disease progression • Time to first treatment in the affected eye Clinical outcomes: • Percentage of people that maintained functional vision in the affected eye (using validated functional tests such as the ETDRS) • Change in functional test scores including measure of variation in vision fluctuation • Technology related adverse events • Detection of AMD in the fellow eye • Proportion of people with a Certificate of Visual Impairment Patient-reported outcomes: • Health-related quality of life (EQ-5D-3L)

	• Vision-related quality of life (for example, Impact of Vision Impairment) • Measures of psychological impact such as, validated measures of anxiety and depression • User acceptability, views, experience and satisfaction • User adherence to home monitoring Clinician reported outcomes: • Clinician confidence in home monitoring technologies • Clinician acceptability and user experience Costs and resource use: • Cost of the technology including subscription costs • Cost of IT infrastructure required for sharing information between apps and hospital or primary care systems • Resource use/cost of providing training and ongoing support to patients using the technologies • Cost of treatment and management • Cost of training clinicians to use the technologies • Staff time and cost at different specialisms and levels of pay • Number of in person visits for vision testing of the affected eye • Number of in person visits for vision testing of the fellow eye. • Number of urgent referrals
Economic analysis	A health economic model will be developed comprising a cost utility or cost-comparison analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.

11. Other issues for consideration

11.1 Potential implementation issues

- These technologies could potentially result in an increase in referrals to secondary care as a result of chance findings or false positives that require assessment.
- Clinician acceptability and experience of the technology is likely to affect adoption and implementation.
- Clinician concerns about medicolegal issues.
- Increased resource requirements and demand on community eye services. This could include: provision of training and ongoing support for people using the technologies, which could be in person or via a phone line; provision of a phone line for people to contact their eye care professional in case of an alert.
- People living in the most deprived areas may have more difficulty accessing the resources required for these technologies, like smartphones or the internet.
- Some people would benefit from digital technologies being available in a language other than English.

11.2 Variation between eyes

People who have macular disease can have one or two affected eyes. When both eyes are affected, each eye may have a different classification of macular disease. The decision problem outlines the use of home monitoring technologies in people who have advanced dry AMD (geographic atrophy) in one or both eyes. The decision problem does not include people who have received care from secondary care services, such as those being treated for neovascular (wet) AMD in one eye. This is because their fellow eye will often be monitored by hospital eye services.

NICE team

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Appendix: Glossary

Age-related eye disease study (AREDS) severity score	Severity scale used to estimate the risk of progression to advanced AMD. It comes from the Age-related eye disease study and is widely used in ophthalmology to guide prognosis, monitoring and patient counselling.
Amsler grid	A tool used to monitor changes in central vision. The Amsler grid consists of a square grid of horizontal and vertical lines with a central dot. Users look at the central dot, one eye at a time. If any lines appear blurry, wavy or missing, it indicates distortion which could be caused by a problem with the macula.
Distortion	Changes in central vision that can cause objects to appear blurry, wavy or misshapen.
Early Treatment Diabetic Retinopathy Study (ETDRS)	A standardised visual acuity test widely used in ophthalmology. It consists of rows of letters of various sizes, arranged in descending order of size. ETDRS uses a letter-by-letter scoring system. ETDRS is commonly used in clinical trials and research. ETDRS requires specific lighting conditions.
Fundus fluorescein angiography	A diagnostic imaging procedure used to examine blood circulation in the retina and choroid, which are parts of the back of the eye (fundus). A fluorescent dye is injected into a vein and a fundus

	camera is used to capture images as the dye circulates through the fundus.
Snellen chart	A visual acuity test widely used in ophthalmology. It consists of rows of letters that decrease size with each row, allowing the examiner to determine the smallest line of letters the person can read accurately. Snellen charts can be used in various settings without the need for specific lighting conditions.
Optical Coherence Tomography (OCT)	A non-invasive imaging technique that uses light waves to produce high-resolution images of the retina and optic nerve.
Visual acuity	A measure of sharpness or clarity of vision measured at a certain distance.

Early-use assessment

HTE10073 Digital technologies to support monitoring of vision change at home for people with age-related macular degeneration

Assessment report overview

This overview summarises key information from the assessment and sets out points for discussion in the committee meeting. It should be read together with the final scope and the external assessment report (EAR). List of abbreviations used in this overview is in appendix A.

1. The technology

The technologies in the scope are digital technologies that measure vision change that are suitable for use at home by people with age-related macular degeneration (AMD). There are several potential use cases for the technologies. This assessment is focused on using the technologies in people with advanced dry AMD (geographic atrophy) to monitor vision changes that indicate progression to the neovascular (wet) AMD. The technologies are being assessed as an adjunct to usual care, not as a replacement for any aspect of usual care.

Five digital technologies for monitoring vision change were included in the scope and EAR: Alleye (Oculocare Medical Inc), Digivis DVA (Cambridge Medical Innovation Ltd), OdySight (Tilak Healthcare), OKKO for AMD (OKKO Health) and Peek Acuity Pro (Peek Vision). The technologies are accessible via an app or web page. The technologies measure hyperacuity, visual acuity, distortion, or a combination of these. Most of the technologies include functionality to share the results with clinicians and /or patients, with the exception of Peek Acuity Pro.

Two of the companies, Peek Vision and OKKO Health, did not provide the information requested by the NICE team. Therefore all information for OKKO for AMD and Peek Acuity Pro was sourced from publicly available sources. Based on the information available it was not possible to conclude whether OKKO for AMD and Peek Acuity Pro are in scope for this assessment. OKKO Health advised NICE that OKKO for AMD is marketed for people with neovascular (wet) AMD. Peek Acuity Pro was developed for use in low and middle income countries as a screening tool. Table 1 presents a summary of the technologies included in the assessment.

Table 1: Summary of included technologies

Technology (company)	Regulatory status	Population	Description of technology and use cases
Alleye (Oculocare Medical Inc)	Class I CE mark	People with retinal disease	**Test type**: Hyperacuity test **Device required**: Smartphone app **Time taken**: 2 to 3 minutes per eye, several times per week **Result reporting**: Results are submitted to a clinical dashboard, monitored by hospital teams, with alarms to prompt review **Indication for use**: Macular diseases such as dry AMD, wet AMD, DMO, and RVO
DigiVis DVA (Cambridge Medical Innovation Ltd.)	Class I CE mark	Any eye condition requiring assessment of distance visual acuity	**Test type**: Distance visual acuity replicating ETDRS chart testing **Device required**: Web based test, requiring 2 internet connected devices **Time taken**: 7.8 minutes **Result reporting**: Reported to clinicians and sent to patients by email or SMS. **Indication for use**: To allow users of ophthalmology services to perform a test of DVA without assistance from a healthcare professional

OdySight (Tilak Healthcare)	Class I CE mark	Adults with chronic macular diseases	**Test type**: Visual acuity, and Amsler grid **Device required**: Smartphone app **Time taken**: Less than 1 minute, twice a week **Result reporting**: Results and alerts reported to users and clinicians **Indication for use**: Adults with chronic macular diseases complicated by choroidal neovascularisation or macular oedema, requiring treatment with intravitreal injections or laser therapy, or at risk of developing choroidal neovascularisation or macular oedema
OKKO for AMD (OKKO Health)	Class I CE mark	People with age-related macular degeneration	**Test type**: Puzzle games to detect changes in visual acuity or distortion **Device required**: Smartphone app **Time taken**: 3 times a week **Result reporting**: The results are shared with the user and clinicians **Indication for use:** the early detection of visual deterioration between appointments for patients with age-related macular degeneration
Peek Acuity Pro (Peek Vision)	Class I CE mark	Adults and children aged 6 years and above	**Test type**: Distance visual acuity **Device required**: Android smart phone app. An additional person is required **Time taken**: Less than 1 minute per eye **Result reporting**: Technology does not record or share any results **Indication for use**: To provide vision testing to help identify people with vision loss and ensure they receive appropriate treatment

Please see section 2 of the EAR for further information about the technologies.

2. The condition

Macular disease refers to conditions that affect the macula, an area of the retina at the back of the eye that is responsible for central vision, fine details and most of colour vision. When a person has macular disease, the macula becomes damaged, causing the vision to become blurred or distorted. Macular disease is the biggest cause of sight loss in the UK and affects nearly 1.5 million people. Several eye conditions can cause macular disease. The most common cause of macular disease is age-related macular degeneration (AMD). Risk factors for age-related macular degeneration are detailed in the scope.

The Royal College of Ophthalmologists uses the following classification for AMD:

- Early AMD or age-related maculopathy
- Intermediate AMD
- Neovascular AMD or wet AMD
- Advanced dry AMD or geographic atrophy
- Advanced wet AMD/disciform scar.

The Royal College of Ophthalmologists classification does not represent a linear progression between each class of AMD. Advanced dry AMD (geographic atrophy) does not necessarily develop before neovascular (wet) AMD. Either pathway may develop independently, and some patients progress directly from intermediate AMD to neovascular (wet) AMD without passing through advanced dry AMD (geographic atrophy).

The terms wet AMD and neovascular AMD are used interchangeably, and are referred to as “neovascular (wet) AMD” throughout the EAR and overview. Similarly, the terms advanced dry AMD and geographic atrophy are used interchangeably, and are referred to as “advanced dry AMD (geographic atrophy)” throughout the EAR and overview. A range of terminology is used in

the published literature to describe the different forms and stages of AMD. These are summarised in table 4, in section 3.1 of the EAR.

Symptoms of the condition include:

- blurry central vision
- straight lines appearing distorted
- difficulty recognising faces
- difficulty seeing in low light
- dark or empty spots in the centre of vision
- difficulty reading, driving or doing close up work.

For more detailed information about the condition please see the scope and section 3.1 of the EAR.

3. Current practice

In the NHS, the referral, diagnosis and treatment of AMD follow the:

- NICE Age-related macular degeneration guideline (NG82)
- Getting it right first time pathway for age-related macular degeneration
- The Royal College of Ophthalmologists commissioning guidance – Age related macular degeneration services

Please see the scope for a description of diagnosis, referral, treatment and monitoring.

People with advanced dry AMD (geographic atrophy) are at risk of developing neovascular (wet) AMD. There is currently no treatment for advanced dry AMD (geographic atrophy) but there is treatment for neovascular (wet) AMD. It is important for detection of neovascular (wet) AMD to happen quicky, as treatment should be offered as soon as possible to reduce the risk of permanent vision loss.

The Royal College of Ophthalmologists commissioning guidance for age-related macular degeneration services states that optical coherence tomography (OCT) is the most sensitive monitoring tool for detecting changes

in AMD. Therefore, OCT should be used to monitor people at high risk of new neovascular (wet) AMD. However, in practice there is variation in whether people with advanced dry AMD (geographic atrophy) can access OCT on the NHS. Some people may be able to access OCT through their optometrist as part of routine sight tests.

Please see figure 1, in section 3.2 of the EAR for a diagram of the clinical pathway.

4. Unmet need

After diagnosis, people with advanced dry AMD (geographic atrophy) 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 eye care professional (usually an optometrist) if they notice changes in vision. The NICE guideline does not recommend any specific tools for self-monitoring of advanced dry AMD (geographic atrophy) at home. Many people are advised to use the Amsler grid, which is freely available but has some limitations. The Amsler grid is not standardised, has poor reproducibility, and only measures distortion. The EDNA study found that the Amsler grid has low sensitivity and moderate specificity for detecting onset of neovascular (wet) AMD.

Given that people with advanced dry AMD (geographic atrophy) do not have their AMD monitored by hospital eye services, the limitations of the Amsler grid and the risk associated with not detecting neovascular (wet) AMD in a timely manner, there is a need for tools that detect vision changes and identify when a person needs to have their vision clinically assessed for onset of neovascular (wet) AMD. Technologies that support self-monitoring of vision could help address the unmet need by detecting changes in vision and sharing information with eye care professionals to prompt an urgent referral for assessment if required, leading to timely diagnosis and treatment and improved patient outcomes. The technologies could also help people with advanced dry AMD (geographic atrophy) to feel empowered by helping them take an active role in managing their condition.

Following scope publication and after the assessment had started, an expert advised that people with intermediate AMD could also benefit from the technologies. The expert advised that progression to neovascular (wet) AMD occurs at a higher rate among people with intermediate AMD than people with advanced dry AMD (geographic atrophy).

Please refer to the scope for more information about the unmet needs for people with AMD

5. Clinical evidence

The external assessment group (EAG) completed a targeted literature search of bibliographic and clinical trial databases to identify relevant clinical evidence. The EAG also identified clinical evidence from the company websites and company submissions to NICE from Oculocare, OdySight and Tilak. The search and selection methods are described in sections 4.1 of the EAR. The search strategies and PRISMA flow diagram are in appendices A and B of the EAR. The excluded studies and reasons for exclusion are detailed in appendix C.

5.1 Overview of key studies

The clinical studies were screened and 4 studies relevant to the assessment were identified and included in the assessment. Three studies reported evidence for Alleye: Dave et al. (2024), Schmid et al. (2019), and Teo et al. (2021) and 1 study reported evidence for OdySight: Bonjean et al. (2025). Cambridge Medical Innovation provided NICE with information on evidence for Digivis DVA. The studies for Digivis DVA were excluded from the assessment because the populations in the studies were not applicable to the protocol for this assessment. No relevant studies were identified for OKKO for AMD and Peek Acuity Pro. Table 2 presents an overview of the included clinical studies.

Table 2: Overview of included clinical studies

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention and comparator	Outcome measures and follow up	Quality and EAG comments
Alleye (Oculocare Medical Inc)	Schmid et al. (2019) Study design: Diagnostic accuracy study Location: Switzerland	People with dry AMD, wet AMD, and healthy controls. (Dry AMD is not defined but likely refers to early, intermediate, and advanced dry AMD) Recruited from outpatient ophthalmology Sample size: 63 Wet AMD eyes 26 Dry AMD eyes 34 Young healthy eyes 19 Age-matched healthy eyes 142 Total	Intervention: Alleye, people performed 4 measurements during 1 session. A regression model was built for this study to determine the outcome of these measurements. Comparator: Comparison was made between dry AMD, wet AMD, and healthy controls. The healthy controls consisted of 2 groups: young healthy eyes without any disease, and age-matched healthy eyes with a monocular condition in 1 eye, and the other eye healthy	Outcomes: Accuracy of Alleye to detect if a person has dry AMD, wet AMD, or is a healthy control Follow up: No follow up	Moderate quality This study provides evidence of the ability of Alleye, combined with a regression model, to detect the differences between dry and wet AMD, and healthy controls. It is not based in the UK, and does not use Alleye in the way it would be used in normal practice, and so there are questions about its generalisability to the NHS.
Alleye (Oculocare Medical Inc)	Dave et al. (2024) Study design: Qualitative study	People with glaucoma or AMD, recruited through a university	Participants: People with glaucoma or AMD, recruited through a university database of	Outcomes: Acceptability and usability of the	Good quality This study offers useful qualitative insights into the use of

	using focus groups and questionnaires Location: UK	database of previous research volunteers Sample size glaucoma n=8 AMD n=7	previous research volunteers Sample size Glaucoma (n=8) AMD (n=7)	apps through focus groups A quantitative system usability scale and acceptability questionnaire Follow up: No follow up	home-monitoring apps for glaucoma and AMD. However, the findings are not specific to AMD, and people with AMD represent only a minority proportion of the study sample. In addition, the study evaluates home-monitoring apps in general rather than examining Alleye specifically. It does not provide any evidence for the efficacy of Alleye.
Alleye (Oculocare Medical Inc)	Teo et al. (2021) Study design: Observational retrospective study Location: Singapore	People with retinal disease whose outpatient appointments were deferred due to the COVID lockdown Non-neovascular AMD made up 138 (12%) of the 732 sample size	Intervention: Alleye for vision self-monitoring Comparator: no comparator	Outcomes: Adherence and willingness to sign up to using the Alleye Follow up: no follow up	Good quality This study provides some evidence for people's willingness to use the Alleye app. However, the sample is not specific to AMD, with AMD only making up a small minority of the total sample. The aims and outcomes focus on the ability to introduce a self-

					monitoring programme in an ophthalmology department, rather than being specific to the use of Alleye for AMD. It does not provide any evidence for the clinical efficacy of Alleye in this population.
OdySight (Tilak Healthcare)	Bonjean et al. (2025) Study design: Observational retrospective study Location: France	People with chronic maculopathy (intermediate and late AMD, DMO, RVO, and myopic neovascularisation). People with AMD had either non-decompensated maculopathy, or eyes undergoing IVI treatment Sample size: 91 people, 145 eyes	Intervention: OdySight for 12 months Comparator: OCT used as a reference standard to confirm exudative AMD following alert from OdySight	Outcomes: Diagnostic performance of OdySight including sensitivity, specificity, PPV and NPV Follow up: 12 months	Moderate quality This study provides evidence of the diagnostic performance of OdySight for detecting recurrence of wet AMD and requirement of treatment. However, due to a lack of true positives being detected, no diagnostic performance could be calculated for the progression of dry AMD to wet AMD.

Abbreviations: AMD: age-related macular degeneration; DMO: diabetic macular oedema; NPV: negative predictive value; PPV: positive predictive value; RVO: retinal vein occlusion

Applicability to scope

The EAG assessed the following aspects of the included studies for applicability to the scope:

- study design and location
- participants and setting
- intervention and comparator
- outcome measures.

The EAG found that the aspects of the studies met the scope partially or fully. For further details see table 6 in section 4.2 of the EAR.

Quality appraisal of studies

The EAG did not use a formal critical appraisal checklist to assess quality of the evidence. This is in accordance with the methods described in the NICE HealthTech programme manual. The EAG have outlined the key risk of bias for each study in section 5.1 of the EAR.

5.2 Results

When considering the decision problem for this assessment, overall, across all 5 technologies there is limited evidence to support the use of digital technologies for the monitoring vision change in people with advanced dry AMD (geographic atrophy), to detect development of neovascular (wet) AMD. Table 3 presents a summary of the results from the evidence for Alleye and OdySight. There was no evidence identified that was directly relevant to the scope, for DigiVis DVA, OKKO for AMD, or Peek Acuity. Clinical evidence is discussed in detail in section 5.2 of the EAR.

Table 3: Summary of results from clinical studies

Technology	Study name	Outcomes(s) and Summary of results
Alleye	Schmid et al. (2019)	Diagnostic performance using area under the receiver operating characteristic (AUROC) (95% CI): • Discrimination between dry and wet AMD: 0.660 (0.520–0.799)
	Dave et al. (2024)	Acceptability and usability of technologies, that includes Alleye, and home monitoring: • Home monitoring viewed positively • Recognised benefits of earlier detection of progression, and more involvement in managing condition • Home monitoring could provide reassurance between clinic visits • Concerns raised about interpretation of results, and possible reduction in face to face contact with clinicians • Practical barriers such as digital literacy and confidence using smartphones identified
	Teo et al. (2021)	User adherence to home monitoring: • 42% (n=138) of people with non-neovascular AMD signed up to use Alleye • 59% (n=80) of people with non-neovascular AMD were compliant with using Alleye (patients who performed the recommended number of tests, at least 2 per week, until the time of analysis)
OdySight	Bonjean et al. (2025)	Diagnostic performance of OdySight in secondary prevention of exudative AMD (people already previously treated for exudative AMD): • Sensitivity: 14.3% • Specificity: 94.3% • Positive predictive value: 7.7% • Negative Predictive Value: 97.1% • Retention of people using OdySight: • 55.8% of people across all diseases at the end of the 12 months

Abbreviations: AMD: age-related macular degeneration; AUROC: Area under the receiver operating characteristic curve

5.3 Out of scope clinical evidence

In view of the limited evidence relevant to the decision problem, the EAG reviewed some evidence for the technologies which is out of scope because the populations do not match the scope.

The Faes et al 2022 study assessed usability and long-term adherence to Alleye among people with neovascular (wet) AMD over an 18-month period.

- by the end of follow-up, 73.6% (n=53) of people continued using the app
- usability ratings were high; 83.3% (n=60) of people reported being very satisfied, and scores on a validated usability questionnaire were similarly positive.
- findings suggest that people with macular disease who are willing to engage in home monitoring programmes generally find Alleye acceptable and easy to use.

The Guigou et al. 2021 study was a real-world study that reported on experiences of 60 people with macular pathologies using OdySight over a 12-month period. 52% of participants had neovascular (wet) AMD.

- adherence to using the app was 51% at 3 months and declined to 12% at 12 months
- participants who showed greater interest and engagement in their treatment were more active and consistent users
- overall user experience of using the app was positive.

Generalisability of the results to people with advanced dry AMD (geographic atrophy) is uncertain because:

- people with dry AMD tend to monitor their vision less frequently than people with neovascular (wet) AMD, and may perceive their condition as less urgent, which could limit their engagement with home monitoring technology.

- unlike people with wet AMD, people with advanced dry AMD (geographic atrophy) currently have no treatment options, which may further reduce their motivation to use home monitoring tools.

Out of scope evidence is described in section 5.8 of the EAR.

5.4 Ongoing studies

The EAG identified 1 ongoing study which was relevant to the decision problem. The study is for OKKO for AMD. It includes people with both wet and dry AMD and includes outcomes listed in the scope for this assessment. However, lack of details about the study means it is uncertain if this study could fill any evidence gaps for OKKO for AMD. Further information is in section 8.1 of the EAR.

6. Health economic evidence

The EAG did a review to identify existing economic evidence using the same search strategy as for the clinical evidence search. This is described in section 4.1 of the EAR. The EAG did not identify any economic studies related to the technologies in this assessment. In addition, economic studies provided by companies were considered if they were relevant to the scope. Three of the companies submitted unpublished economic or costing evidence. One of these, a budget impact analysis for Alleye (Oculocare) was relevant to the scope. These are described in section 6.1 of the EAR.

The EAG identified key economic, implementation and purchasing factors. These are described in table 11 in section 6.4 of the EAR.

The EAG did a review to identify economic models for age-related macular degeneration. The aim of this search was to identify models that could be used directly or could be used to inform new economic modelling by the EAG. They found 1 NICE clinical guideline, 5 NICE technology appraisals and 5 economic evaluations that reported an economic model. A summary of these 5 models is in section 6.3 of the EAR. None of the identified models were suitable to be used directly for this assessment.

6.1 Health economic model

Model structure

The EAG created a simplified Markov cohort model that is not specific to any technology, due to the limited evidence that was available and challenges with modelling the diagnostic process for AMD, which are outlined below. The model is based on a generic technology that was assumed to have better uptake, adherence, specificity and sensitivity than an Amsler grid. The model used an 8-year time horizon with a cycle length of 1 month. An NHS and personal social services perspective and discounting at 3.5% was used in line with the NICE reference case. The model considered events only up to the point of diagnosis. Figure 1 shows a simplified Markov model diagram.

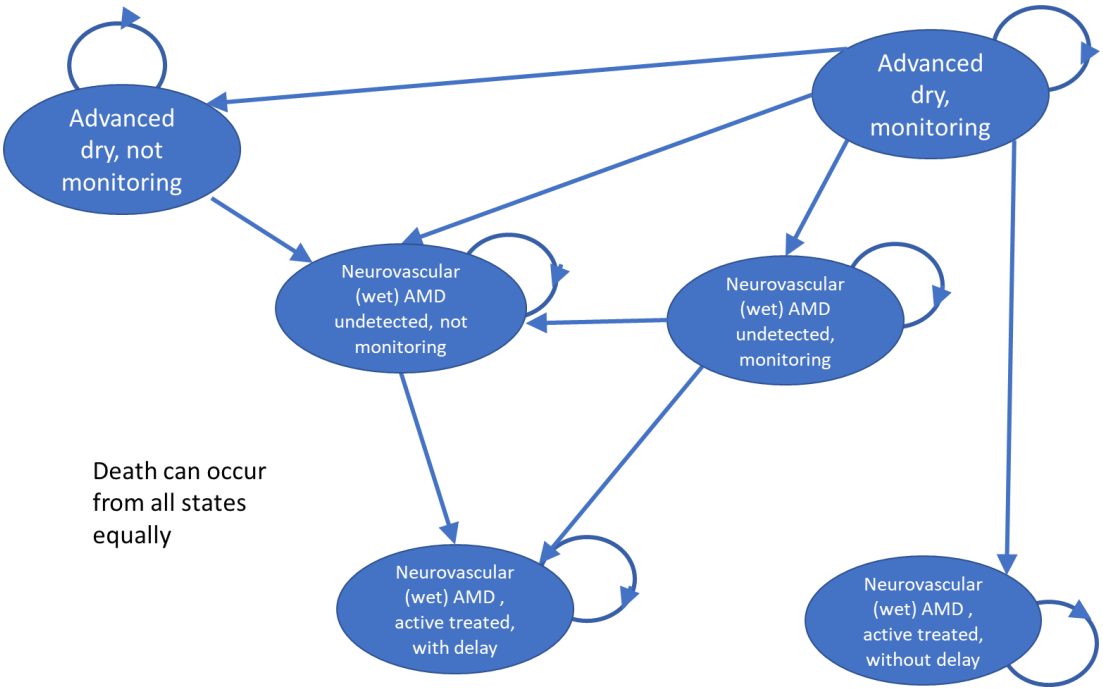

Figure 1: Simplified Markov model diagram

The EAG described the challenges with modelling the diagnostic process for AMD:

- The varying risk factors for progression to neovascular (wet) AMD.
- The possibility of progression to neovascular (wet) AMD in either eye, with different (but not independent) risk factors.

There are additional challenges that are specific, or are likely to have more impact, for advanced dry AMD (geographic atrophy) including:

- Deterioration of visual acuity can occur in both the advanced dry AMD (geographic atrophy) and neovascular (wet) AMD states over time.
- Use of diagnostic tests may be limited by severe deterioration of visual acuity.
- The impact of treating neovascular (wet) AMD will in part be determined by the persons visual acuity at treatment initiation.
- Utilities are determined by visual acuity, which changes over time, and with treatment for neovascular (wet) AMD.

These challenges are typically dealt with by using more complex model structures such as Markov microsimulation or discrete event simulation, however the EAG considered that this was not proportionate to an early use assessment with the current sparsity of clinical evidence.

Model assumptions

Key model assumptions include:

- Modelling is for one eye only, however for some people both eyes may be eligible. Introducing monitoring of both eyes may increase both the number of early detections and the number of false positives.
- Monitoring is carried out 2-3 times per week, however transition to a new state only occurs once per month.
- People either monitor with the selected intervention or do not monitor at all.
- Monitoring costs are only applied while people are actively monitoring.
- Probability of progression from advanced dry AMD (geographic atrophy) to neovascular (wet) AMD is constant over time.
- Probability of stopping monitoring is constant throughout the model duration.
- People who cease monitoring do not restart.
- Effectiveness of both the intervention and standard care are considered constant over time.

- Technology costs are based on assumptions about the size of the clinic, number of staff and duration of patient use.

Further details of the economic modelling are in section 6.4 of the EAR.

Population

The model population was people with advanced dry AMD (geographic atrophy). The model assumes an entry age of 80 years old. The model was based on monitoring one eye. This approach was used because to base it on two eyes would introduce complexity, as the risk of developing neovascular (wet) AMD changes when one eye is already affected.

Comparator

The comparator in the model was standard care for self-monitoring vision change in people with advanced dry AMD (geographic atrophy), including the use of the Amsler grid.

Model inputs

Clinical parameters

Table 4 summarises clinical parameters in the model. Selected key clinical parameters are described below. Full details of all clinical parameters are in section 6.4 of the EAR.

Table 4: Main clinical parameters in the model

Variable	Value	Range for DSA	Source	EAG commentary on availability, quality, reliability and relevance of the source
Monthly probability of developing neovascular (wet) AMD, from advanced dry AMD (geographic atrophy)	0.006	- 50%, 0.012	Chakravarthy 2018, Ciulla 2023	From an observed rate of 0.074 over a 12-month duration. High value from Ciulla 2023, 25% in 24.7 months
Monthly probability neovascular (wet) AMD detected without monitoring	0.3	0,1	Clinical experts	Ranges between 6 weeks and 6 months depending on multiple factors

Variable	Value	Range for DSA	Source	EAG commentary on availability, quality, reliability and relevance of the source
Probability of a referral from primary to secondary care for a non-progressed patient	0.602	+/- 50%	Fulcher 2025	Retrospective analysis showed 39.8% of referrals from primary care resulted in positive diagnosis
Parameters to calculate costs of one off set up during implementation (very small impact on device costs)				
Incidence of advanced dry AMD (geographic atrophy) in UK	44,000	n/a	RCO 2024	RCO Commissioning Guidance Age Related Macular Degeneration Services: Evidence Base
Number of providers	109	n/a	Atlas of Variation 2021	Vision Atlas states: Core ophthalmology services are provided in most NHS Trusts with specialist services in more than 100 locations providing care on a 'Hub and spoke' model with local hospitals. This is for England. 9 health boards in Wales also added
For Interventions	The EAG found no evidence in the population described in the scope, therefore inputs have been assumed and should be treated with caution.			
Initial uptake	0.80	0.42,1		Assumption, with Teo 2021 for lower bound.
Adherence	0.983	- 50%,1	Faes 2025	76% of people were still monitoring at last follow up in 18-month study
Sensitivity	0.8	- 50%,1	Assumption	Informed by Hogg 2024
Specificity	0.9	- 50%,1	Assumption	Informed by Faes 2022 (93.8%) and Bonjean (94.3%)
For standard care (Amsler grid)				
Initial uptake	0.5	- 50%,1	Expert opinion	Between 1/2 to 1/3 will start, and adherence will decrease over time
Adherence	0.8	- 50%,1		
Sensitivity	0.71	- 50%,1	Bjerager 2023	Bjerager et al. (2023) A systematic review and meta-analysis of the diagnostic accuracy of the Amsler Grid
Specificity	0.63	- 50%,1		

DSA: deterministic sensitivity analysis

The key clinical parameters in the model are:

- Likelihood of progressing from advanced dry AMD (geographic atrophy) to neovascular (wet) AMD
- Initial uptake and adherence to monitoring
- Diagnostic accuracy of monitoring
- Delay to treatment that would occur in the absence of monitoring.

The EAG did not identify any evidence for the population for this assessment for initial uptake and adherence, sensitivity and specificity. Although there was evidence available for some of the technologies in alternative populations, the EAG considered that this evidence was not sufficiently applicable as the basis of modelling. Values for these inputs have been assumed and should be treated with caution.

Probability of developing neovascular (wet) AMD among people with advanced dry AMD (geographic atrophy)

The EAG identified 2 sources of evidence to inform the probability of developing neovascular (wet) AMD input. Ciulia et al. (2023) is a conference abstract reporting a large retrospective study of 18,712 eyes in the US. They reported 25% of eyes being diagnosed with geographic atrophy being diagnosed with neovascular (wet) AMD at 24.7 months. Chakravarthy et al. (2018) reported a study of 1,901 patients in the UK with geographic atrophy in both eyes, and 7.4% developing neovascular (wet) AMD in a 1-year period. Consultation with experts led the EAG to select the rate of 7.4% in 1 year for the model base case. This equates to a monthly probability of developing neovascular (wet) AMD of 0.006.

Probability of developing neovascular (wet) AMD among people with intermediate AMD

Experts advised that intermediate AMD may be an alternative population for home monitoring and therefore the EAG investigated this in the scenario analysis. The EAG found 2 sources to inform the rate of progression among people with intermediate AMD. The NICE clinical knowledge summary for AMD states that for people with intermediate AMD there is an 18% rate of

progression to advanced AMD at 5 years (advanced AMD may include both dry and wet AMD). Chakravarthy et al. (2020) analysed retrospective records for 40,543 people in the UK with diagnoses of early or intermediate AMD. They found rates of developing choroidal neovascularisation (CNV) between 3.2 and 15.2 per 100 patient years, depending on the condition of the study eye. The EAG have used the highest rate (for those with CNV in the fellow eye) for the purposes of an exploratory scenario analysis.

Diagnostic accuracy of the technology

Due the sparsity of the evidence and other issues described in the EAR, the EAG used what should be considered a nominal value for the overall monthly sensitivity and specificity, and used sensitivity analysis to investigate the impact of variation.

Sensitivity of the technology in the base case was assumed to be 0.8, this was informed by data from Hogg 2024. Specificity of the technology in the base case was assumed to be 0.9, this was informed by Faes 2022 and Bonjean 2025. For further details see section 6.4 of the EAR.

Diagnostic accuracy of the Amsler grid

Sensitivity of the Amsler grid in the base case was assumed to be 0.71 and sensitivity was assumed to be 0.63. These values were informed by a systematic review and meta-analysis of diagnostic accuracy of the Amsler grid by Bjerager et al, 2023. For further details see section 6.4 of the EAR.

Probability of starting using the technology

Probability of starting using the technology was assumed to be 0.80 in the base case. There was some evidence for initial uptake of the technology. Teo et al 2021 reported 42% for implementation of Alleye during COVID-19. Bonjean et al 2025 reported that 48% of those offered a prescription downloaded OdySight and used it more than twice.

Probability of adhering to using the technology

No evidence was identified for adherence to use of Amsler grids in usual practice. One expert suggested between one half and one third of people

would regularly use Amsler grids, and that this would decline over time. There is some evidence for adherence to digital interventions in people with neovascular (wet) AMD or with a mixture of eye diseases, but none of the evidence is specific to advanced dry AMD (geographic atrophy) or intermediate AMD. Experts suggested that there may be higher motivation for people with neovascular (wet) AMD to self-monitor because there is treatment available.

Mortality

It is assumed that the technology does not influence survival. The probability of death occurring is equal for all states in the model.

Technology costs

The EAG standardised the technology and implementation costs for each technology into implementation costs and monthly patient costs. These are summarised in table 15 in the EAR. For the technologies, monthly costs are based on either a cost per test, per month or per year. Additional parameters included assumptions around the number of patients treated, staff to be trained and time that monitoring would be used for, as these inform how the implementation costs are incorporated into monthly monitoring costs per patient. As the model is exploratory and not linked to a single technology, a mean of the estimated costs for included technologies has been used, alongside sensitivity analysis. Technology cost per month per patient used in the model is described in Table 5.

Resource use

Other costs included are the costs of a primary care eye test (including OCT in primary care for a proportion) and the costs of a review in secondary care. A primary care visit is included for all patients who have an alert (false positive or true positive). Secondary care referral costs are included for all patients who have a true positive and for a small proportion of those with a true negative where OCT results may not have been decisive. Resource use beyond the point of diagnosis is not captured. Resource use is described in section 6.4 of the EAR.

False positives will incur costs and resource use which may be testing in a community setting with or without OCT, or a secondary care triage system. Either of these will result in some referrals to secondary care that do not result in a positive diagnosis. The impact of this depends on uptake and adherence of the monitoring, the specificity, and the demographic in which it is used, as well as the pathway in which monitoring is adopted. Depending on how the pathway is set up, there is potential that some resource use currently occurring in the community could be shifted to secondary care for triaging and testing people who receive alerts.

Table 5 Key cost parameters and resource use in the EAG model base case

Parameter	Value	Range for DSA	Source	EAG commentary on availability, quality, reliability and relevance of the source/s
Technology cost per month per patient	£37.06	+/- 50%	Company RFEs	Mean of all submitted information including set up and training.
Primary care appointment	£24.13	+/- 50%	UK Government 2025	General ophthalmic services fees from 1 April 2025. Cost to primary care optometrist for sight test
Addition of OCT	£23.38	£10, £50	Banister 2022	Bottom up costing for marginal cost of OCT in secondary care (£19.45 inflated from 2019). £10-£50 if paid privately in addition to eye test
Proportion of primary care appointments with funded OCT	0.5	0,1	Assumption based on experts, Fulcher 2025 and Sanders 2024	Experts indicated that some patients would receive OCT, and some would self fund. Studies reported between 9 and 100%
Cost of testing in primary care	£35.82	Calculated from rows above, with 50% of visits receiving OCT		
Secondary care appointment	£181	+/- 20%	NHS Cost Collection 202-45	BZ87A Minor Vitreous Retinal Procedures, 19 years and over, 2024-5 NHS cost collection

Health-related quality of life

Health state utilities are not included in the model due to the lack of clinical effectiveness evidence and the complexities described in previous sections. The EAG have described the approaches used in existing models in the EAR report, and the applicability for future modelling. See section 6.4 of the EAR.

6.2 Model results

Base case

The base case results are presented in the form of a cost-consequence analysis and a cost per additional early diagnosis. The base case results show the costs and consequences up to the point of diagnosis only.

Compared with use of a printed Amsler grid, there is an additional £1,145 per person when monitoring with the digital technology. This is due to the cost of monitoring as well as increased costs of false positives associated with the longer continuation of home monitoring compared to using the Amsler grid.

The EAG base case results in the identification of an additional 12.41 people with neovascular (wet) AMD per 100 people modelled compared with using the Amsler grid. Using the generic technology would cost £9,228 per additional early diagnosis.

The model should be seen as a means to explore the potential of any technologies that improve adherence and accuracy to achieve earlier diagnosis of neovascular (wet) AMD when used in a population with advanced dry AMD (geographic atrophy), and to explore the costs of monitoring.

When interpreting these results it is important to note that earlier diagnosis is expected to have a positive impact on outcomes and subsequent quality of life, however the extent of this is not possible to determine with the current evidence.

The base case results are in tables 16, 17 and 18 in section 6.5 of the EAR.

Sensitivity analysis

Deterministic sensitivity analysis was used to determine the key parameters that influence model outcomes.

In one way sensitivity analysis, the cost of using the technology compared with standard care ranged from -£78 to £2,752. The parameters that had the biggest influence on cost were:

- adherence
- specificity of the intervention
- cost of home monitoring
- probability of starting the intervention
- probability of neovascular (wet) AMD.

The additional number of people diagnosed without delay ranged from -0.79 to 19.43 per 100 people, compared with standard care. The parameters that had the biggest influence on number of people diagnosed without delay were:

- adherence
- probability of developing neovascular (wet) AMD
- sensitivity of the intervention
- probability of starting the intervention.

When cost and additional number of people diagnosed are combined, the additional cost per early detection ranges from £5,109 to £22,184 per person diagnosed early compared with standard care. The parameters that had the biggest influence on cost per early detection were:

- probability of developing neovascular (wet) AMD
- sensitivity and specificity of the intervention
- costs of monitoring.

Probabilistic sensitivity analysis was not completed as the model was exploratory and deterministic sensitivity analysis allowed investigation of key drivers and different scenarios.

Sensitivity analysis results are in section 6.5 of the EAR.

Scenario analysis

Six scenarios were used to investigate the impact of uncertainties not fully captured in the base case and one way sensitivity analysis. The scenarios are described in Table 6. Table 7 summarises the key scenario results.

Table 6: Description of scenarios

Scenario number	Scenario name	Description
1	Best case	100% uptake and adherence, perfect accuracy for intervention (standard care unchanged). Lowest technology cost.
2	Worst case	100% uptake and adherence, but accuracy equivalent to Amsler grid. Highest technology cost.
3a	Secondary care dashboard	Cost of primary care test replaced by 10 minute telephone consultation with ophthalmologist. Accuracy is assumed to be the same as testing in primary care.
3b	Secondary care dashboard	Cost of primary care test replaced by non-face to face follow up consultation, not consultant led. Accuracy is assumed to be the same as testing in primary care.
4	Two eyes	Two eyes entered into the initial cohort and progress through model independently. Cost of monitoring is halved (shared between 2 eyes), but probability of false positive is applied to each eye. Eyes are considered independently
5	Intermediate AMD population	Probability of progression to neovascular (wet) AMD is based on intermediate AMD population
6	3 year time horizon	Reduce time from 8 to 3 years.

Table 7: Key scenario results

	Incremental cost	Incremental number of early diagnoses	Incremental false positives	Incremental cost per early diagnosis
Base case	**£1,145**	**12.41**	**14.80**	**£9,228**
1) Best case	£863	36.69	-7.41	**£2,352**
2) Worst case	£5,941	25.80	176.28	**£23,025**
3a)Secondary care dashboard	£1,115	12.41	14.80	**£8,989**
3b)Secondary care dashboard	£1,255	12.41	14.80	**£10,112**
4) Two eyes	£1,377	24.81	29.60	**£5,549**
5) Intermediate AMD population	£941	21.68	11.17	**£4,342**
6) 3 year time horizon	£823	8.60	8.62	**£9,572**

Experts advised that the intermediate population may be an alternative population for home monitoring and therefore scenario 5 is key for the committee to consider.

See section 6.5 of the EAR for a summary of the results of the scenario analyses.

7. Equality considerations

The final scope and the scoping equality impact assessment describe equality considerations for this assessment. No evidence was found for the subgroups in the scope. The EAG did not identify additional equality issues.

8. Evidence gaps

There was no evidence or limited evidence of relevance to the scope for the following outcomes:

- diagnostic performance
- detection of disease progression

- time to first treatment in the affected eye
- visual and clinical outcomes
- safety and adverse events
- patient usability and acceptability
- clinician experience and system implementation
- costs and healthcare resource use
- patient centred outcomes.

The full evidence gap analysis is presented in section 8.2 and key areas for evidence generation in section 8.3 of the external assessment report (EAR).

9. Key points, limitations and considerations

9.1 Clinical evidence

Key points

- There is uncertainty about who could benefit most from these technologies and where they are best placed in the care pathway.
- The technologies are being considered as an adjunct to standard care and not as a replacement for any aspect of standard care.
- The EAG considers that there is very limited evidence to support the use of Alleye and OdySight for detecting the progression of advanced dry AMD (geographic atrophy) to neovascular (wet) AMD.
- Where these technologies have been implemented, they have typically been part of a specialist clinic, with the team being able to monitor results and respond to alerts. In the current pathway, people with advanced dry AMD (geographic atrophy) are not monitored through hospital eye services, but would attend their usual eye care professional if they noted a change in their vision.
- People with advanced dry AMD (geographic atrophy) may experience loss of visual acuity over time that impedes their use of the technologies.
- The population in the scope is people with advanced dry AMD (geographic atrophy). Following scope publication and after the searches had been completed, two experts advised the EAG that the intermediate AMD

population may benefit more from these technologies than people with advanced dry AMD/geographic atrophy. The EAG's search strategy and inclusion criteria included any evidence reporting outcomes in people with dry AMD; hence it is likely that any evidence for intermediate AMD has been captured and reported in their clinical assessment.

- Key evidence gaps include diagnostic performance, detection of development of neovascular (wet) AMD, impact on time to treatment, impact on functional vision and health-related quality of life, and real-world evidence of their use in the NHS for this population.

Limitations

- The clinical evidence is very limited. There is no evidence that is applicable to the scope for 3 of the technologies: Digivis DVA, OKKO for AMD and Peek Acuity.

Considerations for committee:

- Do the technologies have the potential to address the unmet need?
- Do the studies suggest that the technologies have the potential to be clinically effective?
- Is there enough clinical evidence for these technologies to be used as an option in the NHS while further evidence is generated?
- Should recommendations be made about OKKO for AMD and Peek Acuity, given the uncertainty about whether these technologies are in scope?
- Is intermediate AMD an appropriate population for these technologies?
- Which evidence gaps are most important to address?

9.2 Health economic evidence

Key points:

- There was insufficient evidence to model any of the specific technologies. Instead, the EAG developed an exploratory model to model the impact of a generic digital technology for monitoring.
- Even the best-case scenario (a perfect test, at the lowest cost point) will be cost incurring. This is expected because the impact of earlier diagnosis is

not captured in the model. In this scenario, there is a reduction of false positives compared to the Amsler grid, but this does not counteract the cost of monitoring.

- In the EAG's base case, the incremental cost per early diagnosis in a cohort of 100 people was £9,228 compared with standard care. This is based on the early identification of 12.41 people with neovascular (wet) AMD and 14.80 false positives.
- The key parameters that most influenced model results were probability of developing neovascular (wet) AMD, behavioural factors (adherence and probability of starting the intervention), sensitivity and specificity of the intervention, and costs of monitoring.

Limitations:

- The base case model is based on one eye
- There was a lack of clinical evidence to inform the model parameters
- The model is based on a generic technology and does not provide information for specific individual technologies
- Changes in visual acuity are not modelled, so the model does not capture deterioration in eyesight over time, which impacts a person's ability to use the technology.
- The model does not capture resource use beyond the point of diagnosis.
- False positives will result in some referrals to secondary care that do not result in a positive diagnosis, leading to additional costs and resource use. There is potential that some resource use currently occurring in the community could be shifted to secondary care for triaging and testing people who receive alerts.
- The utility and costs of early or delayed treatment are not included in the model due to the complexities introduced and the scarcity of evidence in scope. The model pathway ceases at the initial diagnosis. As such the model may underestimate the potential cost-effectiveness of the technologies because earlier treatment has the potential to reduce vision loss and therefore increase utilities.

Considerations for committee:

- Do the model results suggest that the technologies have the potential to offer value for money?
- How would these technologies be implemented in the NHS and what impacts on primary and secondary care costs and resource use are most important to consider?

Appendix A Abbreviations

AMD	Age-related macular degeneration
AUROC	Area under receiver operated curve
DSA	Deterministic sensitivity analysis
DVA	Distance visual acuity
EAG	External assessment group
EAR	External assessment report
OCT	Optical coherence tomography
PRISMA	Preferred reporting items in systematic reviews

HealthTech Programme

HTE10073 Technologies to support self-monitoring of vision change for people with macular disease (provisional title)

Professional organisation submission

Thank you for agreeing to give us your organisation's views on this technology or procedure and its possible use in the NHS.

You can provide a unique perspective on the technology or procedure in the context of current clinical practice that is not typically available from the published literature.

To help you give your views, please use this questionnaire. You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type.

Information on completing this submission

- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.
- Your response should not be longer than 10 pages.

About the organisation

Organisation name	The Royal College of Ophthalmologists
Are you (please highlight Yes or No):	An employee or representative of a healthcare professional organisation that represents clinicians? No A specialist in the treatment of people with this condition? Yes – this response was developed with [redacted] a consultant ophthalmologist A specialist in the clinical evidence base for this condition or technology? No Other (please specify):
Please provide a brief description of the organisation (including where funding comes from)	The Royal College of Ophthalmologists represents the ophthalmic profession in the United Kingdom and supports overseas members in low and middle income countries, building a global community to influence eye health policy and to share standards, training, professional learning and development. We are committed to developing and promoting the highest standards of patient care in ophthalmology and work with organisations in the eye health sector and the healthcare system to influence policy development in the UK. For our international members, we provide e-learning, training and support. The governance of the College as a charity and its finances are managed by the Trustee Board.
Has the organisation received any funding from any company with a technology related to the evaluation in the last 12 months?	Possibly if they exhibited at RCOphth Congress 2025 but without a list of companies it is difficult for me to answer this.

If so, please state the name of company, amount, and purpose of funding	
Does the organisation have any direct or indirect links with, or funding from, the tobacco industry?	No

Current care pathway and unmet need

1. Please describe the current standard of care that is used in the NHS for monitoring vision changes in people with macular disease. Please note any clinical guidelines used in the NHS which are relevant to the care pathway.

The standard of care in the NHS for monitoring vision changes in people with macular disease involves different pathways depending on the stage and type of the disease, guided primarily by the NICE (National Institute for Health and Care Excellence) guideline NG82 and commissioning guidance from the Royal College of Ophthalmologists (RCOphth).

Key Clinical Guidelines and Care Pathways

- NICE Guideline NG82 (Age-related macular degeneration) and the accompanying Quality Standard QS180 are the primary clinical guidelines.
- The Royal College of Ophthalmologists (RCOphth) Commissioning Guidance for Age-related Macular Degeneration Services provides detailed, evidence-based recommendations on the standards of care and patient pathways.

The monitoring approach is highly dependent on the stage of the disease:

AMD Stage	**Monitoring in Hospital Eye Services (HES)**	**Patient Self-Monitoring / Primary Care**

Early AMD or late AMD (dry)	Not routinely monitored in HES.	Advised to self-monitor vision and continue routine community optometrist sight tests (usually every 2 years).
Late AMD (wet active)	Monitored regularly in HES (macula service) with both eyes assessed at appointments. The interval between appointments is determined by the clinician.	Advised to report any sudden vision changes immediately to their eye-care professional.
Late AMD (wet inactive)	Monitored at clinically appropriate intervals in HES.	Advised to self-monitor and attend routine optometrist appointments.

Methods and Tools Used for Monitoring

Self-monitoring: Patients are instructed to self-monitor for new symptoms or sudden changes, such as blurred/grey patches, distorted straight lines (metamorphopsia), or objects appearing smaller than normal. An Amsler grid may be used for this purpose.

Optical Coherence Tomography (OCT): OCT is the most sensitive and primary imaging tool used in HES and community services (if available) for monitoring patients at high risk of developing or having active wet AMD. It provides detailed structural information of the retina.

Visual Acuity Assessment: Best-corrected visual acuity is measured, ideally using a LogMAR chart (ETDRS letters), at every monitoring appointment to track changes and treatment response.

Clinical Examination: Ophthalmoscopy/fundoscopy is a core part of the examination.

Fundus Fluorescein Angiography (FFA): This is used if OCT does not exclude neovascular disease to confirm the diagnosis. It is not routinely used for monitoring once a diagnosis is confirmed and treatment established.

	OCTA is used in clinical practice, mainly at the initial presentation, however it can be utilised during monitoring visits specially if patients presented with dry or inactive AMD developed new symptoms to identify new pathology and development of subretinal neovascular membrane.
2. Do technologies for self-monitoring of vision changes have the potential to replace any aspects of current standard care or would they be used as an addition to existing standard care? **Where would the technologies fit in the care pathway?**	Whilst patients with diabetic retinopathy who have already been referred to the hospital eye service need regular monitoring, they would need widefield retinal imaging, vision and OCT scanning which realistically is not likely to be available in the home. Hence many units have set up the imaging hubs for such patients, which can potentially be done closer to patient's homes without visiting the main hospital centre. Diabetic retinopathy screening is already done in community settings and requires colour photos (and sometimes OCT in the new pathway), again home monitoring for that unlikely to be sufficient. In terms of wet AMD, there could be real value in home monitoring (with home OCT). With longer acting treatments becoming available (eg port delivery system, and even gene therapy for wet AMD if becomes licenced in due course), patients would need to attend for treatments less frequently and interim monitoring would be very important, and it would be helpful if that could be done from home. Even with the existing therapies, if home monitoring could reliably be done, there could be more confidence in extending treatments in the treat and extend regimes that are used. In my opinion, home monitoring using checks for distortion/acuity are not reliable enough to detect new recurrence of fluid that we would wish to see for wet AMD treatment pathways. However, there are home OCT scanners which have been used, incorporating AI interpretation of images. Feedback from one consultant based on trailing this with the one patient, is that it looks very impressive. The issue is like to be the business model so its use would depend on the costs. For patients undergoing anti-VEGF treatment for eg DMO, home OCT could be helpful, but they would need periodic full fundal assessment to grade their overall diabetic retinopathy as well. Potentially home OCT in the context of diabetic retinopathy could again be most useful in the context of the port delivery system or gene therapy use. Similar comments for retinal vein occlusion undergoing anti-VEGF treatment. Currently it is best to keep patients who have had wet AMD treated in one or both eyes but no longer needing active treatment in the hospital clinics (often in the imaging hubs) but again home OCT could be a useful adjunct for that group. Patients not under HES: The use of home vision or distortion apps could be useful potentially for patients who have known dry AMD, not yet referred to HES, or who have been discharged from HES, who could potentially convert to wet AMD. Even though the home vision/distortion apps would not necessarily detect early fluid

	occurrence, it may well help to detect things earlier than might otherwise have been the case with the current system. Such patients are likely to have been already given an Amsler chart to check for distortion by their optometrist or hospital clinic and advised to seek attention if any new distortion or blurring. As there are likely to be 'false positives' as drusen/pigment epithelial detachments can cause distortion, not just fluid, and if distortion is better detected with the apps, that will require new pathways to deal with the additional patients requiring OCT.
3. Is there an unmet need for patients with macular disease, or for healthcare professionals managing the condition?	Patients with AMD (or DMO or RVO) respond differently to current treatments like anti-VEGF agents. The duration of treatment effect varies. Patients follow standard local pathways with standardised treatment intervals and extensions. This leads to some patients being over treated while others under treated. This is confounded by clinical capacity constraints and delayed delivery of timely injections. Ideally, patients would need close monitoring (or home monitoring) to identify early changes for each patient and set their personalised treatment intervals required based on their disease' activity only. (personalised medicine). Adopting such methods would identify early recurrences and hence define best treatment interval for each patient and reduce unneeded treatment episodes.

The technology

4. What are the potential benefits for patients and healthcare professionals from technologies for self-monitoring of vision change (consider the potential clinical benefits, cost benefits, benefits to quality of life, and any wider benefits)?	If these technologies are adopted appropriately and linked to local health providers in safe environment: Potential benefits for patients to have early detection of reduced vision hence alerting clinicians to potential early activity and prompt treatments. This would reduce marked recurrences while awaiting hospital appointments and reduce large fluctuations in vision that can be distressful for patients. Prompt intervention in early recurrences would require fewer repeat injections. Reducing fluctuation of retinal leak is shown to have long term benefits on the maintenance of retinal cell structure and integrity. The reduced need for repeat injections episodes would reflect on reduced clinic visits and better quality of life for patients maintaining stable vision with less need for hospital trips and repeat injections. This would in turn reduce hospital treatment costs and free clinical capacity to review other patients with active disease in need for clinic appointments.

5. Are there any groups of patients who would particularly benefit from technologies for self-monitoring of vision change? Are there any groups in which the technologies would be less effective or would be less likely to benefit?	Patients with stable disease such as neovascular AMD whether inactive after long course of treatment and on monitoring phase, or patients on extended treatment intervals (12 weekly and beyond), or patients with dry macular degeneration with high-risk features such as drusenoid deposits, etc. These patients do not require frequent hospital visits and benefit from home monitoring devices – whether for vision or ideally with home OCT. For these patients, change in vision or structural changes in OCT would elicit clinicians of signs of early recurrence and to bring patients back for prompt treatments. These patients would be managed safely with the knowledge that they have a form of home monitoring while maintaining a reduced hospital visit need. The technologies would be less effective in patients with active disease requiring frequent injections as vision is still unstable and fluctuating as well as structural stability hasn't been achieved hence frequent injections would be needed irrespective of home monitoring. Patients with very poor vision would struggle to detect subtle changes with home monitoring apps or devices. Elderly patients with cognitive impairment or dementia will also be unlikely to benefit from such technologies and would struggle to interact with this kind of devices.
6. How would healthcare resource use differ between technologies for self-monitoring of vision changes and current standard care for monitoring of vision change?	The use of self-monitoring technologies will enable patients to monitor their vision without the need for multiple hospital visits and reporting change only when it occurs to treating physicians. This would free available healthcare resources and capacity for more acute patients with active disease or to examine new referrals hence reducing waiting times. The utilisation of finite resources and capacity problems in retinal services could be eased by the adoption of such technologies however the extent of resource savings would rely on the sensitivity and specificity of the adopted technologies and the extent of false positives data resulting in unneeded visits. Such technologies are in its early phases and further refinements will be needed to assess the clinical and costs benefits. Its implementations in real world will need to be monitored and audited to calculate savings and capacity improvements in objective measures that can be replicated in different settings.

	Furthermore, the model of implementing these technologies will dictate how healthcare resources are utilised, whether these are apps downloaded free on patients' phones or virtual reality headsets that need to be loaned from hospitals to patients. The expense of these headsets will need to be acknowledged and factored in any costing model, all depending on which technology would be adopted. In addition, there will be expenses for uploading data to safe date environments (SDEs) for clinicians to review patients' data without breach of confidentiality.

7. Describe any system changes that would be needed if the NHS were to adopt technologies for self-monitoring of vision change. Are there any potential barriers to the adoption of the technology or any changes that may be needed to enable implementation of the technology in the NHS?	System changes will be needed to adopt self-monitoring technologies: Guidance for patients eligible for these self-monitoring will need to be established first, frequency of checks and methods for vision checks (and structural assessment if OCT home monitoring is included). Creation of Safe data environments for uploading patients' data to be linked to local hospital services, systems to alert clinicians of new uploaded data. Allocated clinical time for clinicians to review uploaded data and act upon it. Creation of certain urgent slots (clinics / injections) to action any reported change in vision and / or structural changes requiring prompt treatment as this is the whole concept of home monitoring and early detection hence health providers need to be ready to deal with the influx of reported data. Methods will need to be put in place for monitoring of compliance, as well as trouble shooting and maintenance of these technology devices. Investments and information governance teams will need to be involved to ensure infrastructure is in place to deal with the data in safe environment. Real life continuous validation of results to ensure cost-efficacy and reliability of these new technologies. Patient education and support groups to be available for patients who will need to use these novel technologies.
8. Are there any side effects or adverse effects associated with technologies for self-monitoring of vision change?	At this stage, there are no known adverse effects associated with the use of these technologies, and it should be considered safe for the majority of patients undergoing routine vision checks and imaging at hospital settings.

Equality considerations

9. Are there any equality issues that should be considered for this assessment?	It will depend on how these technologies will be disseminated to patients, whether it will be leased by hospitals to eligible patients or patients would be required to purchase it, or if it is a free app to be downloaded on patients' phones. Risk of inequality will arise if patients are required to purchase such devices as would not be available for areas with low income or high deprivation index. The use of such technologies will require certain level of literacy with the use of technology which might not be available for areas with lower income or higher illiteracy. Racial differences and language barriers might also compromise the adoption of these technologies for non-English speaking communities that can lead to inequality barrier.
10. Could technologies for self-monitoring of vision change reduce or increase health inequalities? How?	As mentioned, the risk of health inequality will rise depending on how these technologies will be adopted in the NHS and whether patients will need to pay or purchase such devices or not. Risk of inequalities will increase based on level of income, level of literacy and familiarity with dealing with digital technology. Such inequalities could be reduced by adopting free downloaded apps on phones with simple instructions. This will be different for home-monitoring OCT which would be more demanding not for image capture but for image uploads, etc. This will need educating patients and might compromise those with poorer background, illiteracy or cognitive impairment for which these technologies won't be suitable.

Key messages

In up to 5 bullet points, please summarise the key messages of your submission	• Current NHS care relies on hospital monitoring for active disease and patient self-monitoring for stable or early macular disease, using established NICE and RCOphth guidance, with OCT and visual acuity testing remaining central and not realistically replaceable by basic home tools.

	• Self-monitoring technologies should be an addition, not a replacement, to existing care, with the greatest potential value in stable or inactive wet AMD, extended treatment pathways, and high-risk dry AMD, particularly if reliable home OCT becomes affordable and workable. • There is a clear unmet need for more personalised monitoring, as fixed clinic schedules lead to both over- and under-treatment, delayed detection of recurrence, avoidable vision loss, and ongoing pressure on retinal service capacity. • If implemented safely and properly, these technologies could improve early detection, reduce vision fluctuations, cut unnecessary injections and hospital visits, improve patient quality of life, and free up NHS capacity, but benefits depend heavily on accuracy, cost, and managing false positives. • Adoption would require major system changes including clear eligibility criteria, secure data infrastructure, clinician time to review data, rapid access pathways for detected change, patient education, and careful handling of equality risks linked to cost, digital literacy, language, and cognitive impairment.

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NICE National Institute for Health and Care Excellence

HealthTech Programme

Medical Technologies Advisory Committee

Digital technologies to support monitoring of vision change at home for people with age-related macular degeneration – 1st meeting

21 May 2026

Expert questionnaires for committee:	
5a	Miss Christiana Dinah, Consultant Ophthalmologist
5b	Dr Mohammed Abid, Advanced Clinical Optometrist – Medical Retina
5c	Mr Nicolas Beare, Reader and Honorary Consultant Ophthalmologist
5d	Mr Richard Allen, Principal Optometrist, Head of Optometry
5e	Mr Vasileios Konidaris, Consultant Ophthalmologist

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology name & indication: HTE10073 Technologies to support self-monitoring of vision change for people with macular disease

Name:	Christiana Dinah
Job title:	Consultant Ophthalmologist
Organisation:	London North West University Healthcare NHS Trust
Completed:	12/11/2025

Please answer the following questions as fully as possible to provide further information about the technologies and/or your experience

1	Please describe your level of experience with the technologies, for example: • Are you familiar with the technologies? • Have you used any of them or are you currently using any of them? If so, please indicate your experience. • Do you know how widely these technologies are used within the NHS? Are these technologies used	I am familiar with these technologies and have tested them out when consulting for companies looking to roll-out these technologies in the NHS. I was involved in the design of a pilot feasibility study for a vision app by Bayer which later got cancelled, I have supported the design of a clinical trial to test a remote home OCT and supported the design of a service evaluation project in a neighbouring hospital testing the Okko health app They are not widely used in the NHS yet

	by clinicians in specialities other than your own?	
2	Please indicate your research experience relating to these technologies (please choose one or more if relevant): (Please highlight your choice(s))	Other (please comment) – I have consulted for a companies creating these technologies and supported clinical trial design for a technology. I have extensive research experience in the diseases being monitored and in trials to assess diagnostic accuracy

Current management

3	Please describe the current standard of care that is used in the NHS. Please note any clinical guidelines used in the NHS which are relevant to the care pathway. What setting would these technologies be used in (primary care, general hospitals, specialist centres for example).	At present, patients with macular diseases are typically diagnosed after presenting with symptoms to their optometrist or GP, at their routine eye care check with optometrists or via diabetic eye screening programme. The diagnosis is typically confirmed with OCT (which is the gold standard), along side visual acuity testing, slit lamp examination and dye angiography if required. NICE guidance for wet AMD, Diabetic retinopathy and the RCOphth guidance for retinal vein occlusion are main guidance used – in addition to some NICE TAGs for intravitreal therapies which make reference to OCT measurements. Functional assessment of visual function and OCT are conducted in hospital eye clinic and optometrists. GPs can also assess visual acuity but do not have OCT technology. Self-monitoring is currently done either using Amsler monitoring which is very crude or instructing the affected individual to view straight edges in every day life (eg edge of wall) for any changes. Devises such as Okkohealth or the Home Vision Monitoring app are being piloted in some regions to help monitor visual function.
4	Do these technologies have the potential to replace current standard care or would it be used as an addition to existing standard care?	Self-monitoring technologies would be tools that the patient can use to detect a change in their disease state. At present, these are mainly tools that measure visual function (eg visual acuity/contrast sensitivity).

	Where would the technologies fit in the care pathway?	However, function may lag anatomy – so home monitoring of the anatomy (eg home OCT would be ideal). With regards to the tools I am aware of in the UK, eg okko health, home monitoring vision app, these could be used to monitor vision change in between treatment to provide reassurance when intervals are extended beyond 12 weeks. These could also be used to monitor patients who have stopped treatment – currently typically monitored every 6-12 weeks in most instances. Current standard of care is Amsler monitoring/real-world detection of distortion, symptomatic detection or incidental detection. These technologies would replace these and can be designed to fit into optimised clinical pathways
5	What are the main aims of these technologies? How innovative are they? Can you name any technologies which are available in the UK and have this function/mode of action? Are there any competing or alternative technologies available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the technology indicated here?	The aim is to detect a change in disease activity by demonstrating a change in function. This can be either detecting reactivation of treated disease or conversion from dry AMD to neovascular (Wet AMD). This is because we know that earlier detection is linked to better VA at treatment start. We know this from randomised controlled trials and from real-world studies which show better outcomes for fellow eyes which tend to be picked up earlier. They would alert to disease activity which can happen any time between visits and therefore trigger initiation of treatment. If high sensitivity and specificity, they would support extended treatment intervals, monitoring once disease stable and potentially reduce eye clinic visits. We would be able to prioritise clinic capacity for those with very active disease and reduce routine footfall whilst maintaining safety via remote escalation pathways They are innovative as they move subjective self-checks to quantified, remotely supervised digital tests or even home OCT imaging.

		They are mainly digital tools (as mentioned above, okko health, myVisionTrack, Alleye, OdySight. Bayer also started developing an app but stopped after COVID). Home OCT (eg by Notal Vision) is available in the US but not in the UK – this allows remote fluid monitoring and focuses on picking up anatomical change – which often occurs before function changes. These have RCT level evidence. Digital apps primarily triage and prompt review whilst home OCT could enable treatment-timing optimisation by tracking fluid daily but not available in the UK outside of trial settings
6	Approximately how many people each year would be eligible for an intervention with these technologies, (give either as an estimated number, or a proportion of the target population)?	30-50% of patients with wet AMD – which is the proportion that can be extended to 10 weeks and beyond on Eylea 2mg including stable wet AMD 50% of DMO/RVO patients High-risk intermediate AMD, fellow eyes of people with unilateral AMD – would be a large target population

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using these technologies?	Reassurance, reduced anxiety, access to care when needed reducing burden of frequent visits, empowerment – increased engagement in care, potential for better vision and therefore quality of life
8	Are there any groups of patients who would particularly benefit from these technologies? Are there any groups in which these technologies would be less effective or would be less likely to benefit? Are there any potential equality issues that should be considered for this condition and technology?	- Of particular benefit would be high-risk intermediate AMD, Stable treated wet AMD, DMO/RVO/Myopic CNV for surveillance of reactivation, patients on longer intervals of treatment, those with access restrictions eg mobility limitations - Groups less likely to benefit would be digitally-limited, those with limited residual vision, those with other ocular co-morbidities - Equality issues: digital exclusion, accessibility issues (eg language, neurodiverse), health literacy

9	What do you consider to be the potential benefits to the system from using these technologies? Could it lead, for example, to a reduced number of appointments, improved care pathway, more efficient NHS staff time use?	May allow earlier detection of disease – therefore better outcomes, likely reduce number of appointments and prioritisation of appointments, may allow use of initiatives such as patient-initiated follow-up, empower patients. In the pipeline, we have longer-acting therapies in phase 3. These are treatments that are dosed once in 6 months and in early studies – approximately 70% did not need any treatment in the interval. However, without a way to monitor in-between, we would have to see all patients frequently to detect the 30% who do need interval treatment. With remote monitoring, we may be able to identify those patients and therefore provide clinicians and patients reassurance to use these longer acting therapies
10	What (if any) clinical facilities (or changes to existing facilities) are needed to implement this technology safely?	A clear clinical pathway should be established for responding to alerts indicating possible disease progression – with designated staff (e.g. ophthalmic technicians, optometrists, or nurse specialists) to review alerts and determine when patients require urgent assessment. A support mechanism (helpdesk or digital team) to troubleshoot connectivity or usability issues and ensure continuity of monitoring. Digital integration and possibly a process for occasional validation against OCT findings to ensure continued accuracy and safety
11	Is any specific training needed in order to use these technologies with respect to efficacy or safety?	Structured instruction for patients – multi/omnichannel eg video, leaflets, in-person demo, clinicians trained in interpreting read-out and triage protocol

Safety and efficacy of the technologies

12	What are the potential harms of the technologies? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	False negatives – missed reactivation leading to visual loss/delayed treatment False positives leading to unnecessary appointments, increased patient and clinic burden Low/inconsistent adherence – this has been reported to be quite low after initial high uptake with some apps Patient worry/concern from regular monitoring Home-Monitoring Vision Tests to Detect Active Neovascular Age-Related Macular Degeneration | Ophthalmology | JAMA Ophthalmology | JAMA Network – suggests high specificity but low sensitivity for 3 of the apps
13	Please list the key efficacy and safety outcomes for these technologies? Please suggest the most appropriate method of measurement for these outcomes and the timescales over which these should be measured (where appropriate) and if there are any challenges in collecting key outcomes.	Safety – false negative false-negative rate; time from "true disease activation" to **clinical confirmation; ΔVA at treatment start** (LogMAR); proportion presenting with **worse than 10 ETDRS letters** compared to baseline Efficacy – sensitivity, specific, positive predictive value, area under ROC curve, time to detection, Health economic evaluation Timeframe – at least 12 months
14	Please list any uncertainties or concerns about the efficacy and safety of these technologies?	Limited well designed studies on the diagnostic accuracy, compliance especially over time, integration into clinical pathways and the robustness of support
15	Are you aware of any additional issues which would prevent (or have prevented) these technologies being adopted in your organisation or across the wider	Digital apps: diagnostic accuracy, resource to optimise clinical pathway

	NHS? This could include costs, resource, staffing for example.	
16	Please list any abstract, real-world evidence, conference proceedings or any major trials or registries that you are aware of for this topic. Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. If you would like to share any studies which are confidential due to their publication status, please contact us via email.	
17	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Prospective diagnostic accuracy studies **masked OCT-based reference standards** to quantify sensitivity/specificity across and **different hardware** and home condition. Also, mixed-methods research to understand predictors of sustained use, optimise training and ensure inclusive interfaces

Further Comments

18	Please add any further comments on your particular experiences or knowledge of the technologies.	

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology name & indication: HTE10073 Technologies to support self-monitoring of vision change for people with macular disease

Name:	Mohammed Abid
Job title:	Advanced Clinical Optometrist – Medical Retina
Organisation:	Manchester Royal Eye Hospital (MREH
Completed:	05/11/25

Please answer the following questions as fully as possible to provide further information about the technologies and/or your experience

1	Please describe your level of experience with the technologies, for example: • Are you familiar with the technologies? • Have you used any of them or are you currently using any of them? If so, please indicate your experience. • Do you know how widely these technologies are used within the NHS? Are these technologies used	Yes, I am familiar with the technologies, although I have not been actively involved in any practical or clinical research relating to them. I am aware of the various theories behind the technologies, the multitude of software and applications approved (or currently in testing), as well as future innovations being explored in the field. I have not previously used any of the technologies, and I do not currently use them in my day-to-day working environment. I understand these technologies have been trialled in other NHS Trusts. However, at present, they are not used at Manchester Foundation Trust,

	by clinicians in specialities other than your own?	whether in the Medical Retina sub-speciality or other sub-specialities within the Trust.
2	Please indicate your research experience relating to these technologies (please choose one or more if relevant): (Please highlight your choice(s))	I have done bibliographic research on a technology or technologies. I have done research on a technology or technologies in laboratory settings (e.g. device-related research). I have done clinical research on a technology or technologies involving patients or healthy volunteers. I have published research on a technology or technologies. I have had no involvement in research on these technologies. Other (please comment)

Current management

3	Please describe the current standard of care that is used in the NHS. Please note any clinical guidelines used in the NHS which are relevant to the care pathway. What setting would these technologies be used in (primary care, general hospitals, specialist centres for example).	The majority of patients with Dry AMD referred to MREH are seen in an outpatient Medical Retina or Macular clinic once. They are provided with a detailed explanation about their condition and reassured before they are discharged with advice and an Amsler grid for self-monitoring. The advice constitutes of lifestyle changes that include smoking cessation (if applicable), UV protection, exercise, and a healthy diet. They are also advised to see their optometrist on an annual basis, but to present immediately to them or to the Emergency Eye Department if they notice any sudden deterioration or new distortion in vision in either eye. Patients with stable neovascular AMD are monitored in a virtual macular clinic for 2 years following their last intravitreal injection treatment. In the first year, they are monitored every 8 weeks before they are monitored every 10 weeks in the second year. Following this, they are discharged with advice,

		as above. At each visit, the patient has an OCT and OCT-Angiogram scan of each eye reviewed by an optometrist before a letter of results is sent to the patient and the GP. These technologies have a role to play both in primary care and hospital settings. In primary care, once a confirmed diagnosis of Dry AMD is made, patients can be advised to monitor at home using the technologies and to present immediately to their optometrist in the case of a new abnormality. This would trigger further investigations by the optometrist who can further refer the patient to hospital in the case of treatable macular condition (e.g., neovascular AMD). Similarly, this can be used in hospital setting in two ways. Dry AMD patients can be advised to use the technology when discharged from hospital care. Additionally, it can be used to monitor for reactivation of neovascular AMD. Patients would have minimal monitoring visits at the hospital (once or twice a year), and they can self-present when an abnormality is noted by the technology.
4	Do these technologies have the potential to replace current standard care, or would it be used as an addition to existing standard care? Where would the technologies fit in the care pathway?	Initially, and up until acceptable levels of specificity and sensitivity are achieved, these technologies would be an adjunct to existing standard care, rather than replacements. They offer opportunities to enhance the care pathway by enabling earlier detection of disease progression, providing more frequent home monitoring between clinic visits, and allowing faster clinical response when changes or abnormalities are detected. In the care pathway, they would typically be used for patients at high risk of developing neovascular AMD following their discharge from hospital. Additionally, they would be used for patients with stable neovascular AMD, serving as surveillance between scheduled ophthalmology visits. As previously mentioned, alerts from self-monitoring tools can prompt timely in-clinic review and imaging, helping to preserve vision by reducing delays to treatment.

5	What are the main aims of these technologies? How innovative are they? Can you name any technologies which are available in the UK and have this function/mode of action? Are there any competing or alternative technologies available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the technology indicated here?	The main aims of the technologies include early detection and/or progression of disease activity, facilitating prompt re-(referral) and treatment, thus improving visual outcomes. They also enable for more frequent and readily available monitoring between ophthalmology reviews. This remote triaging allows for patient prioritisation and personalised treatment/monitoring plans, improving efficiency and patient outcomes. These technologies show varying levels of innovation, which ranges from digital formats of pre-existing tests such as smartphone Amsler grids and hyperacuity applications to validated home telemonitoring devices and home (self-operated) OCT. Digital vision tests represent incremental innovation. Hyperacuity applications are moderately innovative, while home OCTs are highly innovative and transformational. Examples of the above technologies include applications such as myVisionTrack, Alleye, and OdySight, which allow for home-monitoring. Validated hyperacuity testing include ForeseeHome, with the HOME study exploring clinical evidence around it. An example of home OCT is Notal SCANLY. Competing or alternative technologies in the NHS include virtual macular clinics, which I previously mentioned, as well as community OCT services. Although these require patient attendance and image capture by a healthcare professional. Home monitoring technologies are patient-operated and mainly serve as early-warning tools, while virtual clinics are clinician-operated, providing structural imaging (i.e., OCT), which allows for direct and concise re-(treatment) decisions.
6	Approximately how many people each year would be eligible for an intervention with these technologies, (give either as an estimated number, or a proportion of the target population)?	Individuals with macular disease that require ongoing monitoring include AMD, DMO, and myopic CNV. Considering the number of individuals affected by these conditions in the UK and undergoing active monitoring in hospital or other settings (diabetic screening programme), approximately 2

		to 3% of UK adults over the age of 50 years would benefit from these technologies.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using these technologies?	Potential benefits include early detection of disease activity and/or progression, allowing for early intervention and better visual outcomes. They reduce frequent hospital visits and allow patients to be more actively involved in their own eye health and care. They also improve continuity of care, allowing personalised monitoring plans and prioritisation of patients in need of urgent care.
8	Are there any groups of patients who would particularly benefit from these technologies? Are there any groups in which these technologies would be less effective or would be less likely to benefit? Are there any potential equality issues that should be considered for this condition and technology?	Patients who would benefit the most include those with high-risk or progressive macular disease (e.g., those at risk of developing neovascular AMD or treated neovascular AMD), technology-engaged patients, and those with limited access to hospital/community eye services (as they can still get the convenience and reassurance from home-testing). Patients who would benefit the least include those with severe visual impairment (as they may not be able to perform the testing), individuals with low to no digital literacy, cognitive impairment, and non-adherent patients. Potential equality barriers include language and accessibility, health literacy, and access to digital devices and/or other related services (e.g., broadband).

9	What do you consider to be the potential benefits to the system from using these technologies? Could it lead, for example, to a reduced number of appointments, improved care pathway, more efficient NHS staff time use?	These technologies have a great potential to enhance the efficiency and effectiveness of the NHS care pathway for macular disease. Early detection can reduce treatment delays, and in turn, prevent unnecessary visual loss and improved patient outcomes. The above optimises use of clinical resources, reducing routine hospital appointments, allowing staff reallocation to clinics with patients requiring urgent care. Alerts from self-monitoring technologies support efficient triaging, personalised patient follow-up intervals, thus, addressing capacity pressures and overall workflow in ophthalmology services.
10	What (if any) clinical facilities (or changes to existing facilities) are needed to implement this technology safely?	These technologies do not require new physical clinical facilities, as self-monitoring would be done by patients at home. However, secure digital platforms would need to be integrated to pre-existing clinical infrastructure to ensure receipt, storage, and reviewing patient-generated data. Other IT upgrades would be required to ensure this data is linked to the patient's electronic record. New workflows would need to be designed to ensure staff with the appropriate clinical expertise are able to interpret the automatic alerts, triage the patient, and schedule timely in-person hospital follow-ups.
11	Is any specific training needed in order to use these technologies with respect to efficacy or safety?	Yes, maximising the benefits of these technologies requires training for both patients and clinical staff. This would minimise risks of inaccurate monitoring and delayed treatment. Patients require concise instructions on application use, testing schedules, responding to alerts generated by the application, and clear guidance on contacting the hospital. Clinicians with the appropriate clinical expertise require in-depth understanding of means of accessing and interpreting data to allow for timely triaging and follow-ups. This would include training on digital platforms used, data security, and workflow integration.

Safety and efficacy of the technologies

12	What are the potential harms of the technologies? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: • Adverse events reported in the literature (if possible, please cite literature) • Anecdotal adverse events (known from experience) • Theoretical adverse events	Much like all technologies, there is always potential of risk, however, these technologies are generally low risk. A key adverse event would be missed progression where the technology fails to detect early neovascular changes, leading to delayed treatment. The HOME study reported a false negative rate of about 5% (10.1016/j.ophtha.2013.10.027) It also noted a false-positive rate of about 14%. The latter can lead to extra unnecessary hospital visits, increased patient anxiety and their loss of confidence in the technology. Anecdotal adverse events may include patient non-adherence, which can lead to missed progression and delayed treatment. Technical issues with the technology, which can lead to patient frustration or anxiety. Theoretical adverse events may be related to data breaches and privacy risks, inequality or reduced access to care due to patients with low digital literacy, and misinterpretation of alerts by patients leading to increased anxiety and unnecessary emergency visits to their optometrist or the hospital eye service.
13	Please list the key efficacy and safety outcomes for these technologies? Please suggest the most appropriate method of measurement for these outcomes and the timescales over which these should be measured (where appropriate) and if there are any challenges in collecting key outcomes.	Key efficacy outcomes for these technologies comprise of vision preservation, early detection of disease activity/progression, reduced interval to treatment, and patient adherence to regular monitoring. Safety efficacy outcomes include false positive and false negative rates, device/technical related issues, and psychological effects on patients (including quality of life). VA and OCT imaging are the most appropriate clinical measures that can be carried out every 3 or 6 months (which can be extended to 6 or 12 months with increased confidence in these technologies). Other outcomes can be continuously measured through home monitoring using functional home tests, application logs, and patient questionnaires.

		Challenges may include standardisation of clinical assessments, patient adherence, integration of data to clinical records, and reliably capturing patients' true experiences.
14	Please list any uncertainties or concerns about the efficacy and safety of these technologies?	Uncertainties about efficacy include variable reliability metrics (specificity and sensitivity), patient adherence, robustness and long-term evidence, and integration of technologies into pre-existing clinical care. Uncertainties about safety revolve around technical issues, inequity in accessing eyecare, and the psychological impact on patients (e.g., false positives leading to higher anxiety and false negatives leading to mistrust of the technology and delayed treatment).
15	Are you aware of any additional issues which would prevent (or have prevented) these technologies being adopted in your organisation or across the wider NHS? This could include costs, resource, staffing for example.	I am not aware of any issues that have prevented adoption of these technologies in my organisation in the past. However, adopting these technologies in my organisation or across the wider NHS poses various issues. The primary issue is cost. This includes costs of applications, devices, OCT systems, and other subscription and maintenance fees. Other issues include staffing and their training as well as appropriately and securely integrating data (in line with regulations) from these technologies into pre-existing patient records. Patient training and adherence may pose additional issues.
16	Please list any abstract, real-world evidence, conference proceedings or any major trials or registries that you are aware of for this topic. Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent	I do not have any additional resources that would not be found through a comprehensive literature search.

	abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. If you would like to share any studies which are confidential due to their publication status, please contact us via email.	
17	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Yes, there are several aspects that require addressing. Most importantly is the long-term clinical effectiveness or robustness of these technologies. This is especially important with respect to visual preservation and patient adherence. Additional studies comparing the effectiveness of these technologies to current monitoring pathways are necessary for establishing effective and cost-efficient approaches. More observational studies are needed to evaluate patient adherence, equity of access, digital literacy challenges, and data integration into pre-existing NHS care systems. A comprehensive health economic evaluation including cost analyses, earlier detection benefits, and overall reduced clinical burden would be especially beneficial for large scale adoption of these technologies across the NHS. Finally, studies are required to assess patient-reported outcomes that include evaluating confidence, anxiety, application usability, and overall impact on quality of life.

Further Comments

18	Please add any further comments on your particular experiences or knowledge of the technologies.	No further comments.

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology name & indication: HTE10073 Technologies to support self-monitoring of vision change for people with macular disease

Name:	Nicholas Beare
Job title:	Reader and Honorary Consultant Ophthalmologist
Organisation:	University of Liverpool
Completed:	03/11/25

Please answer the following questions as fully as possible to provide further information about the technologies and/or your experience

1	Please describe your level of experience with the technologies, for example: • Are you familiar with the technologies? • Have you used any of them or are you currently using any of them? If so, please indicate your experience. • Do you know how widely these technologies are used within the NHS? Are these technologies used by clinicians in specialities other than your own?	I am a medical retina specialist treating patients with macular conditions including AMD, DMO and RVO. I have conducted my own research on AMD, and macular oedema and am applying for funding for a clinical trial in AMD. I am or have been a PI or Sub-I on many multicentre clinical trials in macular disease and am UK CI for a clinical trial in dry AMD in set-up. I worked with Paul Knox (retired) who conducted research and was an expert on radial shape discrimination for vision monitoring in macular disease. I examined a PhD which included radial shape discrimination in DMO. I was an sub-investigator on the EDNA trial, and NIHR funded study investigating diagnostic monitoring performance of five modalities including Amsler grid, visual acuity and self-reported vision. I recommend Amsler grids and ambient vision self-monitoring to patients with macular disease. I know almost all medical retina specialists and a large proportion of optometrists do the same. I am aware of scientific evidence regarding the accuracy of the Amsler grid. I have not recommended specific new technologies for vision monitoring to patients. These technologies are not used in other specialities. AMD – age-related macular degeneration DMO – diabetic macular oedema RVO – retinal vein occlusion

2	Please indicate your research experience relating to these technologies (please choose one or more if relevant): (Please highlight your choice(s))	I have done bibliographic research on a technology or technologies. I have done research on a technology or technologies in laboratory settings (e.g. device-related research). I have done clinical research on a technology or technologies involving patients or healthy volunteers. I have published research on a technology or technologies. I have had no involvement in research on these technologies. Other (please comment)

Current management

3	Please describe the current standard of care that is used in the NHS. Please note any clinical guidelines used in the NHS which are relevant to the care pathway. What setting would these technologies be used in (primary care, general hospitals, specialist centres for example).	To support self-monitoring of vision change by patients with macular disease the current standard of care is a paper copy of the Amsler grid, or advice on ambient vision monitoring. This would be done in primary care (mostly optometrists and GPs with the specific knowledge) and hospital eye clinics or private providers of NHS macular services.
4	Do these technologies have the potential to replace current standard care or would it be used as an addition to existing standard care? Where would the technologies fit in the care pathway?	New screen based technologies do have the potential to replace current practice but need to account for low technology access or use in the relevant age group. Within the hospital eye clinic the technologies could be recommended to patients with intermediate AMD with a high risk of

		progression to neovascular or atrophic advanced AMD; to patients with advanced AMD in one eye to monitor their fellow

		eye; or to monitor neovascular AMD between or after treatments; or to patients with early DMO, or undergoing DMO or RVO treatment. For intermediate AMD this could include by optometrists or GPs without specialist review.
5	What are the main aims of these technologies? How innovative are they? Can you name any technologies which are available in the UK and have this function/mode of action? Are there any competing or alternative technologies available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the technology indicated here?	Their aim is to enable patients to monitor their vision to facilitate the early detection of deterioration, progression or new disease. They are innovative in that they use technology to improve on the simple Amsler grid. Names: Amsler grid, radial shape discrimination Home Vision Monitor ForeseeHome AMD Monitoring Program myVisionTrack app The Amsler grid is mainly paper copy based, but can be screen based. The others are screen based and use testing algorithms to determine the patients current vision testing threshold. Competing technology is with home or optometric practice based OCT. OCT has been shown to out-perform vision monitoring in detecting progression of AMD, DMO and RVO. There are a number of miniature OCTs aimed at home monitoring available but I understand from the title that these are not within scope of this HTE.
6	Approximately how many people each year would be eligible for an intervention with these technologies, (give either as an estimated number, or a proportion of the target population)?	10-16% of the population over 65 years has intermediate AMD. In the UK this equates to 1.2–2.0 million people. 7.0% of the adult population have diabetes of whom ~40% have diabetic retinopathy. In the UK this equates to 1.9 million people. RVO adds approximately 0.5million. Total about 4 to 5 million in the UK.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using these technologies?	Early detection enabling early treatment which has better outcomes.
8	Are there any groups of patients who would particularly benefit from these technologies? Are there any groups in which these technologies would be less effective or would be less likely to benefit? Are there any potential equality issues that should be considered for this condition and technology?	Particular benefit in patients with intermediate AMD with a high risk of progression to neovascular or atrophic advanced AMD; to patients with advanced AMD in one eye to monitor their fellow eye; or to patients with early DMO, or undergoing DMO or RVO treatment. Less effective in early AMD, diabetes with no retinopathy or background retinopathy only. Access to device-based applications for people who are not familiar with, or struggle to afford smart phones or tablets. This is particularly true for the older population affected by AMD.
9	What do you consider to be the potential benefits to the system from using these technologies? Could it lead, for example, to a reduced number of appointments, improved care pathway, more efficient NHS staff time use?	There is strong evidence that early treatment in neovascular AMD results in better outcomes enabling patients to remain independent. It could lead to reduced treatment and reduced visits to hospital macular services.
10	What (if any) clinical facilities (or changes to existing facilities) are needed to implement this technology safely?	Patients with positive test need to be able to access rapid clinical review to determine the outcome. This would require additional resources to implement. Patients would need to be able to access support with smartphone, and app function.
11	Is any specific training needed in order to use these technologies with respect to efficacy or safety?	No

Safety and efficacy of the technologies

12	What are the potential harms of the technologies? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: • Adverse events reported in the literature (if possible, please cite literature) • Anecdotal adverse events (known from experience) • Theoretical adverse events	Causing additional anxiety and reminding patients of a threat to their vision by regular use. Causing anxiety due to a positive result. Causing unnecessary anxiety through a false positive result. Causing false reassurance through a false negative result. Additional strain on NHS resources to process patients with positive results.
13	Please list the key efficacy and safety outcomes for these technologies? Please suggest the most appropriate method of measurement for these outcomes and the timescales over which these should be measured (where appropriate) and if there are any challenges in collecting key outcomes.	Identification of progression to neovascular AMD. Identification of reactivation of existing neovascular AMD Identification of worsening macular oedema in DMO and RVO Acceptable false positive and false negative rate. Testing should be over at least a year and preferably more. Sample sizes need to calculated based on known progression data.
14	Please list any uncertainties or concerns about the efficacy and safety of these technologies?	Diagnostic accuracy metrics. Few if any safety concerns aside from false negative results
15	Are you aware of any additional issues which would prevent (or have prevented) these technologies being adopted in your organisation or across the wider NHS? This	Resource for dealing with positive results

	could include costs, resource, staffing for example.	
16	Please list any abstract, real-world evidence, conference proceedings or any major trials or registries that you are aware of for this topic. Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. If you would like to share any studies which are confidential due to their publication status, please contact us via email.	
17	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Diagnostic efficacy metrics

Further Comments

18	Please add any further comments on your particular experiences or knowledge of the technologies.	I think that home or optometric based OCT should be included in this assessment. OCT was the best non-invasive test for detecting neovascular AMD in the EDNA study.

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology name & indication: HTE10073 Technologies to support self-monitoring of vision change for people with macular disease

Name:	Richard Allen
Job title:	Principal Optometrist, Head of Optometry
Organisation:	East Suffolk and North Essex NHS Trust
Completed:	11/11/25

Please answer the following questions as fully as possible to provide further information about the technologies and/or your Experience

1	Please describe your level of experience with the technologies, for example: Are you familiar with the technologies? Have you used any of them or are you currently using any of them? If so, please indicate your experience. Do you know how widely these technologies are used within the NHS? Are these technologies used by clinicians in specialities other than your own?	Experienced Specialist Optometrist with many years work in low vision services. Not currently using any modern technologies for self-monitoring of retinal disease, regularly recommend use of Amsler sheets for home monitoring. No regular use of modern technologies for self –monitoring within NHS Trust I work at.

2	Please indicate your research experience relating to these technologies (please choose one or more if relevant): (Please highlight your choice(s))	I have had no involvement in research on these technologies.

Current management

3	Please describe the current standard of care that is used in the NHS. Please note any clinical guidelines used in the NHS which are relevant to the care pathway. What setting would these technologies be used in (primary care, general hospitals, specialist centres for example).	Current standard of care is scheduled OCT of retina/macula to provide objective assessment of active disease within Ophthalmology departments. Some NHS Trusts have developed outreach clinics, with OCT equipment available in peripheral clinic in a community setting to increase reach, but they patient would have to attend central location for treatment. Primary care settings could be utilised if OCT results are compatible with NHS systems and the full imaging data is accessible for reviewing team but I am not aware of any schemes developed in this way.
4	Do these technologies have the potential to replace current standard care or would it be used as an addition to existing standard care? Where would the technologies fit in the care pathway?	If new technology could be proven to have the same sensitivity and specificity profile as current standard of care (OCT) then there is potential for self monitoring to have a place within the care pathway. It is likely that new technology would be utilised to supportand augment the current pathway and permit longer inter-treatment periods, and provide reassurance to patients that during the longer inter-treatment period their disease was not worsening. There is no commercially available home-based OCT technology to provide objective assessment of structural change in disease. Any home based monitoring will require assessment of change in visual function.

5	What are the main aims of these technologies? How innovative are they? Can you name any technologies which are available in the UK and have this function/mode of action? Are there any competing or alternative technologies available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the technology indicated here?	The main aims of the technologies is to identify patients with active, progressing macular disease. There are many app based versions of an Amsler grid available, some have daily/weekly reminder notifications included. There are a variety of ipad and phone based apps that utilise visual acuity, Vernier acuity, contrast sensitivity and moditifcations of Amsler grids to assess for visual changes. There is also Foresee Home by Notal Vision is available in USA, which is a hardware based device that overcomes some of the limitations of positioning, lighting etc necessary for quality assessment and it is linked with the patients ophthalmoloy team so that any abnormal or changed resultsare identified quickly and face to face care then arranged..
6	Approximately how many people each year would be eligible for an intervention with these technologies, (give either as an estimated number, or a proportion of the target population)?	The National Opththalmic Database suggests that there are more than 700,000 people with AMD in the UK, a large majority of these would benefit from home based self monitoring to assist with treat and extend treatment modalities.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using these technologies?	The benefits to patients would be fewer visits to hospital setting, convenience of timing for testing and reassurance that their disease was not getting worse in period between hospital visits. Also, dependent upon planned frequency of testing, much earlier identification of disease progression which should provide better treatment outcomes,
8	Are there any groups of patients who would particularly benefit from these technologies? Are there any groups in which these technologies would be less effective or would be less likely to	These tests should be reasonably sensitive in capable patients with reasonable vision, however the majority of patients within the macular disease cohort are elderly with poor vision so may be a challenge in this cohort.

	benefit? Are there any potential equality issues that should be considered for this condition and technology?	Access to modern technologies is a concern in the elderly cohort – availability of internet access in homes, familiarity with devices, cost of necessary supporting device and any necessary IT support would all have to be factored into any provision of modern technology.
9	What do you consider to be the potential benefits to the system from using these technologies? Could it lead, for example, to a reduced number of appointments, improved care pathway, more efficient NHS staff time use?	The potential benefit to the system would be more efficient use of limited clinical capacity – clinical resources would be directed towards those patients who have active disease required treatment.
10	What (if any) clinical facilities (or changes to existing facilities) are needed to implement this technology safely?	No changes to current clinical facilities required to implement this technology. If technologies provide results/reports to clinicians, then adequate reviewing time should be resourced within clinical teams.
11	Is any specific training needed in order to use these technologies with respect to efficacy or safety?	There may be a large training requirement in order for any home based system to be utilised to obtain quality data. The IT setup, use of app, physical distance, lighting, screen resolution & cleanliness would all need to be conveyed to the patient initially.

Safety and efficacy of the technologies

12	What are the potential harms of the technologies? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature)	The major potential for harm is missing developmen of disease or deterioration, leaving patients with irreconcilable visual loss.

	Anecdotal adverse events (known from experience) Theoretical adverse events	
13	Please list the key efficacy and safety outcomes for these technologies? Please suggest the most appropriate method of measurement for these outcomes and the timescales over which these should be measured (where appropriate) and if there are any challenges in collecting key outcomes.	The key outcome for these technologies is the ability to detect meaningful change that indicates a treatment intervention at an early stage. Current timescales for assessment of retinal disease are guided by constraints of a service at capacity, so any homemonitorin frequency should be ale to be much more freequent.
14	Please list any uncertainties or concerns about the efficacy and safety of these technologies?	The limitations with these technologies in patients with retinal disease are that the patients would require reasonable vision and be cognitively able to perform the tests regularly and in a consistent way.
15	Are you aware of any additional issues which would prevent (or have prevented) these technologies being adopted in your organisation or across the wider NHS? This could include costs, resource, staffing for example.	Given appropriate validation and meeting the necessary sensitivity and specificity criteria I feel that these would be gladly welcomed and adopted within the NHS system as it would permit greater efficiency in medical retina clinics.
16	Please list any abstract, real-world evidence, conference proceedings or any major trials or registries that you are aware of for this topic. Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard	Looking out for yourself: home monitoring for AMD, Acuity journal, College of Optometrists, 2 May 2025 Spring 2025 Balaskas K, Drawnel F, Khanani AM, Knox PC, Mavromaras G, Wang YZ. Home vision monitoring in patients with maculopathy: current and future options for digital technologies. Eye (Lond). 2023 Oct;37(15):3108-3120. doi: 10.1038/s41433-023-02479-y. Epub 2023 Mar 27. PMID: 36973405; PMCID: PMC10042418.

	literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. If you would like to share any studies which are confidential due to their publication status, please contact us via email.	
17	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Any new technology requires full validation in terms of their ability to det

Further Comments

18	Please add any further comments on your particular experiences or knowledge of the technologies.	

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology name & indication: **HTE10073 Technologies to support self-monitoring of vision change for people with macular disease**

Name:	Vasileios Konidaris
Job title:	Consultant Ophthalmologist
Organisation:	University Hospitals of Leicester NHS Trust
Completed:	06/11/25

Please answer the following questions as fully as possible to provide further information about the technologies and/or your Experience

1	• Please describe your level of experience with the technologies, for example: Are you familiar with the technologies? Have you used any of them or are you currently using any of them? If so, please indicate your experience. Do you know how widely these technologies are used within the NHS? These technologies used by clinicians in specialities other than your own?	Indirect measures of AMD severity have been developed to assess changes in visual function as macular disease progresses. A commonly used clinical tool is the Amsler grid, which asks patients to report distortions or blind spots within a grid of horizontal and vertical lines. However, its ability to distinguish between intermediate AMD and new-onset wet AMD is limited, and it does not provide a quantifiable score that can be tracked over time. Visual assessments that generate measurable scores tend to offer more reliable indicators of disease progression. Best-corrected visual acuity (BCVA) is often used as a functional measure in AMD, though it correlates only weakly with disease severity. Other measures, such as low-luminance visual acuity and reading speed, along with their changes over time, are also used to evaluate visual function in AMD. Some assessments employ psychophysical methods involving repeated discrimination judgments of visually similar stimuli. For example, the shape-discrimination hyperacuity (SDH) task requires detecting subtle

		distortions in circular shapes, providing a more sensitive measure of functional impairment in AMD. This test differentiates more effectively between intermediate AMD and new-onset wet AMD than the Amsler grid. However, none of these methods have been shown to track AMD severity in its early, dry stages before the development of wet AMD or geographic atrophy. To my knowledge, apart from the Amsler grid, which remains widely used in the NHS, most other monitoring approaches are primarily employed in research settings. I became familiar with these alternative assessments through my experience as an investigator in clinical trials.
2	Please indicate your research experience relating to these technologies (please choose one or more if relevant): (Please highlight your choice(s))	I have done bibliographic research on a technology or technologies. I have done clinical research on a technology or technologies involving patients or healthy volunteers. I am principal investigator in a study on “Visual assessments for the enhanced monitoring of macular disease”

Current management

3	Please describe the current standard of care that is used in the NHS. Please note any clinical guidelines used in the NHS which are relevant to the care pathway. What setting would these technologies be used in (primary care, general hospitals, specialist centres for example).	The current standard of care for self-monitoring macular disease is the Amsler grid test, an at-home tool used to detect changes in central vision that may indicate retinal disease, particularly macular degeneration. More advanced self-monitoring approaches, such as home-based optical coherence tomography (OCT) for

		selected patients, are emerging. The images captured through these systems can be analysed with the assistance of AI algorithms, offering the potential for earlier and more precise detection of disease progression.
4	Do these technologies have the potential to replace current standard care or would it be used as an addition to existing standard care? Where would the technologies fit in the care pathway?	Home OCT, due to its objectivity and ability to acquire and analyse images in real time, has the potential to replace other monitoring technologies in selected patients. It could also reduce the treatment burden for both patients and hospital eye services by enabling treatment to be tailored precisely to each patient's disease activity. Other monitoring modalities, such as smartphone applications designed to detect metamorphopsia or hyperacuity, can also support self-monitoring. These tools allow patients to identify central or paracentral distortions associated with AMD,

		diabetic macular oedema, or macular oedema secondary to retinal vascular occlusions.
5	What are the main aims of these technologies? How innovative are they? Can you name any technologies which are available in the UK and have this function/mode of action? Are there any competing or alternative technologies available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the technology indicated here?	The goal of self-monitoring technologies is to detect early changes in vision that may signal the onset or progression of macular disease, enabling earlier intervention and improved treatment outcomes. At the same time, these tools aim to reduce the burden of frequent clinic visits for both patients and hospital eye services, while maintaining timely access to treatment. Beyond the Amsler grid test, several smartphone applications, such as Alleye, OKKO Health, and OdySight, are available, though further validation is required and additional study results are forthcoming. The advantage of these apps lies in their ability to track visual trends over time and generate digital alerts for clinical review, supporting proactive disease management.
6	Approximately how many people each year would be eligible for an intervention with these technologies, (give either as an estimated number, or a proportion of the target population)?	More than half of medical retina patients attending hospital appointments could be eligible to use some form of self-monitoring technology, depending on their cognitive abilities, manual dexterity, and familiarity with smartphones or tablets.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using these technologies?	Benefits include a reduced need for clinic visits, resulting in less travel, decreased reliance on relatives or friends for transport, fewer work absences for patients and accompanying family members, and lower travel costs and carbon emissions. Self-monitoring also provides the opportunity to detect early changes in vision and access sight-saving treatment in a timely manner.

8	Are there any groups of patients who would particularly benefit from these technologies? Are there any groups in which these technologies would be less effective or would be less likely to benefit? Are there any potential equality issues that should be considered for this condition and technology?	Careful patient selection is essential. Factors such as cognitive status, manual dexterity, technological confidence, motivation, and the level of home support, particularly for older patients, should be considered. Some individuals may not feel confident or comfortable with self-monitoring.
9	What do you consider to be the potential benefits to the system from using these technologies? Could it lead, for example, to a reduced number of appointments, improved care pathway, more efficient NHS staff time use?	A reduction in routine follow-up appointments for patients with stable disease, combined with early intervention and timely treatment for macular disease, can facilitate better anatomical and functional outcomes.
10	What (if any) clinical facilities (or changes to existing facilities) are needed to implement this technology safely?	Patient education is essential, and additional consultation time will be needed for eligible patients, either with their treating consultant or a non-medical healthcare practitioner.
11	Is any specific training needed in order to use these technologies with respect to efficacy or safety?	Most of the apps to my knowledge are user friendly, and self-training of the healthcare professional is sufficient.

Safety and efficacy of the technologies

12	What are the potential harms of the technologies? Please list any adverse events and potential risks (even if	Theoretical false negative results from the self-monitoring technologies, leading to delayed diagnosis and treatment of disease activity.

	uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
13	Please list the key efficacy and safety outcomes for these technologies? Please suggest the most appropriate method of measurement for these outcomes and the timescales over which these should be measured (where appropriate) and if there are any challenges in collecting key outcomes.	Smartphone apps offer valuable benefits in macular disease management, including increased patient engagement, the ability to track visual trends over time, and potential digital alerts or thresholds that can prompt clinician review. However, practical considerations must be addressed: patients need to be comfortable using smartphones or tablets, and app usability and engagement are critical to success. It's important to note that not all available apps are validated to a high clinical standard. Self-monitoring should be viewed as a complementary tool, not a replacement for regular clinical assessments, imaging such as OCT, or professional decision-making. Careful patient selection is essential, taking into account cognitive status, manual dexterity, comfort with technology, motivation, and home support, especially in older individuals. Some patients may lack confidence in self-monitoring, so clear instructions and standardisation are vital, for example, when using the Amsler grid, ensure consistent lighting, correct viewing distance, testing one eye at a time, and wearing reading glasses if needed. Clinicians should define alert thresholds clearly, such as the appearance of new distortion, blank areas, or a significant drop in visual acuity, and ensure patients understand the urgency of reporting these changes. Patients should be encouraged to document their results, whether through app logs or simple diaries, and bring them to clinic visits for review. Integrating self-monitoring into follow-up pathways, such as treat-and-extend protocols, can provide a useful safety net between appointments. While earlier detection is possible, the long-term impact on visual outcomes remains uncertain, and psychological factors must be considered, as some patients may

		experience anxiety from false alarms or become complacent if they feel well. On-going support and education are therefore essential.
14	Please list any uncertainties or concerns about the efficacy and safety of these technologies?	Validation of the newer technologies (smartphone apps, home OCT, use of AI algorithms for image interpretation).
15	Are you aware of any additional issues which would prevent (or have prevented) these technologies being adopted in your organisation or across the wider NHS? This could include costs, resource, staffing for example.	A clear system must be in place to ensure that patients can promptly self-report to the hospital, or that hospital teams can respond to digital alerts generated by self-monitoring devices when potential changes in macular disease are detected.
16	Please list any abstract, real-world evidence, conference proceedings or any major trials or registries that you are aware of for this topic. Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. If you would like to share any studies which are confidential due to their publication status, please contact us via email.	DRCR Retina Network / Blinder KJ et al.: Home OCT imaging feasibility in newly diagnosed nAMD. Presented and published as abstract / paper 2023–2024 (Ophthalmol Retina 2023/2024). Notal Vision / Heier / Schneider: Pivotal NOA (Notal OCT Analyzer) trial abstracts & AAO/ASRS presentations:Data presented at AAO/ASRS/Angiogenesis, 2023–2024) and more in 2024–2025 (Ophthalmology Science / ASRS materials). Heier JS et al.: Clinical use of home OCT data to manage nAMD (abstract / ASRS poster) ASRS/AAO poster material 2024/2025. MONARCH programme / JAMA Ophthalmology diagnostic accuracy (2024): evaluation of home vision tests / apps. Schneider EW, et al. Pivotal Trial Toward Effectiveness of Self-administered OCT: Notal OCT Analyzer (NOA) Study. Ophthalmology Science / prospective 2024. PMID: 39811265.

		Dolar-Szczasny J, Drab J, Rejdak K. Home-monitoring/remote optical coherence tomography in teleophthalmology in patients with eye disorders: a systematic review. Front Med (Lausanne). 2024;11:1442758. PMID: 39512616.
17	Is there any research that you feel would be needed to address uncertainties in the evidence base?	All newer technologies will require validation, which is underway, with new data reported and published.

Further Comments

18	Please add any further comments on your particular experiences or knowledge of the technologies.	Will be able to provide outcomes of the study on alternative to amsler home monitoring

HTE10073 Technologies to support monitoring of vision change at home for people with age-related macular degeneration

External assessment report

Produced by: CEDAR

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Contains confidential information: Yes

Number of attached appendices: 3

Purpose of the early use assessment report

The purpose of this external assessment report (EAR) by an external assessment group (EAG) for early use assessment is to review the evidence currently available for technologies within the decision problem and advise what further evidence should be collected to help inform future decisions on whether the technologies should be widely adopted in the NHS. NICE has commissioned this work and provided the template for the report. This report is considered by the Committee when it is making decisions about the early use assessment.

Declared interests of the authors

Description of any declared interests with related companies, and the matter under consideration. See NICE's Policy on managing interests for board members and employees.

None.

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Responsibility for report

The views expressed in this report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

Confidential information

Table 1: Summary table of all confidential information and its source in report

Brief description	AIC/CIC	Page numbers	Source
DigiVis DVA budget impact model	CIC	41	Company RFE
Alleye budget impact model	CIC	41,42,43,68	Company RFE

Contents

Abbreviations

Term	Definition
AIC	Academic in confidence
AMD	Age-related macular degeneration
API	Application programming interface
AREDS	Age-related eye disease study
AUROC	Area Under the Receiver Operating Characteristic Curve
BIA	Budget impact analysis
BSE	Best seeing eye
CEA	Cost effectiveness analysis
CEDAR	Centre for Healthcare Evaluation Device Assessment and Research
CI	Confidence interval
CIC	Commercial in confidence
CMI	Cambridge Medical Innovation Ltd
CNV	Choroidal Neovascularisation
CRVO	Central retinal vein occlusion
DME	Diabetic macular edema
DMO	Diabetic macular oedema
DSA	Deterministic sensitivity analysis
DVA	Distance visual acuity
EAG	External assessment group
EAR	External assessment report
ETDRS	Early Treatment of Diabetic Retinopathy Study
EUA	Early use assessment
FCE	Fundus clinical examination
GA	Geographic atrophy
HTA	Health technology assessment
ICER	Incremental cost-effectiveness ratio
IVI	Intravitreal injection
MAUDE	Manufacturer and User Facility Device Experience
MDD	European Union Medical Device Directive 93/42/EEC
MHRA	Medicines & Healthcare Products Regulatory Agency
OCT	Optical coherence tomography
NPV	Negative predictive value

Term	Definition
PPV	Positive predictive value
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QALY	Quality-adjusted life year
RCT	Randomised controlled trial
RFE	Request for evidence
RFI	Request for information
VA	Visual acuity

Executive summary

Background

The topic of this early use assessment is digital technologies to support monitoring at home for people with age-related macular degeneration (AMD). There are 5 technologies in the scope of this assessment: Alleye (Oculocare Medical Inc), DigiVis DVA (Cambridge Medical Innovation Ltd.), OdySight (Tilak Healthcare), OKKO for AMD (OKKO Health), and Peek Acuity (Peek Vision).

The decision problem is described in detail in the published scope and the external assessment group (EAG) approach to the assessment is describe in the published protocol.

Clinical evidence

There were 4 studies identified as the clinical evidence base: 3 for Alleye and 1 for OdySight. These studies are outlined in more detail in Section 4.2. No studies were identified for DigiVis DVA, OKKO for AMD, or Peek Acuity. Evidence for these technologies exists and was submitted by the companies for this assessment, however, studies that do not align with the scope were not included. For Alleye, there was 1 diagnostic accuracy study (Schmid et al. 2019), 1 qualitative study (Dave et al. 2024, Teo et al. 2021), and 1 observational study (Teo et al. 2021). For OdySight, there was 1 diagnostic accuracy study (Bonjean et al. 2025).

The EAG considers there to be little evidence to support the use of Alleye for this decision problem. Schmid et al. (2019), the diagnostic accuracy study, provides evidence of the ability of Alleye, used in conjunction with a regression model, to detect the differences between dry and wet AMD. Diagnostic performance, using area under the receiver operating characteristics (AUROC), is reported as 0.660 indicating a moderate ability to discriminate. This study does not provide any evidence of the ability of Alleye to detect differences specifically between advanced dry AMD (geographic atrophy) and neovascular (wet) AMD, or its ability to detect the conversion of advanced dry AMD (geographic atrophy) to neovascular (wet) AMD. Dave et al. (2024) is a qualitative study, using focus groups and questionnaires. It provides some qualitative evidence regarding the acceptability and usability of home monitoring apps, which includes Alleye among other apps. However, Alleye was not the focus of the study and the people with AMD only consisted of 46.6% (n=7) of the study sample. Teo et al. (2021) provides some evidence of people with dry AMD and their willingness to use Alleye, and their adherence to using it. 42% (n=138) of people were willing to sign up to its use

in a home monitoring programme, and 59% (n=80) of those people were adherent in using it. However, those with dry AMD make up a small proportion of the study sample (12%).

The EAG considers there to be little evidence to support the use of OdySight for this decision problem. The single study available is a retrospective observational diagnostic accuracy study. It evaluated the diagnostic performance of OdySight in the prevention of progression to neovascular (wet) AMD for people diagnosed with dry AMD, and the prevention of recurrence of neovascular (wet) AMD who had been previously treated for it. Due to there being no true positives for detecting wet AMD, no diagnostic performance data could be calculated to evaluate the ability of OdySight to detect changes in AMD that would signal a progression from dry to wet AMD.

There was no evidence identified that was directly relevant to the scope, for DigiVis DVA, OKKO for AMD, or Peek Acuity.

Overall, across all 5 technologies, there is limited evidence to justify their use for the monitoring of people with advanced dry AMD (geographic atrophy) at risk of progressing to neovascular (wet) AMD. Clinical evidence is discussed in detail in Section 5.2, with quality assessment reported in Section 5.1.

Economic evidence

The EAG did not identify any relevant economic studies related to the technologies in this assessment. Two companies submitted budget impact analyses, one of which was in scope (Alleye). These are described in Section 6.1.

Due to the lack of clinical evidence, the EAG created an exploratory model based on a generic technology that was assumed to have better uptake, adherence, specificity and sensitivity than an Amsler grid. The model used an 8-year time horizon, and an NHS perspective, and considered events only up to the point of diagnosis without capturing subsequent consequences (Section 6.4). This resulted in both an increased cost and increased number of early diagnosis when using digital technologies compared to standard care. The cost was made up of both the cost of providing the technology and the increased cost of false positives due to a longer monitoring period.

The incremental cost was £1,145 for digital technologies compared to standard care. Per 100 people there were an additional 12.41 early detections, as well as an additional 14.80 false positives. Within the 8-year period, 37% of people were diagnosed and treated for neovascular (wet) AMD. The majority of people in the model did not convert to neovascular (wet) AMD, and therefore could not benefit in terms of earlier detection. It is

possible that they would experience benefits in terms of reassurance or empowerment, however this is not captured in the model or any available evidence from the included studies. Results and sensitivity analysis are reported in Section 6.4.

A key consideration for this population is that people with advanced dry AMD (geographic atrophy) are likely to experience a deterioration in visual acuity over time. This may impact on both the suitability of the monitoring tools and the impact that earlier treatment can have on visual acuity for those who progress to neovascular (wet) AMD. As visual acuity is the key parameter to determine utilities in most models for people with AMD, this adds complexity, and is the reason, together with limited evidence, that the EAG has not included utilities in the model.

Key limitations of the model include the lack of evidence-based inputs appropriate for the population, the lack of costs and utilities beyond the diagnostic process, simplifications that do not include changes in visual acuity over time and the base case assumption that only one eye is treated.

Given these limitations, the model should be treated with caution, as an example of potential consequences of the introduction of these technologies.

There are significant evidence gaps which are outlined in Section 8.2. In summary these are: diagnostic performance, detection of disease progression, time to first treatment in the affected eye, visual and clinical outcomes, safety and adverse events, patient centred outcomes, and patient usability and acceptability. Key areas for evidence generation are summarised in Section 8.3.

- Key points for decision makers There are significant gaps in the evidence base which means that the benefits of introducing these technologies for the monitoring of people with advanced dry AMD (geographic atrophy) in currently unclear.

- Evidence should be primarily generated on diagnostic performance, and detection of disease progression to neovascular (wet) AMD, as well as real world evidence of their use in the NHS for this population.

- Where these technologies have been implemented, they have typically been part of a specialist clinic, with the team being able to monitor results and respond to alerts. In the current pathway, people with advanced dry AMD (geographic atrophy) are not monitored through hospital eye services, but would attend their usual eye care professional if they noted a change in their vision.

- People with advanced dry AMD (geographic atrophy) may experience loss of visual acuity over time that impedes their use of the technologies.

1. Decision problem

The topic of this early use assessment is digital technologies to support monitoring of vision change at home for people with age-related macular degeneration. The decision problem is described in detail in Table 2 with comments from the EAG. The decision problem can also be found in the published scope.

Table 2: Decision Problem

Aspect of the decision problem	Decision problem
Population	Adults who have advanced dry AMD (geographic atrophy) in one or two eyes that is at risk of progression to neovascular (wet) AMD. Subgroups: • AMD diagnosed before 50 years • People with an additional eye condition that is associated with the risk of developing subretinal neovascularisation • Advanced dry AMD (geographic atrophy) at high risk of progression as defined by: ○ Age-related eye disease study (AREDS) scale Clinical factors including large drusen, pigmentary change, advanced dry AMD (geographic atrophy) with previous neovascular (wet) AMD in the fellow eye and specific OCT features
Interventions	• Alleye • DigiVis DVA • Odysight • OKKO • Peek Acuity
Comparator	Standard care for monitoring advanced dry AMD (geographic atrophy), including: • Self monitoring using the Amsler grid or other ambient references that can detect distortion • Self monitoring without the use of tools Routine sight test with community optometrist with or without OCT
Setting	The technologies are for use in the home setting under the supervision of community optometry or primary care
Outcomes and costs (may include but are not limited to)	Intermediate outcomes: • Diagnostic accuracy for detecting progression to neovascular (wet) AMD compared to OCT as the reference standard • Time to identify disease progression • Time to first treatment in the affected eye Clinical outcomes:

Aspect of the decision problem	Decision problem
	• Percentage of people that maintained functional vision in the affected eye (using validated functional tests such as the ETDRS) • Change in functional test scores including measure of variation in vision fluctuation • Technology related adverse events • Detection of AMD in the fellow eye • Proportion of people with a Certificate of Visual Impairment Patient-reported outcomes: • Health-related quality of life (EQ-5D-3L) • Vision-related quality of life (for example, Impact of Vision Impairment) • Measures of psychological impact such as, validated measures of anxiety and depression • User acceptability, views, experience and satisfaction • User adherence to home monitoring Clinician reported outcomes: • Clinician confidence in home monitoring technologies • Clinician acceptability and user experience Costs and resource use: • Cost of the technology including subscription costs • Cost of IT infrastructure required for sharing information between apps and hospital or primary care systems • Resource use/cost of providing training and ongoing support to patients using the technologies • Cost of treatment and management • Cost of training clinicians to use the technologies • Staff time and cost at different specialisms and levels of pay • Number of in person visits for vision testing of the affected eye • Number of in person visits for vision testing of the fellow eye • Number of urgent referrals
Economic analysis	A health economic model will be developed comprising a cost utility or cost-comparison analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared

2. Technologies

A brief description of the 5 technologies included in the scope can be found in Table 3. Further details on the technologies can be found in the published scope. This summary is based on information provided by NICE, information submitted by the companies, and publicly available information.

Table 3: Description of technologies

Technology (manufacturer)	Version history	Description of technology and use cases	Regulatory status	EAG comments
Alleye (Oculocare Medical Inc)	N/A	**Test type**: Hyperacuity test **Device required**: Smartphone app **Time taken**: 2 to 3 minutes per eye, several times per week **Result reporting**: Results are submitted to a clinical dashboard, monitored by hospital teams, with alarms to prompt review **Indication for use**: Macular diseases such as dry AMD, wet AMD, DME, and RVO	CE-marked Class 1 medical device	There are no versions identified for Alleye
DigiVis DVA (Cambridge Medical Innovation Ltd.)	DigVis DVA V2.0.0	**Test type**: Distance visual acuity replicating ETDRS chart testing **Device required**: Web based test, requiring 2 internet connected devices **Time taken**: 7.8 minutes (mean) **Result reporting**: Reported to clinicians and sent to patients by email or SMS. **Indication for use**: To allow users of ophthalmology services to perform a test of DVA without assistance from a healthcare professional	CE-marked Class 1 medical device	DigiVis DVA only measures DVA, which is not recommended as the sole means to detect progression to neovascular (wet) AMD

Technology (manufacturer)	Version history	Description of technology and use cases	Regulatory status	EAG comments
OdySight (Tilak Healthcare)	OdySight V2.4.0 (1.6.0). Launched 10/12/2025. French reimbursement version to comply with French law. OdySight (app) V1.5.2. Launched 11/04/2024. OdySight (dashboard) V2.3.2. Launched 11/04/2024.	**Test type**: Visual acuity, and Amsler grid **Device required**: Smartphone app **Time taken**: Less than 1 minute, twice a week **Result reporting**: Results and alerts reported to users and clinicians **Indication for use**: Adults with chronic macular diseases complicated by choroidal neovascularisation or macular edema, requiring treatment with intravitreal injections or laser therapy, or at risk of developing choroidal neovascularization or macular edema	CE-marked Class 1 medical device - MDD (May 2018)	The technology is currently not available in the UK. The company intends to launch it in the UK in 2026
OKKO for AMD (OKKO Health)	Version information not known	**Test type**: Puzzle games to detect changes in visual acuity or distortion **Device required**: Smartphone app **Time taken**: 3 times a week **Result reporting**: The results are shared with the user and clinicians **Indication for use:** the early detection of visual deterioration between appointments for patients with age-related macular degeneration	CE-marked Class 1 medical device	The company did not submit any information to NICE. This information is based on publicly accessible records The company states that the technology is only for use between hospital visits for people with neovascular (wet) AMD

Technology (manufacturer)	Version history	Description of technology and use cases	Regulatory status	EAG comments
Peek Acuity (Peek Vision)	Peek Acuity Pro Peek Acuity	**Test type**: Distance visual acuity **Device required**: Android smart phone app. An additional person is required **Time taken**: Less than 1 minute per eye **Result reporting**: Technology does not record or share any results **Indication for use**: To provide vision testing to help identify people with vision loss to help ensure they receive appropriate treatment	Peek Acuity Pro: CE-marked Class 1 medical device Peek Acuity: Not registered for medical use	The company did not submit any information to NICE. This information is based on publicly accessible records Peek Acuity is designed to monitor changes in DVA over time. However, it is not recommended by the company for detecting progression to neovascular (wet) AMD

Abbreviations: AMD: Age-related macular degeneration; CRVO: central retinal vein occlusion; DME: diabetic macular edema; DVA: distance visual acuity; ETDRS: Early Treatment Diabetic Retinopathy Study; MDD: European Union Medical Device Directive 93/42/EEC

1.1 Alleye

Alleye is intended for use by people with AMD to self monitor at home, testing several times a week. It is a hyperacuity test that takes 2 to 3 minutes per eye. If there is a drop in score below a threshold, then a “red” score is given, if this occurs on 3 consecutive occasions an alert is triggered to both the user and the clinical team via a dashboard.

The company has described current usage of the app as being in the context of ongoing care from an NHS team. The clinical team can access patient results and triage patients whose results trigger alerts to determine the next actions. The periodic feedback and option of additional support may increase uptake and adherence. However, it is also possible to delegate the responsibility to act on a trigger alert to the patient.

Alleye is an app, and requires people to have access to a smart phone or a tablet, with internet access available, to download the app. People are required to have sufficient central visual acuity (with glasses if needed) to use the app. Optimum results are for patients with corrected visual acuity greater than 60 EDTRS. Patients with corrected visual acuity of less than 35 EDTRS should not use the app.he company stated that there are multiple language options available.

1.2 DigiVis DVA

DigiVis DVA is intended to allow administration of a visual acuity test remotely to a wide variety of people requiring distance visual acuity testing, prior to a telephone consultation. It is a web-based test for distance visual acuity, allowing people to test their vision at home. It replicates ETDRS chart testing, using 2 devices to test at distance. DigiVis DVA can also be used during appointments, and also configured as a self testing kiosk device to enable community testing and use in clinics, however this is not included in the current scope.

Tests are individually ordered for patients by the clinical team. This can be through the DigiVis Portal website, or using an application programming interface (API) that allows staff to order tests and view results through their own systems. Patients then receive an invitation link to complete their test a week before their telephone consultation. They can receive a report of the results by email or SMS that is suitable for interpretation by a clinician. There is no alert system to clinicians following a change in vision. The company note that scheduled monitoring combined with a short telephone consultation may improve long term adherence.

DigiVis DVA requires people to have access to 2 internet connected devices. It is not recommended for use by anybody with severe visual impairment. The company stated that the DigiVis DVA is available in English only, and has closed captioning available for the video tutorial.

1.3 OdySight

OdySight is an app that provides 2 tests: visual acuity based on a tumbling E test, and an Amsler grid. The visual acuity test takes less than 1 minute per eye. It also has information modules, a gaming function to increase adherence, and the ability to deliver questionnaires if additional information is required. Results are reported to both the user (within the app) and to clinicians via a web browser platform. Alerts are notified to both user and clinician, and are triggered by changes in the visual acuity test only following a confirmatory re-test. The company stated that medical teams should set up a system to follow up alerts and contact patients who are not using the app correctly.

OdySight requires people to have access to a smartphone or a tablet, with internet access available. People must have the ability to establish a baseline measurement of visual acuity to use the app. The company stated that there is built in voice guidance and video demonstrations in the tutorials, with 3 languages available including English.

1.4 OKKO for AMD

OKKO for AMD is an app that uses 2 games to measure; near visual acuity (using circles in different sizes rather than letters), and distortion (using a circle of dots that contains misalignment). The user is able to log treatments, changes in glasses or operations on the app. The app also includes an educational module. Alerts are generated if there is significant difference from baseline testing in either visual acuity or distortion. Results are shared with both users and clinicians.

User requirements for the technology are not known.

1.5 Peek Acuity

Peek Acuity is an app that is available to download for free and provides distance visual acuity testing. The company providing this use it as part of a wider system when working with partners in low and middle income countries but provide the app as a standalone item available free of charge for all users. The testing requires a second person to hold the phone, and delivers a tumbling E test, reporting results as logMAR or Snellen units. Results are not stored or shared in any way, and cannot be integrated into an electronic healthcare system.

Peek Acuity requires people to have access to an Android smart phone or a tablet, with internet access available, to download the app. No visual requirements are known. There are tutorials on the app for new users and a calibration process when used for the first time that requires users to measure the size of the E symbol on the phone screen. If the symbol is not in the correct range, the app should not be used on that phone. The website states that it is available in English only. It is designed to be very simple to use.

3. Clinical context

This early use assessment will focus on the use of digital technologies to support monitoring at home for people with AMD. This section describes the clinical context of this assessment, including the condition and relevant clinical pathways.

3.1 Age-related macular degeneration

Macular disease refers to conditions that affect the macular, an area of the retina responsible for central vision, fine details, and most colour vision. Damage to the macula can cause vision to be blurred or distorted.

AMD is a progressive macular disease which usually affects people over the age of 55. The Macular Society reports that AMD is the leading cause of sight loss in the UK, affecting more than 700,000 people (Macular Society).

The Royal College of Ophthalmology uses the following classification for AMD (Royal College of Ophthalmologists 2024):

- Early AMD or age-related maculopathy
- Intermediate AMD
- Neovascular AMD or wet AMD
- Advanced dry AMD or geographic atrophy

This classification does not represent a linear progression between each class of AMD.

The terms neovascular AMD and wet AMD are used interchangeably and are referred to as “neovascular (wet) AMD” throughout this report. Similarly, the terms advanced dry AMD and geographic atrophy are used interchangeably and are referred to as “advanced dry AMD (geographic atrophy)” throughout this report. A range of terminology is used in the published literature to describe the different forms and stages of AMD. The EAG has sought to align terminology with that used by NICE and as defined in the scope. However, where alternative terms are used in the literature, these have been retained to ensure accuracy and clarity. The table below presents the terms encountered

in the evidence base and their correspondence to the NICE terminology outlined above.

Table 4: AMD terminology

NICE Terminology	Terminology used in literature
Early AMD or age-related maculopathy	• Non-neovascular AMD • Dry AMD
Intermediate AMD	• Non-neovascular AMD • Non-decompensated maculopathy • Dry AMD
Advanced dry AMD or geographic atrophy	• Non-neovascular AMD • Non-decompensated maculopathy • Dry AMD
Neovascular AMD or wet AMD	• Eyes undergoing IVI treatment • Exudative nvAMD • Exudative AMD

Abbreviations: AMD: Age-related macular degeneration; nvAMD: neovascular age-related macular degeneration; IVI: Intravitreal injections

Classification depends on the severity of the damage to the macula. Most people with AMD have early AMD or age-related maculopathy and show no symptoms. This condition can remain stable for years, but it can progress and sight loss might become more noticeable. Advanced dry AMD (geographic atrophy) is caused by deterioration of the macula, where cells die off but are not renewed. Neovascular (wet) AMD develops when abnormal blood vessels grow into the macula where they leak blood or fluid, leading to scaring of the macula and a rapid loss of central vision. Symptoms of the condition include:

- blurry central vision
- straight lines appearing distorted
- difficulty recognising faces
- difficulty seeing in low light
- dark or empty spots in the centre of vision
- difficulty reading, driving or doing close up work

3.2 Clinical pathways

The relevant NICE guidelines for the referral, diagnosis, and treatment of AMD are presented in Table 5 below. Referral, diagnosis, and treatment of AMD also follow the:

- Getting it right the first time pathway for age-related macular degeneration

- Royal College of Ophthalmologists commissioning guidance - Age related macular degeneration services

Table 5: Relevant NICE Guidelines

Guideline	Topic	Recommendations
NG82 (NICE, 2018)	Diagnosis of AMD in adults.	Early AMD and advanced dry AMD (geographic atrophy) should be diagnosed using OCT. People with asymptomatic early, intermediate, or advanced dry AMD (geographic atrophy) should be referred to hospital eye services if they develop visual symptoms that suggests neovascular (wet) AMD, and be offered OCT
NG82 (NICE, 2018)	Monitoring of AMD in adults.	People with early and advanced dry AMD (geographic atrophy) should not be routinely monitored through hospital eye services but should continue to attend routine sight tests. These people are advised to self monitor their AMD and contact an eye care professional if their vision changes. People with neovascular (wet) AMD should receive ongoing monitoring with OCT from hospital eye services All people with AMD should be given advice on how to detect vision changes at home
NG82 (NICE, 2018)	Treatment of AMD in adults.	There are no treatment options for early AMD, intermediate or advanced dry AMD (geographic atrophy) Pharmacological management of AMD includes offering intravitreal anti-vascular endothelial growth factor (VEGF) treatment for neovascular (wet) AMD

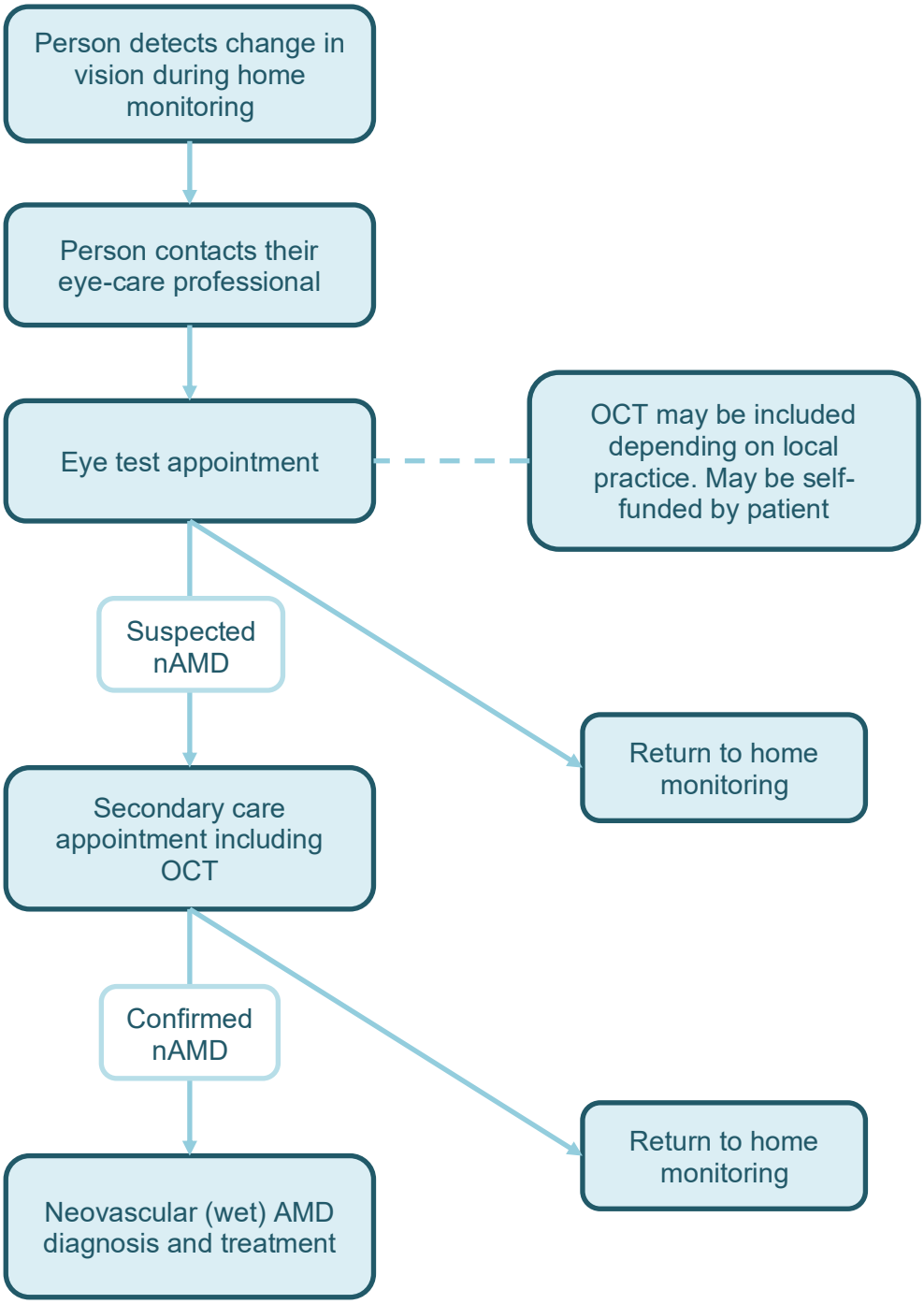
Abbreviations: AMD: Age-related macular degeneration; OCT: Optical coherence tomography; VEGF: Vascular endothelial growth factor

People with advanced dry AMD (geographic atrophy) are at risk of their AMD progressing to neovascular (wet) AMD and therefore requiring treatment. It is important for this detection to happen quickly, as treatment should be offered as soon as possible to help avoid permanent vision loss.

The Royal College of Ophthalmologists commissioning guidance for age-related macular degeneration services states that optical coherence tomography (OCT) is the most sensitive monitoring tool for detecting changes in AMD. Therefore, OCT should be used to monitor people at high risk of new neovascular (wet) AMD. However, in practice there is variation in whether people with advanced dry AMD (geographic atrophy) can access OCT on the NHS. Some people may be able to access OCT through their optometrist as part of routine sight tests.

The clinical pathway for people with dry AMD at risk of progressing to neovascular (wet) AMD is presented in Figure 1 below.

Figure 1: Clinical pathway of dry AMD home monitoring



Abbreviations: AMD: Age-related macular degeneration; OCT: Optical coherence tomography; nAMD: neovascular age-related macular degeneration

Potential place for digital technologies to support monitoring of vision change at home

Given that most people with advanced dry AMD (geographic atrophy) do not undergo regular routine OCT monitoring, there is a need for tools that can detect early vision changes and help identify individuals who require clinical assessment for the onset of neovascular (wet) AMD. The current standard of

care is to provide patients with an Amsler grid. This diagnostic tool consists of a grid of horizontal and vertical lines used to monitor a person's central visual field. People are instructed to identify any areas of distortion, blurring, or blank spots, which can indicate progression of their AMD. Clinical experts advise that this is typically done at home, with people instructed to monitor their vision using it weekly. Although this tool is freely available, there is some evidence to suggest the tool has limitations relating to its suitability for detecting neovascular (wet) AMD, including a systematic review by Bjerager et al. (2023).

Technologies that support self monitoring of vision could improve detection of neovascular (wet) AMD and share this information with eye care professionals to prompt an urgent referral for assessment, leading to more timely diagnosis, treatment, and improved patient outcomes. The technologies could also help patients to feel empowered by helping them take an active role in managing their condition.

3.3 Equality issues

Equalities issues and considerations for this early use assessment are described in the equalities impact assessment (EIA) alongside the scope. No additional equality issues have been identified during the assessment.

4. Clinical evidence

4.1 Search strategies and study selection

The EAG conducted a systematic literature search to identify relevant clinical and economic evidence. Inclusion and exclusion criteria for this assessment it outlined in the published protocol. Details of the EAG searches are provided in Appendix B.

The titles and abstracts of the identified studies were screened by one reviewer and 20% of excluded records were checked by a second reviewer against the pre-specified inclusion and exclusion criteria. Full texts of the included records were obtained and screened by one reviewer and a random 20% of exclusions were checked by a second reviewer.

In line with the published protocol, studies with full text publications were prioritised for inclusion in this assessment. Conference proceedings were included if they reported data that could be used as inputs in the economic model (Section 6.4).

4.2 Included and excluded studies

A PRISMA diagram depicting the study selection process is in Appendix B.

A total of 4 studies were included in this assessment. Four studies had full text publications available. Eleven studies were provided by the companies. These were provided by the companies as part of their “request for evidence” (RFE) submissions submitted to NICE.

Two studies were diagnostic accuracy studies, 1 for Alleye and 1 for OdySight. These studies focused on testing and validating the technologies on test accuracy (sensitivity and specificity) and performance in detecting changes in vision. One study was a qualitative study, and 1 was an observational study, both focused on the adherence and use of Alleye by people being treated by outpatient ophthalmology services. There were no studies identified for OKKO for AMD, Peek Acuity, or DigiVis DVA that were aligned with the scope of this assessment.

The studies included in the clinical review are summarised in Table 6. A rating of green indicates an element that meets the scope fully, amber meets the scope partially, and red indicates that it does not meet the scope.

Table 6: Description of key studies in the evidence base

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcomes measures and follow up	EAG comments
Alleye (Oculocare Medical Inc)	Author Schmid et al. (2019) Design Diagnostic accuracy study Location Switzerland **Green**	Participants People with dry AMD, wet AMD, and healthy controls. (Dry AMD is not defined but likely refers to early, intermediate, and advanced dry AMD) Recruited from outpatient ophthalmology Sample size 63 Wet AMD eyes 26 Dry AMD eyes 34 Young healthy eyes 19 Age-matched healthy eyes 142 Total **Green**	Intervention Alleye, people performed 4 measurements during 1 session. A regression model was built for this study to determine the outcome of these measurements. Comparator Comparison was made between dry AMD, wet AMD, and healthy controls. The healthy controls consisted of 2 groups: young healthy eyes without any disease, and age-matched healthy eyes with a monocular condition in 1 eye, and the other eye healthy **Amber**	Outcomes Accuracy of Alleye to detect if a person has dry AMD, wet AMD, or is a healthy control Follow up No follow up **Green**	This study provides evidence of the ability of Alleye, combined with a regression model, to detect the differences between dry and wet AMD, and healthy controls It is not based in the UK, and does not use Alleye in the way it would be used in normal practice, and so there are questions about its generalisability to the NHS

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcomes measures and follow up	EAG comments
Alleye (Oculocare Medical Inc)	Author Dave et al. (2024) Design Qualitative study using focus groups and questionnaires Location UK **Green**	Participants People with glaucoma or AMD, recruited through a university database of previous research volunteers Sample size Glaucoma (n=8) AMD (n=7) **Amber**	Intervention Three home monitoring technologies for vision. This includes Alleye Comparator No comparator **Green**	Outcomes Acceptability and usability of the apps through focus groups A quantitative system usability scale and acceptability questionnaire Follow up No follow up **Green**	This study offers useful qualitative insights into the use of home-monitoring apps for glaucoma and AMD. However, the findings are not specific to AMD, and people with AMD represent only a minority proportion of the study sample. In addition, the study evaluates home-monitoring apps in general rather than examining Alleye specifically It does not provide any evidence for the efficacy of Alleye

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcomes measures and follow up	EAG comments
Alleye (Oculocare Medical Inc)	**Author** Teo et al. (2021) **Design** Observational retrospective study **Location** Singapore Green	**Participants** People with retinal disease whose outpatient appointments were deferred due to the COVID lockdown **Sample size** Non-neovascular AMD made up 138 (12%) of the 732 sample size Amber	**Intervention** Alleye for vision self monitoring **Comparator** No comparator Green	**Outcomes** Adherence and willingness to sign up to using the Alleye **Follow up** No follow up Green	This study provides some evidence for people's willingness to use the Alleye app. However, the sample is not specific to AMD, with AMD only making up a small minority of the total sample. The aims and outcomes focus on the ability to introduce a self monitoring programme in an ophthalmology department, rather than being specific to the use of Alleye for AMD It does not provide any evidence for the clinical efficacy of Alleye in this population

Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcomes measures and follow up	EAG comments
OdySight (Tilak Healthcare)	**Author** Bonjean et al. (2025) **Design** Observational retrospective study **Location** France **Green**	**Participants** People with chronic maculopathy (intermediate and late AMD, DME, RVO, and myopic neovascularization). People with AMD had either non-decompensated maculopathy, or eyes undergoing IVI treatment **Sample size** 91 people 145 eyes **Amber**	**Intervention** OdySight for 12 months **Comparator** OCT used as a reference standard to confirm exudative AMD following alert from OdySight **Green**	**Outcomes** Diagnostic performance of OdySight including sensitive, specificity, PPV and NPV **Follow up** Followed up after 12 months **Green**	This study provides evidence of the diagnostic performance of OdySight for detecting recurrence of wet AMD and requirement of treatment. However, due to a lack of true positives being detected for, no diagnostic performance data could be calculated for the progression of dry AMD to wet AMD

Abbreviations: AMD: age-related macular degeneration; DME: diabetic macular edema; NPV: negative predictive value; PPV: positive predictive value RVO: retinal vein occlusion

5. Clinical evidence review

5.1 Quality appraisal of studies

This section outlines key risks of bias identified for each study, as well as consistent limitations identified across the evidence base (Table 6). As outlined in the protocol, the EAG did not use formal critical appraisal checklists to assess the quality of evidence. This is in accordance with the methods described in the NICE HealthTech programme manual (NICE, 2025). Therefore, this section does not constitute a comprehensive summary of the quality of each study.

There were 4 studies identified as the clinical evidence base, 3 for Alleye, and 1 for OdySight. There were no studies identified for Peek Acuity, OKKO for AMD, or DigiVis DVA.

Alleye

The 3 studies for Alleye include 1 qualitative study, 1 observational study, and 1 diagnostic accuracy study.

The study by Schmid et al. (2019) tests the diagnostic performance of Alleye used alongside a regression model built for this study to determine the outcome of these measurements. It compares those with wet AMD to healthy controls, as well as comparing wet AMD against dry AMD. It has a moderate sample size of 142 eyes assessed: 63 eyes with wet AMD, 26 with dry AMD, 19 age matched eyes without AMD, and 34 young healthy eyes. The EAG considers this to be a study of moderate quality. It compares against both age-matched controls and young healthy people, ensuring that the effects of aging can be isolated from the effects of AMD. However, its cross-sectional design, in addition to using a clinically known population compared to an undiagnosed cohort, does not allow changes to be detected over time limiting its applicability to the decision problem. Additionally, although the study demonstrates the ability of the technology, combined with an algorithm, to differentiate between eyes with dry and neovascular (wet) AMD, it does not provide a measurement of sensitivity and specificity of the use of the app as used in practice. It therefore does not reflect the use in the NHS of detecting the conversion of advanced dry AMD (geographic atrophy) to neovascular (wet) AMD. The authors report that their results are not adequate to understand the relationship between changes in the Alleye score and the transition of advanced dry AMD (geographic atrophy) to neovascular (wet) AMD.

The study by Dave et al. (2024) is a good quality qualitative study that utilised focus groups and questionnaires to explore the perceptions, attitudes, and

concerns of people with glaucoma and AMD. It provides useful qualitative data regarding the usability of Alleye. However, the study may be subject to selection bias as a sample of technologically literate people alone were recruited. Several apps were used in the study, and the results are not specific to Alleye. The study also had a small sample size of 15 people, with only 7 of those being people with AMD. This limits its generalisability to the wider, often digitally excluded, NHS AMD population. It also lacks ecological validity as people were instructed to use the app supervised in a university setting, rather than the home monitoring setting the app is intended to be used in.

The study by Teo et al. (2021) is a good quality observational study of adherence with, and willingness to use, Alleye among people whose ophthalmology outpatient appointments were deferred during the COVID-19 pandemic. It provides real-world evidence on the adoption of Alleye, including data on user adherence and demographic characteristics. However, the generalisability of the findings to the NHS is limited, as the study was conducted during a COVID-19 lockdown within the Singapore healthcare system. In addition, its relevance to AMD is restricted because only 12% (n=330) of the sample of 2274 had a diagnosis of AMD.

OdySight

The single included study for OdySight is a diagnostic accuracy study. Bonjean et al. (2025) conducted a retrospective observational diagnostic accuracy study assessing the performance of OdySight for monitoring primary and secondary prevention of exudative maculopathies. The EAG considers the quality of this study to be moderate.

Within the context of age-related macular degeneration and the terminology used in the study, primary prevention refers to individuals with intermediate or advanced AMD who have never previously required treatment for neovascular (wet) AMD, whereas secondary prevention refers to those with a history of treatment for neovascular (wet) AMD. For alignment with the decision problem, only the results relating to primary prevention in AMD are relevant.

The study enrolled a small sample of 43 participants, contributing data from 67 eyes. However, this sample was divided across multiple maculopathies, including AMD, DME, RVO, and myopic neovascularisation. When restricting the analysis to primary prevention in AMD, the sample size reduces substantially to 18 eyes.

The study was conducted within a specialist private ophthalmology practice in France, which may differ from NHS clinical pathways and population

characteristics. As a result, the generalisability of the findings to NHS settings is likely to be limited.

5.2 Results from the evidence base

The evidence base consisted of 4 key studies across the 2 of the technologies in scope. These results are summarised in Table 7:

- Alleye: 3 studies
- OdySight: 1 study

Table 7: Summary of results from the evidence base

Technology	Study name	Outcomes(s) and Summary of results
Alleye*	Schmid et al. (2019)	Diagnostic performance using area under the receiver operating characteristic (AUROC) (95% CI): • Discrimination between dry and wet AMD: 0.660 (0.520–0.799)
	Dave et al. (2024)	Acceptability and usability of technologies, that includes Alleye, and home monitoring: • Home monitoring viewed positively • Recognised benefits of earlier detection of progression, and more involvement in managing condition • Home monitoring could provide reassurance between clinic visits • Concerns raised about interpretation of results, and possible reduction in face to face contact with clinicians • Practical barriers such as digital literacy and confidence using smartphones identified
	Teo et al. (2021)	User adherence to home monitoring: • 42% (n=138) of people with non-neovascular AMD signed up to use Alleye • 59% (n=80) of people with non-neovascular AMD were compliant with using Alleye (patients who performed the recommended number of tests, at least 2 per week, until the time of analysis)
OdySight	Bonjean et al. (2025)	Diagnostic performance of OdySight in secondary prevention of exudative AMD (people already previously treated for exudative AMD): • Sensitivity: 14.3% • Specificity: 94.3% • Positive predictive value: 7.7% • Negative Predictive Value: 97.1% Retention of people using OdySight: • 55.8% of people across all diseases at the end of the 12 months

Abbreviations: AMD: age-related macular degeneration; AUROC: Area under the receiver operating characteristic curve

5.3 Diagnostic test accuracy

Diagnostic test accuracy was assessed using the area under the receiver operating characteristic (AUROC) in 1 study, Schmid et al. (2019). This study compared the diagnostic performance of Alleye, used alongside a regression model, to discriminate between different disease states of AMD (dry AMD,

and wet AMD) and healthy controls. A regression model was used in the study to determine the outcome of the measurements made by Alleye. A total of 143 eyes were assessed: 63 eyes with wet AMD, 26 with dry AMD, 19 age matched eyes without AMD, and 34 young healthy eyes. AUROC analyses showed that the technology, when used alongside the regression model, had good discrimination for identifying neovascular (wet) AMD when compared with age matched healthy eyes. Diagnostic performance was higher when compared with young healthy controls. The ability of the test to distinguish between dry AMD and wet AMD was more limited. Detection of dry AMD compared with young healthy controls showed moderate to good discrimination. Table 8 below summarises the results of Schmid et al. (2019).

Table 8: Summary of Schmid et al. (2019)

Comparison	AUROC (95% CI)	Interpretation
Wet AMD vs age matched healthy eyes	0.845 (0.759, 0.932)	Good discrimination
Dry AMD vs wet AMD	0.660 (0.520, 0.799)	Moderate discrimination
Wet AMD vs young healthy controls	0.969 (0.940, 0.997)	Excellent discrimination
Dry AMD vs young healthy controls	0.799 (0.675, 0.923)	Good discrimination

Abbreviations: AUROC: area under the receiver operating characteristic curve; AMD: age related macular degeneration.

Diagnostic accuracy outcomes (sensitivity, specificity, PPV, and NPV) were also reported in Bonjean et al. (2025) for OdySight. These figures relate only to secondary prevention, as they were derived from a cohort of people with previously treated wet (neovascular) AMD. Using OCT as a reference standard, there was a sensitivity of 14.3%, a specificity of 94.3%, a PPV of 7.7%, and an NPV of 97.1%. The results therefore do not reflect the performance of OdySight in individuals with advanced dry AMD (geographic atrophy) who are at risk of progressing to neovascular (wet) AMD, and consequently have limited applicability to the decision problem.

5.4 User adherence to home monitoring

User adherence to home monitoring was reported in 1 study; Teo et al. (2021). People used Alleye to perform self testing at home. A total of 2,774 patients with retinal disease were invited to participate in the home monitoring programme, of whom 26% (n=732) enrolled. Of these 2,774 participants, 12% (n=330) were diagnosed with non-neovascular AMD. Among those 330 with non-neovascular AMD, 42% (n=138) agreed to sign up for home monitoring. Of those 138, 59% (n=80) met the predefined criteria for adherence, defined as performing testing at least twice weekly. Across the study cohort, 245 patients completed 11,592 tests using the mobile

application, corresponding to a mean of 46.9 tests per user during the study period. These findings suggest that while uptake of home monitoring was relatively low, patients who engaged with the programme were able to perform repeated self testing over time.

User uptake and adherence were also reported in Bonjean et al. (2025) for OdySight. The study reported several measures related to uptake and adherence. Of the 91 people prescribed OdySight, 76% (n=69) downloaded the app. When restricted to people who subsequently used the app, 47% (n=43) of the initially prescribed population contributed data to the analyses. Among those included in the analysis, 55.8% (n=24) remained active users at 12 months. No subgroup analyses were reported specifically for people with AMD, which limits the relevance and generalisability of these usage and adherence findings to the dry AMD population in the decision problem.

5.5 User acceptability and user experience

Patient acceptability and user experience was reported in 1 study, Dave et al. (2024). Fifteen people took part in focus groups and questionnaires. Seven of those 15 were diagnosed with unspecified AMD. People generally viewed home monitoring positively and recognised potential benefits, including earlier detection of disease progression and greater involvement in managing their condition. Some people felt that home monitoring could provide reassurance between clinic visits and reduce the need for frequent hospital appointments. However, concerns were also raised regarding potential anxiety associated with interpreting test results, the reliability of home based measurements, and the possibility that remote monitoring could reduce face to face contact with clinicians. People also identified practical barriers such as the level of digital literacy, confidence in using smartphone technology, and the need for appropriate training and support. Overall, the findings suggest that while home monitoring technologies may be acceptable to many people, successful implementation may depend on adequate support and clear communication regarding the role of the technology within clinical care.

5.6 Adverse events and clinical risk

A search of the MAUDE database and MHRA (field safety notices/device safety information) identified 1 MHRA field safety notice for Peek Acuity. This was reported on 21/05/2018 with the MHRA reference 2018/005/024/291/006. No further information was provided for this field safety notice.

Adverse events were not reported in any of the studies included in the clinical evidence review.

5.7 Clinical evidence summary and interpretation

In this section, key findings from the evidence are summarised narratively for each technology. It was not appropriate to undertake meta analysis of outcomes reported across the evidence base for any of the technologies in this early use assessment due to the lack of available evidence for the technologies. Evidence gaps are discussed in Section 8.

Alleye

When considering the decision problem of this assessment, the EAG considers that there is very limited, moderate-quality evidence to support the use of Alleye for detecting the progression of advanced dry AMD (geographic atrophy) to neovascular (wet) AMD.

Of the 3 studies identified for this technology, only 1 evaluated its diagnostic performance to distinguish between dry and wet AMD. This study (Schmid et al., 2019) assessed Alleye's ability, alongside a regression model, to distinguish between clinically diagnosed groups of wet AMD, dry AMD, and healthy controls. The study reported good discrimination when comparing wet AMD with healthy eyes, particularly when compared with younger healthy controls. However, its ability to distinguish dry AMD from wet AMD was only moderate. The study used a cross-sectional design with an already diagnosed cohort. The ability to distinguish between two disease states does not provide evidence of Alleye's ability to detect progression from one state to another. The authors also acknowledged that their study could not inform how changes in Alleye scores relate to disease progression.

Two further studies provide qualitative and observational data on engagement with the technology, and people's perceptions of home monitoring. Teo et al. (2021) explored adherence to Alleye during the COVID-19 pandemic and found relatively low uptake, with only around half of invited patients enrolling. Among users who did engage, 59% were able to complete the recommended frequency of home testing. Nevertheless, the context of the study, carried out in Singapore during COVID-19 lockdown restrictions, limits the relevance of its findings to routine AMD monitoring in the NHS. Only 12% of participants had non-neovascular AMD, further reducing direct generalisation of the results in this population.

Dave et al. (2024) explored user experience and acceptability among people with glaucoma and unspecified AMD using supervised testing sessions. Participants generally expressed positive attitudes towards home monitoring and recognised potential benefits such as reassurance and increased involvement in their own care. However, practical challenges and concerns were also raised, including anxiety about interpreting results, uncertainties

about reliability, and difficulties for people with limited digital literacy. The study population was technologically literate and tested the app under supervised, university-based conditions, which does not reflect the intended home monitoring context or the broader NHS AMD population.

OdySight

When considering the decision problem of this assessment, the EAG considers there to be limited direct evidence supporting the use of OdySight for detecting progression from advanced dry AMD (geographic atrophy) to neovascular (wet) AMD. The single study included in this review (Bonjean et al. 2025) was of moderate quality but had a small and heterogeneous sample. Crucially, no subgroup analysis was conducted for people with advanced dry AMD (geographic atrophy) at risk of progressing to neovascular (wet) AMD, meaning the study does not provide diagnostic accuracy data relevant to the decision problem.

The reported sensitivity (14.3%) and specificity (94.3%) relate solely to individuals with previously treated wet AMD (secondary prevention) and therefore do not inform the performance of OdySight in the target population of untreated dry AMD. Measures of uptake and adherence were reported, but these also lacked AMD-specific subgroup analyses, limiting their relevance to the intended population.

Overall, the available evidence is limited and indirect. As a result, substantial uncertainty remains regarding both the diagnostic performance and real world usability of OdySight for monitoring people with advanced dry AMD (geographic atrophy) at risk of progressing to neovascular (wet) AMD.

5.8 Out of scope evidence

During screening of the literature, potentially relevant studies were identified but excluded because they were conducted in populations outside the scope of this early use assessment. Refer to PRISMA diagram in Appendix B for further detail. The EAG also acknowledges that the companies submitted evidence relating to use of the technologies in populations outside the scope of this assessment. In many cases, the excluded evidence focused on people with neovascular (wet) age-related macular degeneration (AMD), rather than those with advanced dry (geographic atrophy) AMD. While this evidence may have relevance to the usability and adherence to the technologies, the generalisability of the results to people with advanced dry AMD (geographic atrophy) is uncertain. Clinical experts consulted by the EAG noted that people with dry AMD tend to monitor their vision less frequently than people with neovascular (wet) AMD, and may perceive their condition as less urgent, which could limit their engagement with home monitoring technology.

Additionally, unlike people with wet AMD, individuals with advanced dry AMD (geographic atrophy) currently have no treatment options, which may further reduce their motivation to use home monitoring tools.

For some of the technologies there were studies demonstrating implementation in the NHS, but that did not meet the inclusion criteria for the main body of the report, or for the out of scope information. For Alleye, there were 4 studies (Eppenberger et al. 2021; Huemer et al. 2024; Islam et al. 2021; Mendall et al. 2024). For OKKO for AMD, there were 2 (Campbell et al. 2022; Campbell et al. 2024). For DigiVis DVA, there were 2 (Thirunavukarasu et al. 2022; Nct, & Cambridge University Hospitals. 2020). There were none for Peek Acuity or OdySight.This section summarises the out of scope evidence from 2 studies that met the following criteria:

- Technology in scope
- Population included people with any type of AMD
- The majority of the study sample were people with AMD
- Outcomes of the study are related to usability and adherence of use of the technologies

Alleye

One study (Faes et al. 2022) assessed usability and long-term adherence to Alleye among people with neovascular (wet) AMD over an 18-month period. By the end of follow-up, 73.6% (n=53) of people continued using the app. Usability ratings were high; 83.3% (n=60) of people reported being very satisfied, and scores on a validated usability questionnaire were similarly positive. These findings suggest that people with macular disease who are willing to engage in home monitoring programmes generally find Alleye acceptable and easy to use.

OdySight

One real world observational study (Guigou et al. 2021) reported on the experiences of people with macular pathologies, 52% of whom had neovascular (wet) AMD, using OdySight over a 12-month period. The study measured adherence with app use, which was 51% at 3 months and declined to 12% at 12 months. Participants who showed greater interest and engagement in their treatment were more active and consistent users. Overall user experience with the app was described as very positive. This study was conducted in France, limiting its generalisability to the NHS in the UK.

6. Economic evidence

6.1 Existing economic evidence

The search strategy outlined in Section 4.1 was sufficiently broad to identify any relevant economic studies. Any additional studies provided by the companies were considered if they were relevant to the scope. The EAG did not identify any relevant economic studies.

Technology specific economic evidence

Three companies submitted unpublished economic or costing evidence, however only 1 of these was fully applicable to the scope. The evidence is summarised in Table 9.

Table 9 Economic evidence submitted by companies

Company	Type of evidence	Intervention	Comparator	Results
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Cambridge Medical Innovation Ltd (CMI) (DigiVis DVA) submitted a budget impact analysis (BIA) that compared use of DigiVis DVA to support visual acuity testing in secondary care, with current NHS standard care.

[redacted]

[redacted]The EAG have not critiqued the BIA for DigiVis DVA as it does not address the current scope,

where the digital technology would be used during a period where the eye is not being actively monitored by health care professionals.

Tilak (OdySight) submitted a business plan as a basis for the cost structure of their technology. This relates to their cost of delivery rather than the economic impact of introducing the technology to the NHS and so is not included as economic evidence.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Other economic evidence

During the searches for economic evidence and model structures, a small amount of economic evidence was identified that was outside the scope, but did look at the diagnostic process using monitoring that could be used at home. Five studies primarily informing model structures are reported in Section 6.3. One cost analysis study was for ForseeHome, which is a device rather than a digital technology, but is used for self monitoring at home. This study has been summarised briefly in Table 10.

Table 10: Summary of economic evidence relevant to the decision problem, but not in scope

Study	Intervention and comparator	Population and setting	Methods	Key findings
Witternborn 2017	Daily home based monitoring using ForeseeHome	People with AMD ranging from early AMD to CNV in 1 eye	Cost-analysis of study data	Monitoring was cost saving for people with existing CNV in 1 eye, but was not cost-effective for early AMD

Abbreviations: AMD: age related macular degeneration; CNV: choroidal neovascularization

Witternborn et al. (2017) carried out cost-effectiveness modelling based on a study for an alternative home monitoring device, ForseeHome. The population ranged from early to late AMD, and results were broken down into several stages of AMD development. They found the cost-effectiveness to be highly dependent on the risk of progression, with use in high-risk populations being cost-effective or even cost saving.

6.2 Identification of key economic, implementation and purchasing factors

The costs included are from an NHS and Personal Social Services perspective, however impacts on patients such as time, requirements for digital literacy, or availability of a smartphone or tablet are also noted. OdySight, Alleye and OKKO are designed for people to use at home for routine monitoring between healthcare appointments, and would typically be monitored by a clinical team. Peek Acuity is designed for use by people at home and does not integrate with a clinical system. DigiVis DVA can also be used by people at home, but this would typically be in connection with a remote appointment with a healthcare professional. DigiVis DVA and Peek Acuity measure visual acuity only. Alleye measures hyperacuity only. OdySight measures visual acuity and also uses an Amsler grid, and OKKO measure both visual acuity and distortion. Table 11 is based on information submitted by companies to NICE, and in response to questions from the EAG. Where this was not available, information was sourced from company websites.

Costs of reversing the decision are low, but vary somewhat depending on the technology adopted and the number of patients initially included. There may be some additional costs where integration of the reporting system into the secondary care IT system is optional.

Table 11 Description of technology costs and implementation factors

	Alleye	DigiVis DVA	OdySight	OKKO	Peek Acuity
System set up costs					
Minimum clinical system set up	£0 for a stand alone set up with dashboard	£1,500 Includes DigiVis portal and remote technical and clinical support	£0 for a stand alone set up with dashboard	Not known	£0 It does not have a clinician interface
Additional information	Varying levels of integration with NHS systems are available	Additional onsite support available at £900 per day Integration with NHS systems optional	Possible costs to add identification of patients and healthcare staff within the system	Not known	No clinician interface
Other infrastructure	Normal IT requirements	Normal IT requirements	Normal IT requirements	Not known	None required
Staff training					
Training costs	Included	Included	Included	Not known	None
Staff trained	Medical staff who onboard patients, review dashboards and run escalation pathway	Administrator for portal and key personnel Cascading to other staff	The medical team	Not known	No training for staff
Training time	60 min full induction or 20 min for staff onboarding patients only	1 x administrator for 1 hour (up to half day) 1 hour for clinicians	30 min	Not known	None

	Alleye	DigiVis DVA	OdySight	OKKO	Peek Acuity
Support and materials	Induction materials, SOP for alerts, onboarding script	Staff user guides and advice	Support material and Support team for technical questions	Not known	None required
Per patient costs					
Licensing costs	£300 per year[#]	£5 per test[##]	£60 per month	Not known	Free
Set up time per patient	10-15 minutes	Approximately 10 minutes	1 hour including education session	Not known	Manual calibration with app
Who trains patients	By nurse, ophthalmic technician, optometrist or orthoptist	By clinical staff	By clinical staff, but technical support available from company	Not known	User, via app
Support and materials from company	Information leaflet and tutorial in app. In app AI chat	Video tutorial and voice prompts, patient information leaflet templates	Patient leaflet, tutorial in app, online help in website and app, reminder service and support team for technical help. Phone stand provided	Step by step instructions. App sends reminders if tests are missed	Instructions on app and 2 minute video tutorial

[#] Locally agreed discounts (for example, volume-based or time-limited early adoption pricing for high-risk geographic atrophy cohorts) can be provided separately

[##]Current price for completed tests, may be subject to NHS or volume discounts)

6.3 Relevant economic models

Searches for health economic modelling for age-related macular degeneration were completed in Medline, Embase and NHS EED, using filters for the UK (Ayiku 2017,2019) and economic models (CDA 2026). In addition, NICE guidance and the NIHR HTA library were searched. The aim of the searches was primarily to identify model structures that could either be used directly, or to inform new economic modelling by the EAG.

Searches of Medline, Embase and NHS EED identified 781 records after deduplication (Appendix A). Rayyan was used to identify studies that included either cost or modelling in their title, abstract or key words. A further sift by 1 researcher identified 92 studies of interest, of which 66 reported health economic evidence related to macular degeneration. In addition, those not included, but of interest were 9 reviews of models, 7 studies on disease progression and 10 on calculations of utility values.

Of the 66 included title and abstracts, 60 described health economic modelling, with 27 being Markov cohorts and 13 were either microsimulation, discrete event simulation or required patient level data, 1 used multiple decision trees. The remaining 19 were unknown (at title/abstract). The majority of models (47/60) related to treatment of neovascular (wet) AMD and therefore had limited relevance to the current scope. Due to the number of records, the full text was not accessed for these studies.

There were 8 records relating to testing or screening, with 1 Markov model (Mowatt 2014), 2 publications from a single study using a hybrid cohort – individual model, 3 publications from a single study that used microsimulation modelling (Hernandez 2022, Banister 2022 and Scotland 2022) and 2 unknown (Bojke 2008, Hopley 2004). These were obtained as full text and the 5 included studies summarised briefly in Table 12.

In addition, the EAG searched the NICE website with the term “age related macular degeneration”, and restricted to published guidance. This resulted in 20 items which were searched to include 1 clinical guideline (NG82) and 5 technical appraisals that reported health economic evidence relating to AMD.

The EAG also searched the NIHR HTA library with the term “macular”, resulting in 227 results which were sifted to include studies with economic evidence for diagnostic strategies, resulting in 4 that were potentially informative for new modelling work. Of these, 3 were also identified in the EAG economic model search strategy.

Finally a search of the Tufts cost effectiveness analysis (CEA) registry with the term “macular degeneration” gave 78 results, with one study selected by the EAG as relevant and summarised in Table 10.

There are many challenges in modelling advanced dry AMD (geographic atrophy), which are in addition to those tackled by the existing models for neovascular (wet) AMD. These are highlighted by Intorcia et al. (2023) in a review that concluded that there were differences from neovascular (wet) AMD including high levels of heterogeneity in prognostic factors for visual function, more gradual disease progression and limited possibility of vision improvement. The authors concluded that there were no existing models that were suitable for advanced dry AMD (geographic atrophy).

For the studies that modelled disease progression focusing on advanced dry AMD (geographic atrophy), this was largely framed around loss of visual acuity over time, with a continuing advanced dry AMD (geographic atrophy) diagnosis, rather than conversion to neovascular (wet) AMD.

Table 12: Summary of relevant modelling studies

Study	Intervention and comparator	Population and setting	Methods and model type	Outcomes
Banister et al. (2022)	OCT, FCE, Amsler grid, visual acuity tests and self reported	Unaffected eyes of people with existing wet AMD in one eye	Microsimulation Markov model with 6 states and 25 year time horizon.	OCT, FCE, Amsler grid, visual acuity tests and self reported
Mowatt et al. (2014)	OCT offered in different settings or with different staff	People with suspected wet AMD, or monitoring those previously diagnosed	Markov model that includes accurate and inaccurate diagnosis and subsequent treatment. 32 states for each strategy.	The outcomes were utilities based on visual acuity
Bojke et al. (2008)	Amsler grid and PDT vs PDT without screening vs neither	Unaffected eyes of people with existing wet AMD in one eye	Markov and decision tree model to estimate perfect value of information	The outcomes were utilities based on visual acuity
Karnon et al. (2008)	Self reported screening for early AMD vs no screening	General population	Hybrid cohort-individual sampling model, using 11 disease states, 9 of	Based on visual acuity score of both eyes in different model states

			which are wet AMD. Lifetime horizon	
Hopley et al. (2004)	Screening and treatment with zing and antioxidants vs standard care	Early AMD	Multicohort combined prevalence and incidence model. 5 year time horizon, annual cycles	The outcomes were utilities based on visual acuity. Screening and treatment had an ICER of £22,700

Abbreviations AMD age related macular degeneration; FCE: fundus clinical examination; ICER: incremental cost effectiveness ratio; OCT: optical coherence tomography PDT: photodynamic therapy

6.4 Early economic model

The EAG did not identify any clinical effectiveness evidence available that was both in scope and directly applicable to the required model inputs. Although some technologies had evidence in different populations, the EAG considered that this was not sufficiently applicable as the basis of modelling.

The EAG have summarised the known technology and implementation costs for each technology in Table 11, and have standardised these into an implementation cost, and monthly patient cost in Table 13.

The EAG have also created a simplified exploratory model that describes the progression of a cohort from advanced dry AMD (geographic atrophy) to neovascular (wet) AMD over time. This demonstrates the potential impact of introducing digital technologies for home monitoring in this population. The results are described in terms of costs per additional early diagnosis, with additional information including the numbers of tests completed, numbers of referrals to primary and secondary care and the number of people who are treated promptly or delayed. The model does not attempt to continue to the impact of this delay on costs or quality of life due to the complexity of the required modelling and the sparsity of evidence that is specific to the advanced dry AMD (geographic atrophy) population.

Technology costs

The costs below (Table 13) are based on assumptions around the size of a clinic, number of staff and duration of patient use. The assumptions are described; however, it should be noted that varying these assumptions makes a negligible difference to the monthly cost per patient unless taken to extremely small numbers of patients.

It is assumed that set up costs apply to a clinic, or group of clinics who will use the app with 300 patients with advanced dry AMD or geographic atrophy per year, and 4 staff are responsible for onboarding patients, with set up fees and

staff training costs being averaged over 3 years. Patients require a small amount of time for the onboarding process, and they are assumed to use the app for an average of 1 year.

Table 13 Summary of technology costs

	Alleye	DigiVis DVA	OdySight	OKKO	Peek Acuity
Minimum implementation costs including staff training	£103	£1,640	£206	unknown	£0
Monthly cost per patient including clinic set up, staff training and patient onboarding	£26.45	£23.26[#] (£50.86)	£61.47	Unknown	£0
[#] Assumes DigiVis DVA is administered weekly only, as each test needs to be initiated by staff. Costs in brackets are for testing every 3 days in line with the other technologies					

Model structure

The EAG created a simplified Markov cohort model (Figure 2) that is not specific to any one technology due to the limited evidence that was available in scope. This can be used to discuss the potential implications of introducing home monitoring, in terms of the number of people receiving earlier treatment, and the number of false positives that occur. The starting age was 80 years old, with a cycle length of 1 month and time horizon of 8 years. An NHS and personal social services perspective and discounting at 3.5% was used in line with the NICE reference case (PMG 36)

There are a number of challenges in modelling the diagnostic process for AMD, and these include:

- The varying risk factors for progression to neovascular (wet) AMD.
- The possibility of progression to neovascular (wet) AMD in either eye, with different (but not independent) risk factors.

There are additional challenges that are specific, or are likely to have more impact, for advanced dry AMD (geographic atrophy) including:

- Deterioration of visual acuity can occur in both the advanced dry AMD (geographic atrophy) and neovascular (wet) AMD states over time.
- Use of diagnostic tests may be limited by severe deterioration of visual acuity.

- The impact of treating neovascular (wet) AMD will in part be determined by the persons visual acuity at treatment initiation.
- Utilities are determined by visual acuity, which changes over time, and with treatment for neovascular (wet) AMD.

Fleckenstein et al. (2024) report that for people with advanced dry AMD (geographic atrophy) in a 2 year time frame, approximately half will experience moderate vision loss (≥15 letters on the ETDRS chart), and one-quarter will experience severe vision loss (≥30 letters on the ETDRS chart).

These challenges are typically dealt with by using more complex model structures such as Markov microsimulation or discrete event simulation, however the EAG considered that this was not proportionate to an early use assessment with the current sparsity of clinical evidence.

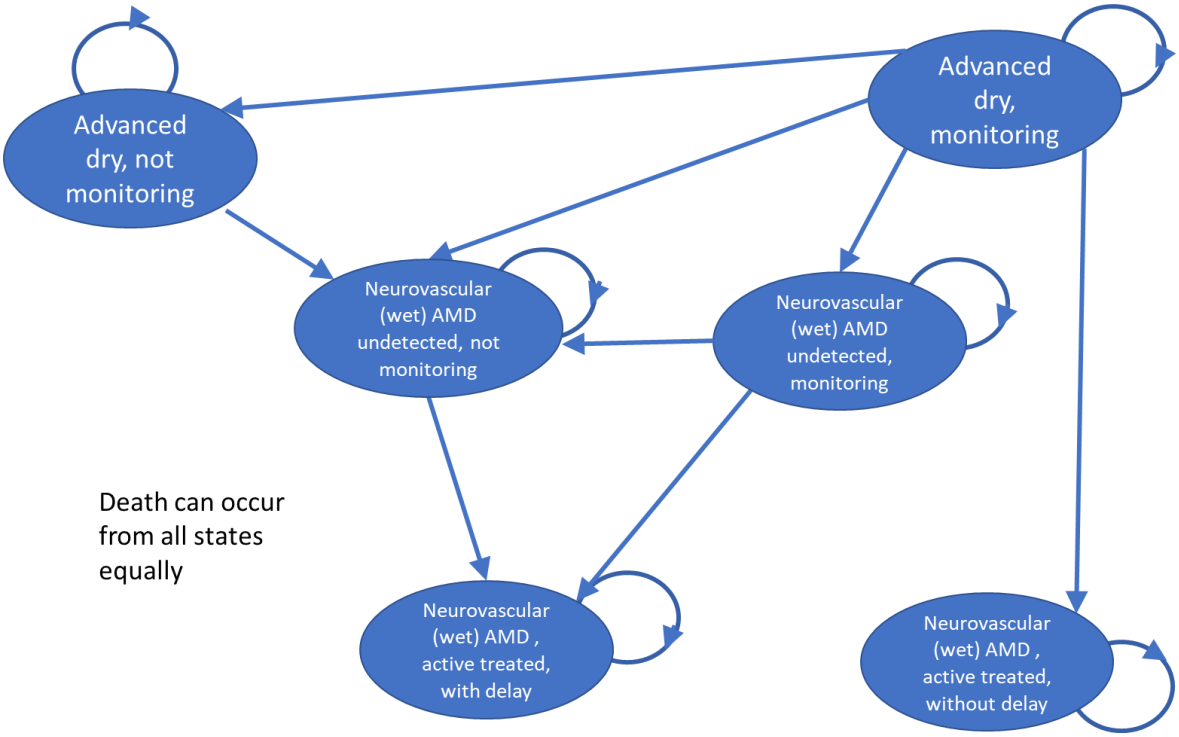


Figure 2 EAG simplified Markov model

Model assumptions

Key model assumptions include:

- Modelling is for one eye only, however for some people both eyes may be eligible. Introducing monitoring in both eyes may increase both the number of early detections and the number of false positives.

- Monitoring is carried out 2-3 times per week, however transition to a new state only occurs once a month.
- People either monitor with the selected intervention or do not monitor at all.
- Monitoring costs are only applied while people are actively monitoring.
- Probability of progression from advanced dry AMD (geographic atrophy) to neovascular (wet) AMD is constant over time.
- The probability of stopping monitoring is constant throughout the model duration.
- People who cease monitoring do not restart.
- Effectiveness of both the intervention and standard care are considered constant over time.
- Changes in visual acuity are not modelled.
- The utility and costs of early or delayed treatment are not included in the model due to the complexities introduced and the scarcity of evidence in scope. The model pathway ceases at the initial diagnosis.

Pathway from monitoring to secondary care

NICE guidance NG82 (NICE, 2018) states that people with early and advanced dry AMD (geographic atrophy) should not be routinely monitored through hospital eye services but should continue to attend routine sight-tests. They are advised to self monitor their AMD and contact an eye-care professional if their vision changes.

Based on this pathway, the EAG model base case assumes that if an alert is raised by the technology, the user would contact their community eye-care professional who would conduct an examination, with possible OCT. This would result in a referral to secondary care services if indicated. The EAG considered that this reflected the introduction of the technology without additional pathway change.

Information from the companies, as well as expert opinion indicated that they would expect the technologies to have a dashboard of results at a secondary care level with alerts received by the secondary care team. Therefore, the EAG have modelled an alternative scenario in which the secondary care team

would receive alerts, and use a telephone triage to ascertain if referral was required, followed by a secondary care visit as needed.

Clinical parameters

The key clinical parameters (Table 14) are the likelihood of progressing from advanced AMD (geographic atrophy) to neovascular (wet) AMD, adherence and diagnostic accuracy for monitoring, and the delay to treatment that would occur in the absence of monitoring.

The EAG has taken an approach of an exploratory model to show the potential for a digital technology that improved uptake, adherence and accuracy to impact on patient care and outcomes. In reality, the evidence for many outcomes is lacking and there is no certainty that these improvements can be realised.

Progression from advanced dry AMD (geographic atrophy) to neovascular wet) AMD

The EAG identified 2 alternative clinical inputs. Ciulla et al. (2023) is a conference abstract reporting a large retrospective study of 18,712 eyes in the US. They reported 25% of eyes with geographic atrophy being diagnosed with nAMD (wet) at 24.7 months. Chakravarthy et al. (2018) reported a study of 1,901 patients in the UK with geographic atrophy in both eyes, and 7.4% developing neovascular (wet) AMD in a 1-year period. Consultation with experts led the EAG to use the rate of 7.4% in 1 year for the model base case.

Expert advice included the suggestion that intermediate AMD may be an alternative population for home monitoring and therefore the EAG investigated this as an additional scenario. The NICE clinical knowledge summary for AMD states that for people with intermediate AMD there is an 18% rate of progression to advanced AMD at 5 years. It should be noted that advanced AMD may include both dry and wet advanced AMD. Chakravarthy et al. (2020) analysed retrospective records for 40,543 people in the UK with diagnoses of early or intermediate AMD. They found rates of developing choroidal neovascularisation (CNV) between 3.2 and 15.2 per 100 patient years, depending on the condition of the study eye. The EAG have used the highest rate (for those with CNV in the fellow eye) for the purposes of an exploratory scenario analysis.

Initial uptake and adherence to monitoring

No evidence was identified for adherence to use of Amsler grids in normal practice. One expert suggested that between half and one third of people would regularly use Amsler grids, and that this would decline over time.

There is some evidence for adherence to digital interventions in people with neovascular AMD, or with a mixture of eye diseases. None of this is specific to advanced dry AMD (geographic atrophy) or intermediate AMD. Experts suggested that there may be higher motivation for monitoring and adherence for people receiving treatment for neovascular (wet) AMD than for other forms of AMD that are not eligible for treatment.

For uptake, Teo et al. (2021) reported 42%, for an implementation of Alleye during COVID, and Bonjean et al. (2025) reported that 48% of those offered a prescription downloaded OdySight and used it more than twice. There is however qualitative evidence pointing towards the acceptability of digital technologies, and uptake is likely to be dependent on the support offered to patients in starting and using the technology. As an exploratory model of the potential impact of a digital technology the EAG have used an assumption of 80%, but with broad ranges for sensitivity analysis.

The EAG have used data from Faes et al. (2023) for the base case, where the authors reported 73.6% of people continued in the study at 18 months follow up. However, this is higher than several other studies such as Bonjean et al. (2025) who reported 55.7% of people being active in the study with an average duration of 5.8 months, or 58% at 1.5 months from Teo et al. (2021) and should be seen as an exploratory value.

Diagnostic accuracy of monitoring

Diagnostic accuracy of monitoring will depend on the visual acuity of patients at the point of testing, as well as environmental and other personal factors. This point was emphasised by an expert with lived experience. Therefore, although the current model uses constant values over time, this may not reflect the experience of users particularly where they have had advanced dry AMD (geographic atrophy) for a longer duration.

Several of the digital technologies trigger an alert after a number of repeated tests, and tests would typically be repeated several times a week. Therefore, the accuracy of monitoring in real world implementation will be different to the accuracy of a single test in a trial setting. Although this may not formally be the case for the Amsler grid, it is likely that the point at which users seek professional assessment is different from the interpretation of a clinician on a single supervised Amsler grid test. The EAG noted that Banister et al. (2022) found that when they implemented measured sensitivity and specificity results into a model, the model calculated an exaggerated number of false positives. They resolved this by re-calculating the specificity based on observed false positives.

For these reasons, combined with the sparsity and variation in available evidence the EAG used what should be considered a nominal value for the

overall monthly sensitivity and specificity, and used sensitivity analysis to investigate the impact of variation.

The sensitivity and specificity of Amsler grids is based on a systematic review and meta-analysis of diagnostic accuracy reported by Bjerager et al. (2023). The authors included 10 studies with a total of 1,890 eyes to calculate a sensitivity of 71% (95%CI, 60%-80%) and specificity of 63% (95%CI,49%-51%) to detect neovascular AMD when the comparators were people with non-neovascular AMD. The authors noted that in the included studies, testing was carried out in a controlled environment that may not reflect home monitoring. Banister et al. (2022) reported a sensitivity of 26.5% and specificity of 93.7% for Amsler grid in a supervised setting to detect neovascular (wet) AMD in people with neovascular (wet) AMD in the fellow eye, but either no AMD or non-neovascular AMD in the study eye.

For the digital technologies, no evidence was available that was appropriate for the population described in the scope. Assumptions of values have been made by the EAG in order to explore the potential impact of monitoring at home in this population. Due to the lack of appropriate evidence in this population, the model is not linked to any single technology and should be considered exploratory only.

Accuracy of primary care referrals to secondary care

Fulcher et al. (2025) reported results of a retrospective analysis of referrals to a secondary care unit in Bradford between March 2019 and March 2021. They found that 39.8% of referrals for suspected neovascular (wet) AMD from primary care resulted in a positive diagnosis of neovascular (wet) AMD. For these patients, OCT data was included in the referral in 9.1% of cases pre-COVID and 23.7% during COVID. Similar results were reported by Muen and Hewick (2011) who found 37% of referrals resulting in a positive diagnosis of neovascular (wet) AMD. Sanders et al. (2024) reported a retrospective analysis of all patients referred and assessed for neovascular (wet) AMD in 2 phases (i) April 2019 to March 2020 n=394, and (ii) April 2020 to March 2021 n= 414, within Swansea Bay University Health Board. They reported 26% of referrals requiring treatment in phase 1, rising to 56% in a specialist community optometry hub. Both phases included the use of OCT.

The EAG model therefore used 39.8% for the number of referrals that result in diagnosis of neovascular (wet) AMD. The accuracy in the model was constant regardless of the proportion of patients who received OCT during primary care.

Accuracy of secondary care referrals

The model assumes that diagnosis at secondary care is accurate and requires 1 outpatient visit with appropriate testing, and that this is applied to all those who enter either of the treated states.

Detection of progression without monitoring

This has been estimated as a monthly probability of 0.3, based on responses by clinical experts to EAG questions, with sensitivity analysis applied to investigate the impact.

Clinical experts suggested ranges from 6 weeks to 6 months, and 2 to 3 months. Experts noted that this would depend on the visual acuity in the unaffected eye, as this will impact on how likely the person with AMD was to notice the deterioration. Experts with lived experience noted that results from home monitoring were very dependent on environmental conditions and personal factors.

Table 14 Main clinical parameters

Variable	Value	Range for DSA	Source	EAG commentary on availability, quality, reliability and relevance of the source
Monthly probability of developing neovascular (wet) AMD, from advanced dry AMD (geographic atrophy)	0.006	- 50%, 0.012	Chakravarthy 2018, Ciulla 2023	From an observed rate of 0.074 over a 12 month duration. High value from Ciulla 2023, 25% in 24.7 months
Monthly probability neovascular (wet) AMD detected without monitoring	0.3	0,1	Clinical experts	Ranges between 6 weeks and 6 months depending on multiple factors
Probability of a referral from primary to secondary care for a non-progressed patient	0.602	+/- 50%	Fulcher 2025	Retrospective analysis showed 39.8% of referrals from primary care resulted in positive diagnosis
Parameters to calculate costs of one off set up during implementation (very small impact on device costs)				
Incidence of advanced dry AMD (geographic atrophy) in UK	44,000	n/a	RCO 2024	RCO Commissioning Guidance Age Related Macular Degeneration Services: Evidence Base

Variable	Value	Range for DSA	Source	EAG commentary on availability, quality, reliability and relevance of the source
Number of providers	109	n/a	Atlas of Variation 2021	Vision Atlas states: Core ophthalmology services are provided in most NHS Trusts with specialist services in more than 100 locations providing care on a 'Hub and spoke' model with local hospitals. This is for England. 9 health boards in Wales also added
For Interventions	The EAG found no evidence in the population described in the scope, therefore inputs have been assumed and should be treated with caution.			
Initial uptake	0.80	0.42,1		Assumption, with Teo 2021 for lower bound.
Adherence	0.983	- 50%,1	Faes 2025	76% of people were still monitoring at last follow up in 18-month study
Sensitivity	0.8	- 50%,1	Assumption	Informed by Hogg 2024
Specificity	0.9	- 50%,1	Assumption	Informed by Faes 2022 (93.8%) and Bonjean (94.3%)
For standard care (Amsler grid)				
Initial uptake	0.5	- 50%,1	Expert opinion	Between 1/2 to 1/3 will start, and adherence will decrease over time
Adherence	0.8	- 50%,1		
Sensitivity	0.71	- 50%,1	Bjerager 2023	Bjerager et al. (2023) A systematic review and meta-analysis of the diagnostic accuracy of the Amsler Grid
Specificity	0.63	- 50%,1		

Resource use and cost parameters

For the technologies, monthly costs are based on either a cost per test, per month or per year. Additional parameters included assumptions around the number of patients treated, staff to be trained and time that monitoring would be used for, as these inform how the implementation costs are incorporated into monthly monitoring costs per patient. Most variations on these parameters have very limited impact on the overall findings. As the model is not linked to a single technology, but is exploratory, a mean of the estimated costs for included technologies has been used, alongside sensitivity analysis.

Other costs included (Table 15) are the costs of a primary care eye test (including OCT in primary care for a proportion) and the costs of a review in secondary care. A primary care visit is included for all patients who have an alert (false positive or true positive). Secondary care referral costs are included for all patients who have a true positive and for a small proportion of those with a true negative where OCT results may not have been decisive.

Cost of primary care visit

The cost of the primary care visit is made up of 2 components, the NHS fee for a standard eye test, of £24.13, with an additional cost of OCT for a proportion of patients. The additional cost is based on a bottom-up costing for the marginal cost of OCT in secondary care (Banister 2022), however it falls within the range of costs charged by community optometrists for a privately funded OCT carried out in addition to an eye test. Expert advice was that some people would receive an OCT at a primary care visit, although some of these would be privately funded. The EAG base case assumes an OCT if funded for 50% of visits, however this is tested extensively in sensitivity analysis and has only a small impact on overall costs.

Cost of secondary care dashboard and triage

The cost of a dashboard is included in the technology costs for all companies. The EAG have assumed that there would be minimal monitoring of the dashboard, but that the team would rely on the alert system to trigger an action. At this point there would be a telephone call to the user to discuss their monitoring results and any other symptoms or tests, followed by a secondary care referral if needed. In the absence of other information, the accuracy of the triage system is assumed to be similar to a primary care appointment.

Cost of secondary care referral

Secondary care referral costs are based on data from the NHS Cost Collection 2024-25, of £181. This would include a consultant appointment and OCT within the same visit.

Table 15 Key cost parameters

Parameter	Value	Range for DSA	Source	EAG commentary on availability, quality, reliability and relevance of the source/s
Technology cost per month per patient	£37.06	+/- 50%	Company RFEs	Mean of all submitted information including set up and training.
Primary care appointment	£24.13	+/- 50%	UK Government 2025	General ophthalmic services fees from 1 April 2025. Cost to primary care optometrist for sight test

Parameter	Value	Range for DSA	Source	EAG commentary on availability, quality, reliability and relevance of the source/s
Addition of OCT	£23.38	£10, £50	Banister 2022	Bottom up costing for marginal cost of OCT in secondary care (£19.45 inflated from 2019). £10-£50 if paid privately in addition to eye test
Proportion of primary care appointments with funded OCT	0.5	0,1	Assumption based on experts, Fulcher 2025 and Sanders 2024	Experts indicated that some patients would receive OCT, and some would self fund. Studies reported between 9 and 100%
Cost of testing in primary care	£35.82	Calculated from rows above, with 50% of visits receiving OCT		
Secondary care appointment	£181	+/- 20%	NHS Cost Collection 202-45	BZ87A Minor Vitreous Retinal Procedures, 19 years and over, 2024-5 NHS cost collection

Health state utilities

Health state utilities are not included in the model due to the lack of clinical effectiveness evidence and the complexities described in previous sections. However the EAG have described the approaches used in existing models, and the applicability for future modelling.

Previous evaluations accepted by NICE have demonstrated an acceptance that utilities should be based on visual acuity rather than an EQ-5D value. The NICE guideline for diabetic retinopathy (NG242) published in 2024 includes a health economic appendix which compares the different available studies and their strengths and limitations. Those widely used include Brown et al. (1999), Sharma et al. (2000), Czoski-Murray et al. (2009) and more recently Pennington et al. (2020). The 2018 NICE guideline NG82 for age-related macular degeneration uses Czoski-Murray et al. (2009) in the base case, with the following equation:

Utility = 0.860 + 0.001 * age in years – 0.368 * BSE VA

Where BSE is the best seeing eye, and VA is visual acuity.

Brown et al. (2000) is used as a scenario analysis, with age weighting being added from the general population values from EQ-5D.

Future modelling in the topic would likely be based on visual acuity, and allow the associated utilities to deteriorate in the model with or without progression to neovascular (wet) AMD, as well as making allowances for age and visual acuity of the second eye. These considerations could be implemented using a microsimulation Markov approach and informed by individual patient level data from real world evidence.

Model validation

The model structure, assumptions and calculations were reviewed by a second health economist within the EAG team. Inputs were taken from peer reviewed sources, standard references and expert advice. Questions on the pathway and key inputs were circulated to experts for comments as part of the validation process.

Presentation of results

Results were presented in the form of a cost-consequences table and a cost per additional early diagnosis. Deterministic sensitivity analysis was used to determine the key parameters that influence the model outcomes. Where alternative values had been identified these were used as high or low values. Where these were not available a 50% variation was used where there were high levels of uncertainty for the correct parameter values, with a maximum of 1 for probabilities. Probabilistic sensitivity analysis was not completed as the model was exploratory and deterministic sensitivity analysis allowed investigation of key drivers and different scenarios.

Best and worst case scenarios were used to explore combinations of parameters. Both used full uptake and 100% adherence, but varied the sensitivity and specificity. This is because the largest impact of the technology is seen when it is used for longest period of time. A worst case would be prolonged use of a monitoring technology that incurred costs but did not improve outcomes.

Additional scenarios considered triage in secondary care rather than people contacting primary care eye services, a shorter time horizon and a rate of conversion to neovascular (wet) AMD based on a population with intermediate AMD.

Finally, a scenario was created that made a simplified consideration of users monitoring both eyes. This allowed two eyes to enter the model, however they are both treated independently in terms of progression to neovascular (wet) AMD, and diagnosis. The cost of monitoring is shared between two eyes, but each eye may generate false positives.

6.5 Results from the economic modelling

Base case results

The base case results (Table 16, Table 17, Table 18) show the costs and consequences up to the point of diagnosis only, and parameters are based on very limited evidence. The model should be seen as a means to explore the potential of any technologies that improve adherence and accuracy to achieve earlier diagnosis of neovascular (wet) AMD when used in a population with advanced dry AMD (geographic atrophy), and to explore the costs of monitoring.

When interpreting these results it is important to note that earlier diagnosis is expected to have a positive impact on outcomes and subsequent quality of life, however the extent of this is not possible to determine with the current evidence.

The EAG base case uses a generic technology with a monitoring cost of £37 per month, and sensitivity and specificity of 80% and 90% respectively. It assumes that 80% of the cohort would take up the intervention and calculates that 65% of those eligible would still be using it after 1 year. Compared with use of a printed Amsler grid, there is an additional £1,145 per person when monitoring with the digital technology. This is due to the cost of monitoring as well as increased costs of false positives associated with the longer continuation of home monitoring compared to using the Amsler grid.

The EAG base case results in the identification of an additional 12.41 people with neovascular (wet) AMD per 100 people modelled compared to using the Amsler grid. Using the generic technology would require a cost of £9,228 per additional early diagnosis.

Table 16 Cost breakdown per person

	Digital technologies for monitoring vision change in AMD	Standard care	Incremental
Costs	**£1,342**	**£197**	**£1,145**
Technology costs	£914	£0	£914
Costs for true positive	£71	£70	£1
Costs for false positive	£357	£127	£230
		Cost per earlier diagnosis	**£9,228**

Table 17 Events per 100 people

Consequences up to point of treatment start (per 100 people)	Digital technologies for monitoring vision change in AMD	Standard care	Incremental
Number treated for neovascular (wet) AMD	36.58	36.25	0.33
Number of false positives	22	7	14.80
Number of early detections	13	1	12.41
Number of delayed detections	23	35	-12.07

Table 18 Time spent in each state, per person

Time in model states, per person	**Digital technologies for monitoring vision change in AMD**	**Standard care**	**Incremental**
Total years in advanced dry AMD (geographic atrophy) state	4.95	4.95	0.00
Total duration of monitoring	2.22	0.20	2.02
Total years in undetected neovascular (wet) AMD	0.06	0.10	-0.04
Total years in neovascular (wet) AMD, early detection state	0.63	0.05	0.57
Total years in neovascular (wet) AMD, delayed detection state	0.83	1.36	-0.54

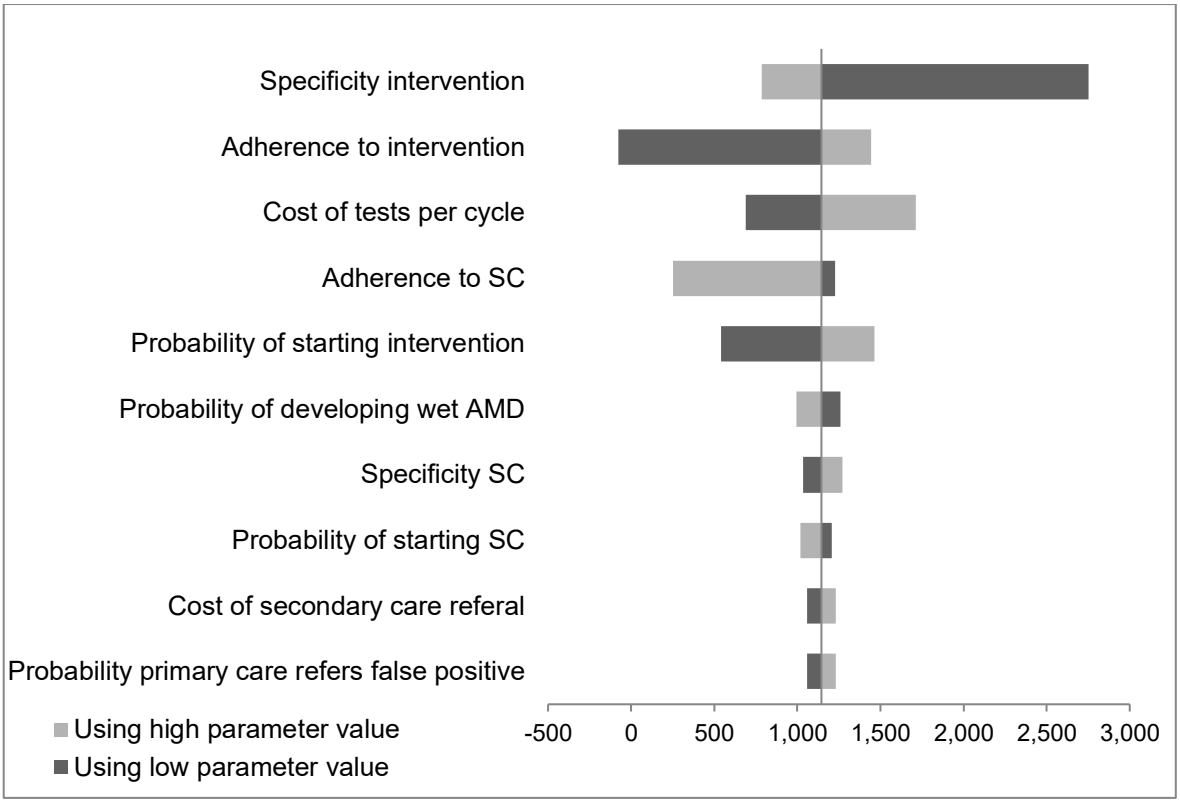
Sensitivity analysis results

Using one way sensitivity analysis, the cost per person of using a monitoring technology compared to standard care ranges from -£78 to £2,752 (Figure 3). The biggest drivers of cost are adherence, specificity of the intervention, cost of the home monitoring, probability of starting the intervention and probability of developing neovascular (wet) AMD.

When looking at the additional number of people diagnosed without delay, this ranged from -0.79 to 19.43 per 100 people compared to standard care (Figure 4). The largest drivers were adherence, probability of developing neovascular (wet) AMD, sensitivity of the intervention and probability of starting the intervention.

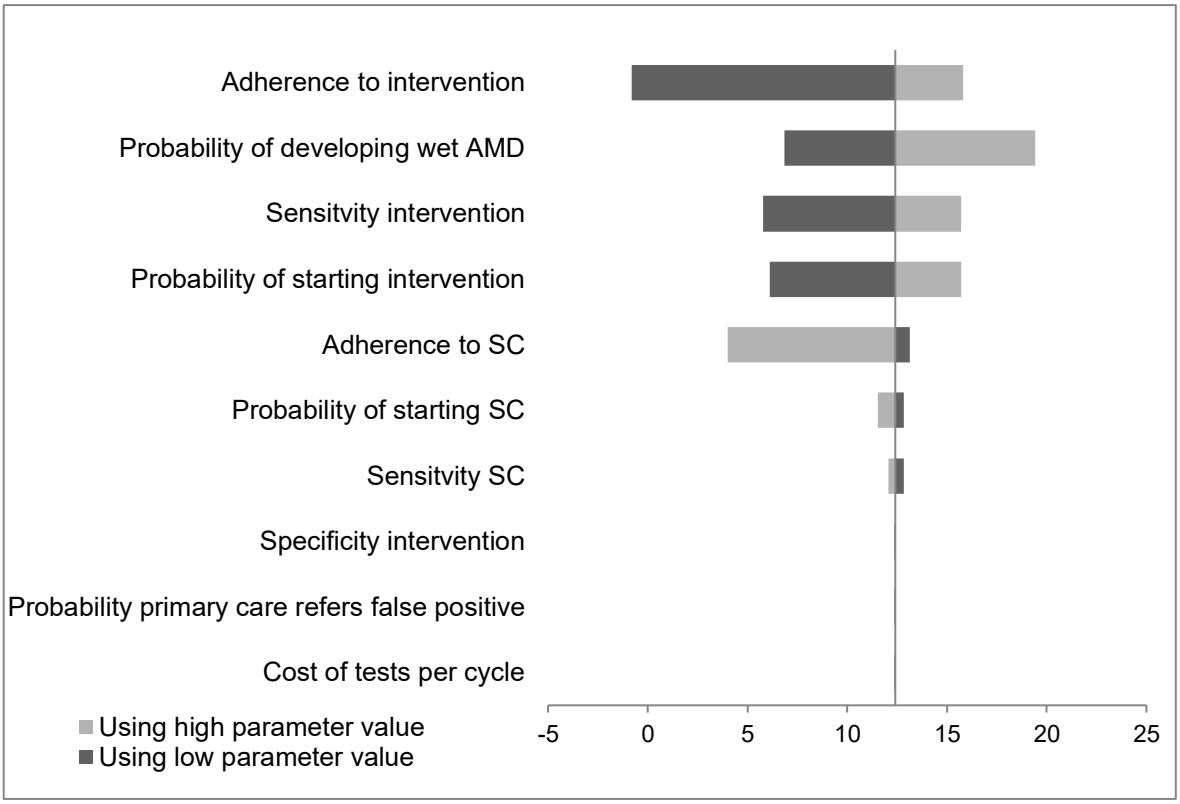
When these are combined to give the cost per additional early detection, the range is from £5,109 to £22,184 per person diagnosed early compared to standard care (Figure 5). The key drivers are probability of developing neovascular (wet) AMD, intervention sensitivity and specificity and costs of monitoring.

A high value for adherence to standard care is taken as 0.99, however values beyond this can result in extreme ranges. A value of 0.999 results in the intervention being cost saving (due high numbers of false positives in the standard care arm), but with less than 1 additional early detection per 100 people. A value of 1 results in the intervention being cost saving, but resulting in 0.06 fewer earlier detections per 100 people.



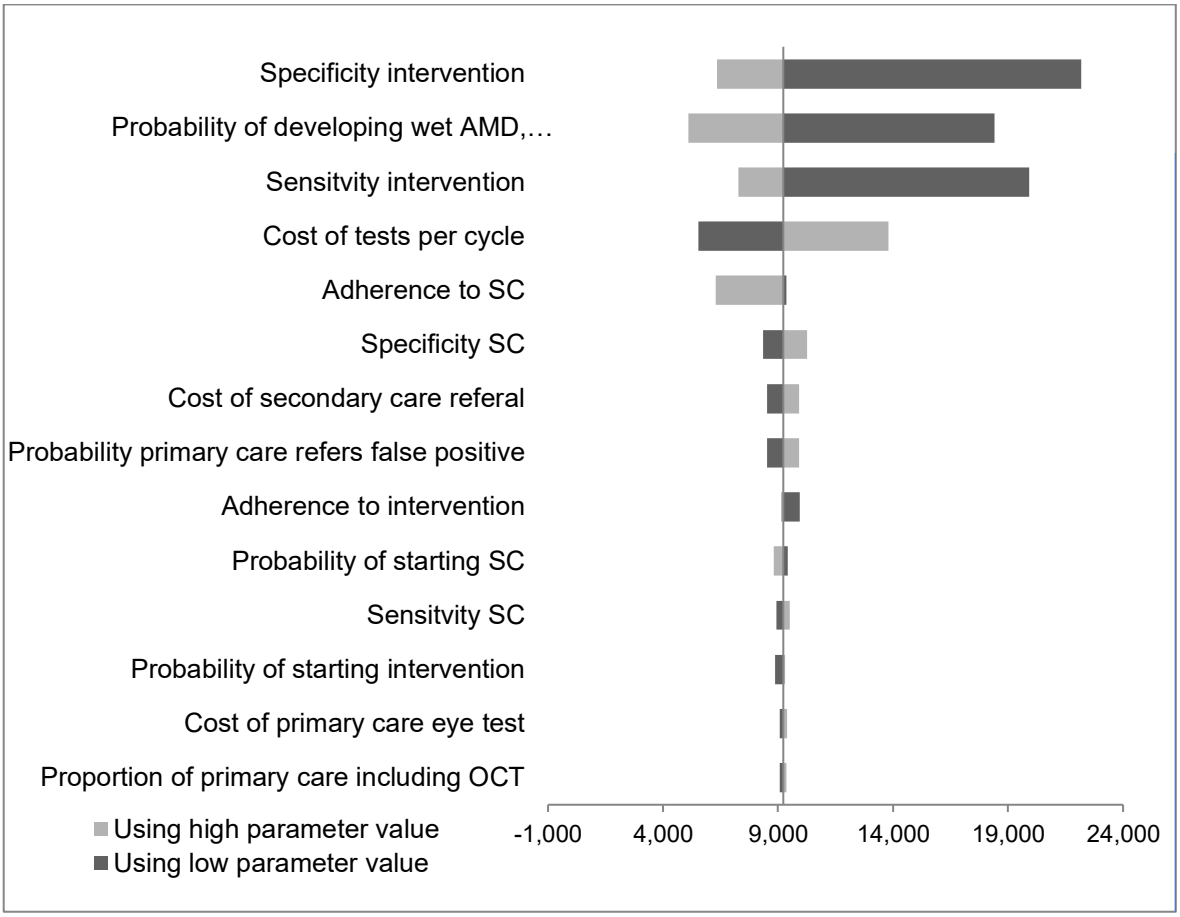
AMD: age related macular degeneration; OCT Optical coherence tomography; SC: standard care

Figure 3 Tornado diagram for EAG base case, incremental cost



AMD: age related macular degeneration; OCT Optical coherence tomography; SC: standard care

Figure 4 Tornado diagram for EAG base case, incremental early diagnoses



AMD: age related macular degeneration; OCT Optical coherence tomography; SC: standard care

Figure 5 Tornado diagram for EAG base case, incremental cost per additional early diagnosis

Scenario analysis results

Six scenarios were used to investigate the impact of uncertainties not fully captured in the base case results and one way sensitivity analysis. The scenarios are summarised in Table 19, and the results in Table 20.

Table 19 Summary of scenarios

Scenario name	Description
1. Best case	100% uptake and adherence, perfect accuracy for intervention (standard care unchanged). Lowest device cost
2. Worst case	100% uptake and adherence, but accuracy equivalent to Amsler grid. Highest device cost
3. (a) Secondary care dashboard	Cost of primary care test replaced by 10 minute telephone consultation with

	ophthalmologist. Accuracy is assumed to be the same as testing in primary care
3. (b) Secondary care dashboard	Cost of primary care test replaced by non-face to face follow up consultation, not consultant led. Accuracy is assumed to be the same as testing in primary care
4. Two eyes	Two eyes entered into the initial cohort and progress through model independently. Cost of monitoring is halved (shared between 2 eyes), but probability of false positive is applied to each eye. Eyes are considered independently
5. Intermediate AMD population	Probability of progression to neovascular (wet) AMD is based on intermediate AMD population
6. 3 year time horizon	Reduce time from 8 to 3 years

Table 20 Key scenario results

	Incremental cost	**Incremental number of early diagnoses**	**Incremental false positives**	**Incremental cost per early diagnosis**
Base case	**£1,145**	**12.41**	**14.80**	**£9,228**
1. Best case	£863	36.69	-7.41	**£2,352**
2. Worst case	£5,941	25.80	176.28	**£23,025**
3. (a)Secondary care dashboard	£1,115	12.41	14.80	**£8,989**
3. (b)Secondary care dashboard	£1,255	12.41	14.80	**£10,112**
4. Two eyes	£1,377	24.81	29.60	**£5,549**
5. Intermediate AMD population	£941	21.68	11.17	**£4,342**
6. 3 year time horizon	£823	8.60	8.62	**£9,572**

Key points to note are that even the best case scenario (a perfect test, at the lowest cost point) will be cost incurring. It does reduce the false positives compared to the Amsler grid, but this does not counteract the cost of monitoring. The worst case scenario (monitoring with accuracy the same as Amsler grid, but 100% use and the highest price point) incurs large costs both through the extended monitoring and the resultant higher level of false positives.

The use of a secondary care dashboard with an assumption of 10 minutes of clinical time results in very similar findings to the base case, but will shift resource use from primary to secondary care. Where the cost is taken as a non face to face consultation, the resulting incremental cost per early detection is higher than the base case.

When including a simplified approach to including 2 eyes, there are more eyes available to move to neovascular (wet) AMD, and therefore an increased number of early identifications. However, there is also increased monitoring (occurring for each eye) resulting in increased false positive results.

A shorter time horizon reduces both the costs and numbers of early identifications, however the cost per early diagnosis remains almost unchanged.

For the intermediate AMD population, a higher probability of conversion to neovascular (wet) AMD results in increased earlier diagnosis and slightly reduced false positive, reducing the incremental cost per early diagnosis by over half compared to the base case.

6.6 Summary and interpretation of the economic evidence

The EAG did not identify any published economic evidence that met the decision problem in the scope. Two companies submitted budget impact analyses, however only 1 was fully relevant to the scope (Alleye). This demonstrated the expected use of a triage model of care, and potential impact of false positive alerts, but did not consider the rate of conversion to neovascular (wet) AMD. The BIA resulted in [redacted]

Although there are many models published that consider age-related macular degeneration, the majority focus on treatment of neovascular (wet) AMD. The EAG identified a small number that consider either diagnosis or screening, however none of these were directly applicable to the scope. The majority used microsimulation, or similar methods to incorporate the heterogenous populations and the impact of changes in visual acuity at different points in the pathway.

There was insufficient clinical evidence to create a health economic model for any of the technologies in the scope. Therefore, the EAG created a simplified model to explore the potential impact of monitoring a technology that improves uptake and adherence and is more accurate than an Amsler grid. The model explored the proportion of people with advanced dry AMD (geographic atrophy) that might develop neovascular (wet) AMD in the model's 8 year time

horizon, and the impact of false positives depending on the technology characteristics. The model does not capture the pathway beyond diagnosis, and therefore does not include any potential consequences of earlier diagnosis.

The EAG used a base case with a generic technology that was assumed to have better uptake, adherence, specificity and sensitivity than an Amsler grid, together with an 8-year time horizon, and an NHS perspective. This resulted in an incremental cost of £1,145 compared to standard care. Per 100 people there were an additional 12.41 early detections, as well as an additional 14.80 false positives. Within that 8-year period, 37% of people were diagnosed and treated for neovascular (wet) AMD. The majority of people in the model did not convert to neovascular (wet) AMD and therefore could not benefit in terms of earlier detection. It is possible that they experience benefits in terms of reassurance or empowerment, however this is not captured in the model or any available evidence.

The intervention is bringing an additional monitoring function into the pathway at an early stage, and the health economic modelling currently ceases at the point of diagnosis. Therefore, it is to be expected that all the technologies are cost incurring, as most benefits would be expected to occur after diagnosis, due to an earlier treatment start for neovascular (wet) AMD. Although utilities are not included in the model, the earlier treatment has potential to reduce vision loss and therefore increase utilities.

It is also the case that costs may be higher for those technologies that successfully increase adherence and uptake. When monitoring is used for longer it has potential to increase both early detection and the number of false positives. This means that technologies that improve monitoring are likely also to incur higher costs for any given accuracy level.

False positives will incur additional costs and resource use which may be testing in a community setting with or without OCT, or a secondary care triage system. Either of these will result in some referrals to secondary care that do not result in a positive diagnosis. The impact of this depends on uptake and adherence of the monitoring, the specificity, and the demographic in which it is used, as well as the pathway in which monitoring is adopted. There is potential that some resource use currently occurring in the community could be shifted to secondary care for triaging and testing people who receive alerts.

Given that many people will remain in the advanced dry AMD (geographic atrophy) state for a number of years, it is likely that they will experience significant deterioration of their eyesight. This may impact on their ability to use the monitoring system fully, or change the accuracy of monitoring. In addition, the treatments available for neovascular (wet) AMD will not alter the

loss of sight that is due to advanced dry AMD (geographic atrophy), and therefore as time passes in the model, the ability to gain utilities by earlier treatment may diminish. This is not considered in the current model.

This complexity, and the bilateral nature of eye disease means that the current model can be seen as exploratory only, but highlights both the rate of conversion to neovascular (wet) AMD, the potential for earlier detection and the cost of false positive alerts. Current guidance (NG82), including clinical and cost-effectiveness evidence, recommends treating people who have changed to neovascular (wet) AMD within 2 weeks to avoid further deterioration of vision. However, it is not currently possible to determine what the impact of this earlier treatment would be on the modelled population.

7. Integration into the NHS

Key considerations identified by the EAG relating to the integration of these technologies into the NHS are summarised in this section. This is informed by evidence from studies identified that were set in the UK, responses to questions posed by the EAG to clinical experts, and submissions received by NICE from the companies and professional organisations during this assessment.

Clinical pathway

The current clinical pathway for people with advanced dry AMD (geographic atrophy) does not involve regular clinical review within the NHS. Possible progression of a person's disease might be identified at a routine sight test, or by the person themselves through home self monitoring, at which point they can be reviewed by ophthalmology in the NHS through primary care.

Home self monitoring is performed by people using tools such as the Amsler grid. The inclusion of these technologies in the clinical pathway would replace the use of the Amsler grid and other tools. For Alleye, OdySight, and OKKO for AMD, the self monitoring performed by people at home is shared with clinicians in the NHS. This allows clinicians to identify any potential progression in disease themselves and alert people to this, prompting the requirement for a clinical review. Previous implementations have used this in a specialised clinic setting, and people receiving an alert at home would contact the clinic, go through a virtual triage process prior to clinical review in secondary care if needed. These have typically been for people with neovascular (wet) AMD.

DigiVis DVA is designed to be fully integrated into NHS clinical pathways, allowing clinicians to communicate with people and prompt them perform a vision test ahead of an ophthalmology appointment. However, it is not

intended to be integrated into the clinical pathway outlined in the decision problem.

Peek Acuity does not have a method to integrate into the clinical pathway. It is a tool that clinicians can instruct people to use at home, however no test results are stored on the user's phone, or shared with the NHS.

IT integration and ongoing technical support

Information provided by the companies for Alleye, DigiVis DVA, and OdySight states that these technologies can function as a stand alone interface and integration into NHS systems is optional.

For Alleye, and OdySight, ongoing technical support is provided to both patients and staff by the companies.

Staff training

Information from 3 of the companies states that additional staff training would be required for Alleye, DigiVis DVA, and OdySight. This training is included within the price of the technology to the NHS. The training would be minimal in nature, taking up no more than an hour of the staff member's time. Support and training materials are also provided to staff.

8. Evidence gap analysis

8.1 Ongoing studies

The EAG identified 1 ongoing study which was relevant to the decision problem. This is presented in Table 21.

This study is for OKKO for AMD. It includes a sample of both people with dry and wet AMD, and includes outcomes listed in the scope of this assessment. However, the lack of details about the study leaves it unknown if this study can fill any evidence gaps for OKKO for AMD.

Table 21: Summary of relevant ongoing studies

Study details, status	Population	Device, Comparator	Outcomes relevant to scope	EAG Comments
OKKO for AMD (1 study)				
Study name OKKO Health Hyperacuity, Contrast and Colour Game Validation in Age-related Macular Degeneration **Study number:** NCT05569226 **Study design:** Cross-sectional cohort study **Location:** Bristol, UK **Status:** Unknown **Estimated study completion date:** 01/06/2023 **Aim:** To assess the use of OKKO for AMD in people with dry and wet AMD	**Population:** People with dry or wet AMD **Estimated enrolment**: 50 **Inclusion criteria:** • Participants with AMD in at least 1 eye • Willing to travel to the clinic in Exmouth/Bristol • Able to hold and use a smartphone **Exclusion criteria:** • Significant ocular pathology other than AMD • Unable to provide written informed consent	**Device**: OKKO **Intervention:** Use of OKKO for an unknown period **Comparator:** Unknown	**Primary outcome(s):** • Visual acuity collected in the OKKO Health app and via ETDRS chart • Contrast sensitivity collected in the OKKO Health app and via Pelli Robson chart • Colour sensitivity collected in the OKKO Health app and via City University colour test/Mollon-Reffin colour vision test **Secondary outcome(s):** • Visual distortion assessed using the OKKO Health app and Amsler chart • Scans obtained from OCT	Very limited information is available for this study. All details reported were obtained from the ClinicalTrials.gov registry entry The company was contacted for further information, but none was provided

8.2 Evidence gap analysis

Table 22 summarises the evidence gaps related to groups of outcomes in the scope of this assessment for each technology. **GREEN** indicates there is good evidence available, **AMBER** indicates there is partial evidence available, even if that evidence is limited, **RED** indicates there is no evidence available.

It should be noted that Table 22 is focused on evidence for the decision problem described in the scope, and does not reflect the available evidence for these technologies in other populations.

Table 22: Evidence gap analysis

Outcomes	Alleye	DigiVis DVA	OdySight	OKKO	Peek Acuity
Diagnostic performance	AMBER	RED	RED	RED	RED
Detection of disease progression	RED	RED	RED	RED	RED
Time to first treatment in the affected eye	RED	RED	RED	RED	RED
Visual and clinical outcomes	AMBER	RED	RED	RED	RED
Safety and adverse events	RED	RED	RED	RED	RED
Patient centred outcomes	RED	RED	RED	RED	RED
Patient usability and acceptability	AMBER	RED	AMBER	RED	RED
Clinician experience and system implementation	AMBER	AMBER	AMBER	RED	RED
Costs and healthcare resource use	AMBER	AMBER	AMBER	RED	RED

8.3 Key areas for evidence generation

The only evidence available that is within scope is for Alleye and OdySight. This evidence covers diagnostic performance, visual and clinical outcomes, and patient usability and acceptability. Significant evidence gaps exist for the

other technologies across all outcomes in scope. Key gaps identified by the EAG as priorities for evidence generation are summarised in Table 23 below.

Table 23: Areas for evidence generation

Evidence gap	Recommended outcomes to be collected
Diagnostic performance and detection of disease progression	• Diagnostic accuracy for detecting progression to neovascular (wet) AMD from advanced dry (geographic atrophy) AMD • Sensitivity and specificity of the technologies to detect neovascular (wet) AMD • Time to identify and confirm disease progression • Time to first treatment after disease progression • Detection of AMD in the fellow eye
Visual and clinical outcomes	• Percentage of people that maintained functional vision in the affected eye • Change in functional test scores • Proportion of people with a Certificate of Visual Impairment
Patient centred outcomes and usability	• Vision related quality of life • User acceptability, views, experience and satisfaction using the technologies of people with advanced dry AMD (geographic atrophy) • User adherence to home monitoring with the technologies
Clinician experience and system implementation	• Clinician confidence in home monitoring technologies • Clinician acceptability and user experience

Where evidence is generated for the technologies, sufficient detail should be collected and reported in relation to:

- The demographics of included participants.
- Visual acuity of participants at baseline and subsequently.

- Specifics about the participant's AMD condition (dry, geographic atrophy, neovascular etc.).
- The type of setting (primary/community or secondary care).
- If staff are involved in the usage of the technologies.
- The specific generation or version of technology being investigated.

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10. Appendices

Appendix A: Search strategies

Appendix B: PRISMA flow diagram

Appendix C: Excluded studies

Appendix A: Search strategies

The EAG conducted a search for clinical and economic evidence as directed in the published protocol. Five bibliographic databases were searched from inception to February 2026 using a combination of free text terms and indexed terms. The searches included generic terms for smartphone apps, device names, company names, and terms for macular degeneration. Two clinical trial registries were also searched for ongoing trials. Relevant guidelines were identified by searching guideline databases. The MHRA alerts and MAUDE database were searched for any safety notices or adverse events for the technologies. The companies' websites were searched for additional literature and evidence provided by companies in RFEs was also considered.

Clinical and economic database searches

Date	Database Name	Total number of records retrieved	Total number of records from database after de-duplication
18.02.2026	Medline ALL	231	
18.02.2026	Embase	448	
20.02.2026	Cochrane Library CDSR CENTRAL	 1 48	
20.02.2026	INAHTA	1	
20.02.2026	Clinical Trials.gov	77	
20.02.2026	ICTRP	12	
27.02.2026	NICE	1	
27.02.2026	SIGN	0	
27.02.2026	Health Technology Wales	1	
27.02.2026	MHRA	1	
27.02.2026	FDA MAUDE	0	
Database searches total **Guideline searches total** **Safety notices total**		**818** **2** **1**	**587**

Company websites searches

Date	Company websites	Total number of records retrieved	Total number of records after de-duplication
12.01.2026	Oculocare Medical Inc Alleye	19	
12.01.2026	OKKO Health	0	
12.01.2026	Cambridge Medical Innovation Ltd DigiVis DVA	4	
12.01.2026	Tilak Healthcare Odysight	3	
12.01.2026	Peek Vision Peek Acuity	9	
Total		**35**	**13**

Company RFE searches

Date	Company Name	Total number of records retrieved	Total number of records after de-duplication
24.02.2026	Oculocare Medical Inc	13	
24.02.2026	Cambridge Medical Innovation Ltd	8	
24.02.2026	Tilak Healthcare	4	
Not received	Peek Vision	NA	
Not received	OKKO Health	NA	
Total		**25**	**11**

EAG Search strategies for clinical and economic evidence

Ovid MEDLINE(R) ALL <1946 to February 18, 2026>

1	macular degeneration/	20092
2	geographic atrophy/	1362
3	(macula* adj2 (degenerat* or disease* or pathologi*)).tw.	31634
4	Maculopath*.tw.	6294
5	(AMD and macula*).tw.	14448
6	(AMD adj3 (age or advance* or dry or late)).tw.	3124
7	geographic atroph*.tw.	2224
8	atrophic AMD.tw.	183
9	or/1-8	41477
10	Smartphone/	12820
11	Mobile Applications/	16613
12	(smartphone* or app or apps or mHealth or mobile*).tw.	220467
13	(web* adj3 application*).tw.	7985
14	"puzzle games".tw.	31
15	(hyperacuity and app).tw.	6
16	or/10-15	229396
17	9 and 16	158
18	alleye.tw.	10
19	DigiVis.tw.	4
20	Odysight.tw.	4
21	OKKO.tw.	0
22	Peek Acuity.tw.	16
23	Oculocare.tw,in.	9

24	cambridge medical innovation.tw,in.	0
25	Tilak Healthcare.tw,in.	4
26	Peek Vision.tw,in.	47
27	"Peek Community".tw.	3
28	or/18-27	83
29	OKKO.tw,in.	76
30	tilak.tw,in.	2759
31	or/29-30	2835
32	9 and 31	1
33	17 or 28 or 32	236
34	exp animals/ not humans.sh.	5425543
35	33 not 34	231

Embase <1974 to 2026 Week 07>

1	age related macular degeneration/	34538
2	geographic atrophy/	4026
3	(macula* adj2 (degenerat* or disease* or pathologi*)).tw.	45073
4	Maculopath*.tw.	8029
5	(AMD and macula*).tw.	21980
6	(AMD adj3 (age or advance* or dry or late)).tw.	5220
7	geographic atroph*.tw.	3871
8	atrophic AMD.tw.	300
9	or/1-8	61259
10	smartphone/	43832
11	exp mobile application/	39648

12	(smartphone* or app or apps or mHealth or mobile*).tw.	302461
13	(web* adj3 application*).tw.	11167
14	"puzzle games".tw.	36
15	(hyperacuity and app).tw.	14
16	or/10-15	326913
17	9 and 16	356
18	alleye.tw.	19
19	DigiVis.tw.	10
20	Odysight.tw.	9
21	OKKO.tw.	10
22	Peek Acuity.tw.	27
23	Oculocare.tw,in.	12
24	cambridge medical innovation.tw,in.	0
25	Tilak Healthcare.tw,in.	4
26	Peek Vision.tw,in.	40
27	"Peek Community".tw.	4
28	or/18-27	114
29	OKKO.tw,in.	15
30	tilak.tw,in.	3254
31	or/29-30	3269
32	9 and 31	10
33	17 or 28 or 32	448

Cochrane Library

ID	Search	Hits
#1	MeSH descriptor: [Macular Degeneration] this term only	1614
#2	MeSH descriptor: [Geographic Atrophy] this term only	222
#3	(macula* NEAR/1 (degenerat* or disease* or pathologi*)):ti,ab,kw	4295
#4	(Maculopath*):ti,ab,kw	465
#5	(AMD and macula*):ti,ab,kw	2570
#6	(AMD NEAR/2 (age or advance* or dry or late)):ti,ab,kw	387
#7	(geographic atroph*):ti,ab,kw	578
#8	(atrophic AMD):ti,ab,kw	56
#9	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8	4746
#10	MeSH descriptor: [Smartphone] this term only	1386
#11	MeSH descriptor: [Mobile Applications] this term only	2816
#12	(smartphone* or app or apps or mHealth or mobile*):ti,ab,kw	34318
#13	(web* NEAR/2 application*):ti,ab,kw	917
#14	("puzzle games"):ti,ab,kw	16
#15	(hyperacuity and app):ti,ab,kw	0
#16	#10 OR #11 OR #12 OR #13 OR #14 OR #15	34926
#17	#9 AND #16	25
#18	(alleye):ti,ab,kw	0
#19	(DigiVis):ti,ab,kw	0
#20	(Odysight):ti,ab,kw	1
#21	(OKKO):ti,ab,kw	3
#22	(Peek Acuity):ti,ab,kw	13

#23	(Oculocare)	0
#24	("cambridge medical innovation")	0
#25	(Tilak Healthcare)	1
#26	("Peek Vision")	5
#27	("Peek Community")	3
#28	#18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27	24
#29	(OKKO)	3
#30	(tilak)	79
#31	#29 OR #30	82
#32	#9 AND #31	0
#33	#17 OR #28 OR #32	49

INAHTA

29 #28 OR #17 1

28 #27 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 0

27 Peek Community 0

26 Peek Vision 0

25 Tilak 0

24 cambridge medical innovation 0

23 Oculocare 0

22 Peek Acuity 0

21 OKKO 0

20 Odysight 0

19 DigiVis 0

18	alleye	0
17	#16 AND #9	1
16	#15 OR #14 OR #13 OR #12 OR #11 OR #10	210
15	(hyperacuity AND app)	0
14	"puzzle games"	0
13	(web* AND application*)	64
12	(smartphone* OR app OR apps OR mHealth OR mobile*)	123
11	"Mobile Applications"[mh]	49
10	"Smartphone"[mh]	23
9	#8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1	140
8	atrophic AMD	0
7	geographic atroph*	2
6	(AMD AND (age OR advance* OR dry OR late))	40
5	(AMD AND macula*)	40
4	Maculopath*	4
3	(macula* AND (degenerat* OR disease* OR pathologi*))	134
2	"Geographic Atrophy"[mh]	0
1	"Macular Degeneration"[mh]	115

Clinicaltrials.gov

Query	Hits
Alleye (Intervention/treatment)	2
DigiVis (Intervention/treatment)	1
Odysight (Intervention/treatment)	3
OKKO (Intervention/treatment)	4
Peek Vision (Intervention/treatment)	4
Oculocare (Intervention/treatment)	0
Tilak (Intervention/treatment)	0
OKKO Health (Intervention/treatment)	4
Peek Acuity (Intervention/treatment)	6
Macular degeneration (Condition/disease) Smartphone (Other terms)	8
Macular degeneration (Condition/disease) App (Other terms)	19
Macular degeneration (Condition/disease) Home monitoring (Other terms)	25
Macular degeneration (Condition/disease) Digital monitoring (Other terms)	1
Total **Total after deduplication**	**77** **58**

ICTRP

Query	Hits

alleye or digivis or odysight or okko or peek vision or oculocare or cambridge medical or tilak or peek acuity (in the intervention)	8
macular degeneration (in the condition) AND "home monitoring" or "digital monitoring" or smartphone or app or application or "digital tool" (in the intervention)	4
Total deduplicated	**12 (no duplicates)**

NICE Guidance

Query	Hits	Relevant/additional relevant
Macular degeneration	12	1
AMD	12	0
Geographic atrophy	0	NA

Scottish Intercollegiate Guideline Network (SIGN)

Query	Hits	Relevant
Macular	0	NA
AMD	0	NA
Geographic	0	NA

Heath Technology Wales

Filter by	Hits	Relevant
Eye	8	1

MHRA

Query	Hits

Alleye	0
DigiVis	0
Odysight	0
OKKO	0
“Peek Acuity”	1
Oculocare	0
“Cambridge Medical Innovation”	0
Tilak	0
“Peek Vision”	1 (duplicate)

MAUDE

Query	**Hits**
Alleye	0
DigiVis	0
Odysight	0
OKKO	0
“Peek Acuity”	0
Oculocare	0
“Cambridge Medical Innovation”	0
Tilak	0
“Peek Vision”	0

Economic modelling database searches

Additional economic searches were carried out to identify relevant evaluation and modelling:

Date	Database Name	Total Number of records retrieved	Total number of records from database after de-duplication
11.03.26	Medline (ALL)	233	
11.03.26	Embase	707	
11.03.26	NHS EED	55	
Total		**995**	**781**

Ovid MEDLINE(R) ALL <1946 to March 10, 2026>

1 macular degeneration/ 20140

2 geographic atrophy/ 1366

3 Wet Macular Degeneration/ 3564

4 (macula* adj2 (degenerat* or disease* or pathologi*)).tw. 31798

5 Maculopath*.tw. 6320

6 (AMD and macula*).tw. 14524

7 (AMD adj3 (age or advance* or dry or late or wet or neovascular)).tw. 5698

8 geographic atroph*.tw. 2242

9 or/1-8 41991

10 Economics/ 27558

11 exp "Costs and Cost Analysis"/ 286258

12 Economics, Nursing/ 4015

13 Economics, Medical/ 9323

14 Economics, Pharmaceutical/ 3179

15 exp Economics, Hospital/ 26450

16 Economics, Dental/ 1922

17 exp "Fees and Charges"/ 31852

18 exp Budgets/ 14472

19 budget*.ti,ab,kf. 42333

20 (economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ti,kf. 328694

21 (economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ab. /freq=2 469715

22 (cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab,kf. 271359

23 (value adj2 (money or monetary)).ti,ab,kf. 3629

24 exp models, economic/ 17208

25 economic model*.ab,kf. 5073

26 markov chains/ 17879

27 markov.ti,ab,kf. 35126

28 monte carlo method/ 35380

29 monte carlo.ti,ab,kf. 70543

30 exp Decision Theory/ 14882

31 (decision* adj2 (tree* or analy* or model*)).ti,ab,kf. 57580

32 or/10-31 1075339

33 exp United Kingdom/ 412101

34 (national health service* or nhs*).ti,ab,in.337243

35 (english not ((published or publication* or translat* or written or language* or speak* or literature or citation*) adj5 english)).ti,ab. 160311

36 (gb or "g.b." or britain* or (british* not "british columbia") or uk or "u.k." or united kingdom* or (england* not "new england") or northern ireland* or northern irish* or scotland* or scottish* or ((wales or "south wales") not "new south wales") or welsh*).ti,ab,jw,in. 2778408

37 (bath or "bath's" or ((birmingham not alabama*) or ("birmingham's" not alabama*) or bradford or "bradford's" or brighton or "brighton's" or bristol or "bristol's" or carlisle* or "carlisle's" or (cambridge not (massachusetts* or boston* or harvard*)) or ("cambridge's" not (massachusetts* or boston* or harvard*)) or (canterbury not zealand*) or ("canterbury's" not zealand*) or chelmsford or "chelmsford's" or chester or "chester's" or chichester or "chichester's" or coventry or "coventry's" or derby or "derby's" or (durham not (carolina* or nc)) or ("durham's" not (carolina* or nc)) or ely or "ely's" or exeter or "exeter's" or gloucester or "gloucester's" or hereford or "hereford's" or hull or "hull's" or lancaster or "lancaster's" or leeds* or leicester or "leicester's" or (lincoln not nebraska*) or ("lincoln's" not nebraska*) or (liverpool not (new south wales* or nsw)) or ("liverpool's" not (new south wales* or nsw)) or ((london not (ontario* or ont or toronto*)) or ("london's" not (ontario* or ont or toronto*)) or manchester or "manchester's" or (newcastle not (new south wales* or nsw)) or ("newcastle's" not (new south wales* or nsw)) or norwich or "norwich's" or nottingham or "nottingham's" or oxford or "oxford's" or peterborough or "peterborough's" or plymouth or "plymouth's" or portsmouth or "portsmouth's" or preston or "preston's" or ripon or "ripon's" or salford or "salford's" or salisbury or "salisbury's" or sheffield or "sheffield's" or southampton or "southampton's" or st albans or stoke or "stoke's" or sunderland or "sunderland's" or truro or "truro's" or wakefield or "wakefield's" or wells or westminster or "westminster's" or winchester or "winchester's" or wolverhampton or "wolverhampton's" or (worcester not (massachusetts* or boston* or harvard*)) or ("worcester's" not (massachusetts* or boston* or harvard*)) or (york not ("new york*" or ny or ontario* or ont or toronto*)) or ("york's" not ("new york*" or ny or ontario* or ont or toronto*))))).ti,ab,in.
2040807

38 (bangor or "bangor's" or cardiff or "cardiff's" or newport or "newport's" or st asaph or "st asaph's" or st davids or swansea or "swansea's").ti,ab,in.
83256

39 (aberdeen or "aberdeen's" or dundee or "dundee's" or edinburgh or "edinburgh's" or glasgow or "glasgow's" or inverness or (perth not australia*) or ("perth's" not australia*) or stirling or "stirling's").ti,ab,in. 299858

40 (armagh or "armagh's" or belfast or "belfast's" or lisburn or "lisburn's" or londonderry or "londonderry's" or derry or "derry's" or newry or "newry's").ti,ab,in. 40710

41 or/33-40 3576004

42 (exp africa/ or exp americas/ or exp antarctic regions/ or exp arctic regions/ or exp asia/ or exp australia/ or exp oceania/) not (exp United Kingdom/ or europe/) 3691210

43 41 not 42 3346305

44 9 and 32 and 43 235

45 exp animals/ not humans.sh. 5432505

46 44 not 45 235

47 limit 46 to english language 233

Embase <1974 to 2026 March 09>

1 age related macular degeneration/ 34788

2 geographic atrophy/ 4057

3 wet macular degeneration/ 6631

4 (macula* adj2 (degenerat* or disease* or pathologi*)).tw. 45417

5 Maculopath*.tw. 8100

6 (AMD and macula*).tw. 22136

7 (AMD adj3 (age or advance* or dry or late or wet or neovascular)).tw. 9490

8 geographic atroph*.tw. 3900

9 or/1-8 62440

10 Economics/ 249277

11 Cost/ 67575

12 exp Health Economics/ 1209019

13 Budget/ 38692

14 budget*.ti,ab,kf. 57045

15 (economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ti,kf. 406548

16 (economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ab. /freq=2 673841

17 (cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab,kf. 379334

18 (value adj2 (money or monetary)).ti,ab,kf. 4863

19 Statistical Model/ 185060

20 exp economic model/ 5673

21 economic model*.ab,kf. 7815

22 Probability/ 183777

23 markov.ti,ab,kf. 46265

24 monte carlo method/ 62098

25 monte carlo.ti,ab,kf. 76289

26 Decision Theory/ 1954

27 Decision Tree/ 32838

28 (decision* adj2 (tree* or analy* or model*)).ti,ab,kf. 75708

29 or/10-28 2403551

30 exp United Kingdom/ 512852

31 (national health service* or nhs*).ti,ab,in,ad. 577005

32 (english not ((published or publication* or translat* or written or language* or speak* or literature or citation*) adj5 english)).ti,ab. 77905

33 (gb or "g.b." or britain* or (british* not "british columbia") or uk or "u.k." or united kingdom* or (england* not "new england") or northern ireland* or northern irish* or scotland* or scottish* or ((wales or "south wales") not "new south wales") or welsh*).ti,ab,jx,in,ad. 4190652

34 (bath or "bath's" or ((birmingham not alabama*) or ("birmingham's" not alabama*) or bradford or "bradford's" or brighton or "brighton's" or bristol or "bristol's" or carlisle* or "carlisle's" or (cambridge not (massachusetts* or boston* or harvard*)) or ("cambridge's" not (massachusetts* or boston* or

harvard*)) or (canterbury not zealand*) or ("canterbury's" not zealand*) or chelmsford or "chelmsford's" or chester or "chester's" or chichester or "chichester's" or coventry or "coventry's" or derby or "derby's" or (durham not (carolina* or nc)) or ("durham's" not (carolina* or nc)) or ely or "ely's" or exeter or "exeter's" or gloucester or "gloucester's" or hereford or "hereford's" or hull or "hull's" or lancaster or "lancaster's" or leeds* or leicester or "leicester's" or (lincoln not nebraska*) or ("lincoln's" not nebraska*) or (liverpool not (new south wales* or nsw)) or ("liverpool's" not (new south wales* or nsw)) or ((london not (ontario* or ont or toronto*)) or ("london's" not (ontario* or ont or toronto*)) or manchester or "manchester's" or (newcastle not (new south wales* or nsw)) or ("newcastle's" not (new south wales* or nsw)) or norwich or "norwich's" or nottingham or "nottingham's" or oxford or "oxford's" or peterborough or "peterborough's" or plymouth or "plymouth's" or portsmouth or "portsmouth's" or preston or "preston's" or ripon or "ripon's" or salford or "salford's" or salisbury or "salisbury's" or sheffield or "sheffield's" or southampton or "southampton's" or st albans or stoke or "stoke's" or sunderland or "sunderland's" or truro or "truro's" or wakefield or "wakefield's" or wells or westminster or "westminster's" or winchester or "winchester's" or wolverhampton or "wolverhampton's" or (worcester not (massachusetts* or boston* or harvard*)) or ("worcester's" not (massachusetts* or boston* or harvard*)) or (york not ("new york*" or ny or ontario* or ont or toronto*)) or ("york's" not ("new york*" or ny or ontario* or ont or toronto*"))))).ti,ab,in,ad. 3312945

35 (bangor or "bangor's" or cardiff or "cardiff's" or newport or "newport's" or st asaph or "st asaph's" or st davids or swansea or "swansea's").ti,ab,in,ad. 136302

36 (aberdeen or "aberdeen's" or dundee or "dundee's" or edinburgh or "edinburgh's" or glasgow or "glasgow's" or inverness or (perth not australia*) or ("perth's" not australia*) or stirling or "stirling's").ti,ab,in,ad. 457037

37 (armagh or "armagh's" or belfast or "belfast's" or lisburn or "lisburn's" or londonderry or "londonderry's" or derry or "derry's" or newry or "newry's").ti,ab,in,ad. 64675

38 or/30-37 5142325

39 (exp "arctic and antarctic"/ or exp oceanic regions/ or exp western hemisphere/ or exp africa/ or exp asia/) not (exp united kingdom/ or europe/) 4036277

40 38 not 39 4835116

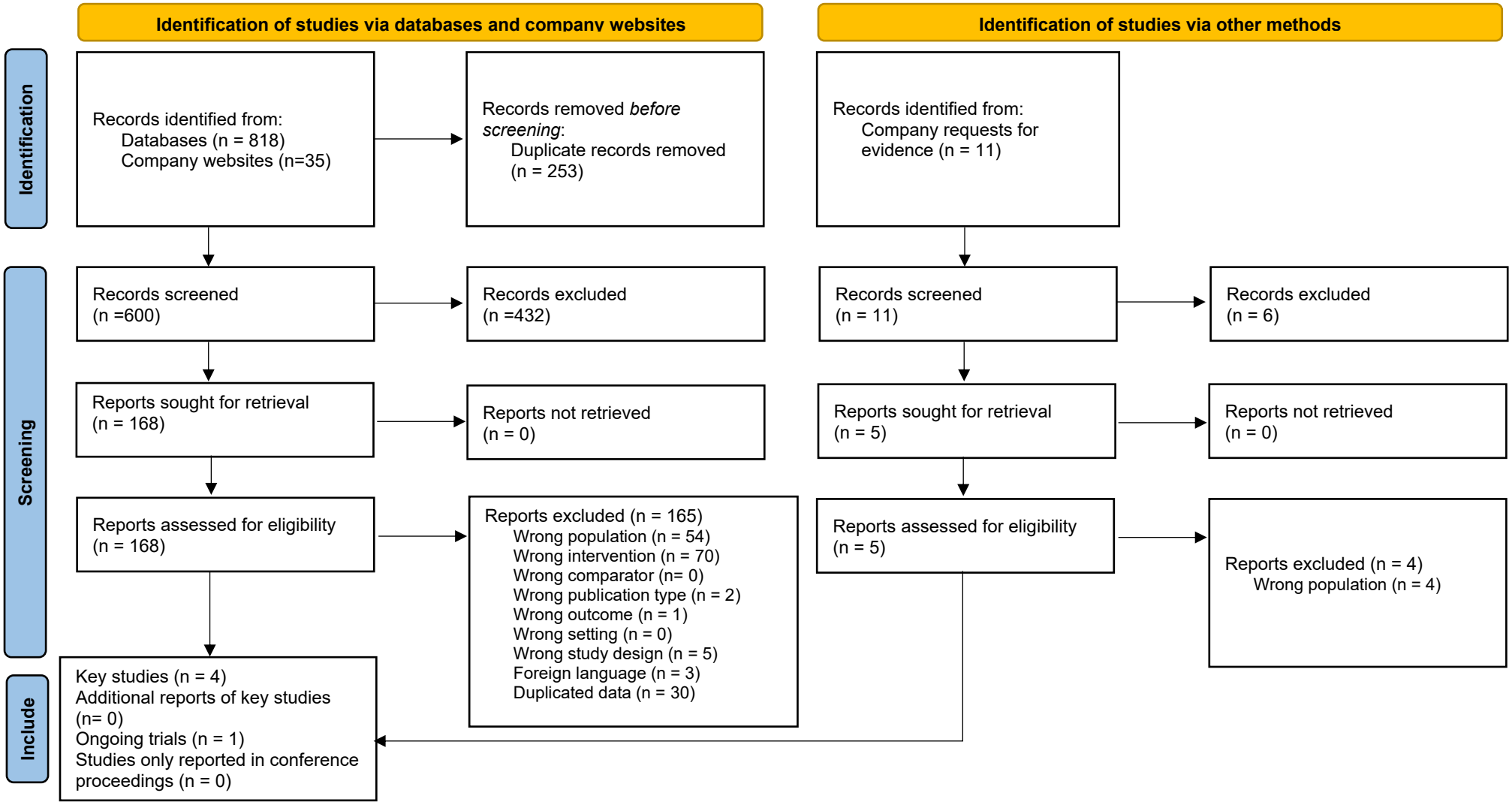
41 9 and 29 and 40 709

42	limit 41 to english language	707

NHS EED

1	MeSH DESCRIPTOR Macular Degeneration	149
2	MeSH DESCRIPTOR geographic atrophy	0
3	MeSH DESCRIPTOR Wet Macular Degeneration	19
4	(macula* adj2 (degenerat* or disease* or pathologi*))	214
5	(Maculopath*)	12
6	(AMD and macula*)	71
7	(AMD adj3 (age or advance* or dry or late or wet or neovascular))	11
8	(geographic atroph*)	5
9	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8	223
10	(#9) IN NHSEED	55

Appendix B: PRISMA flow diagram



Appendix C: Excluded studies

Reference	Reason for exclusion
Le Dinahet, J., & Cochener-Lamard, B. (2026). [Study of French ophthalmologists' impressions of the telemonitoring tool, Odysight©]. Analyse de la perception des ophtalmologistes francais vis-a-vis de l'outil de telesurveillance Odysight©. 49(3), 104790. https://doi.org/10.1016/j.jfo.2026.104790	Foreign language
Neroev, V. V., Zaytseva, O. V., Petrov, S. Y., & Bragin, A. A. (2024). Artificial intelligence in ophthalmology: the present and the future. Rossiiskii Oftal'mologicheskii Zhurnal, 17(2), 135–141. https://doi.org/10.21516/2072-0076-2024-17-2-135-141	Foreign language
Tripp, A., Brink, S., Lemmen, K. D., Mussinghoff, P., & Pauleikhoff, D. (2022). Can Digital Instruments Like the Macula-App Support AMD Therapy? Konnen digitale Instrumente wie die Makula-App die AMD-Therapie unterstutzen?, 239(6), 793–798. https://doi.org/10.1055/a-1711-4306	Foreign language
A 16 Week Evaluation of the Novartis Health Management Tool in Assessing Self-test Visual Function in Patients With AMD Treated With Ranibizumab. clinicaltrials.gov.	Wrong intervention
Actrn, & University of Auckland, N. (2022). Home Monitoring of Age-Related Macular Degeneration. In.	Wrong intervention
Ahn, S. J., & Kim, Y. H. (2024). Clinical Applications and Future Directions of Smartphone Fundus Imaging. Diagnostics (Basel, Switzerland), 14(13). https://doi.org/10.3390/diagnostics14131395	Wrong intervention
Akca, S., Garip, Z., Ekinci, E., & Atban, F. (2024). Automated classification of choroidal neovascularization, diabetic macular edema, and drusen from retinal OCT images using vision transformers: a comparative study. Lasers in medical science, 39(1), 140. https://doi.org/10.1007/s10103-024-04089-w	Wrong intervention
Al-Aswad, L. A., Elgin, C. Y., Patel, V., Popplewell, D., Gopal, K., Gong, D., Thomas, Z., Joiner, D., Chu, C.-K., Walters, S., Ramachandran, M., Kapoor, R., Rodriguez, M., Alcantara-Castillo, J., Maestre, G. E., Lee, J. H., & Moazami, G. (2021). Real-Time Mobile Teleophthalmology for the Detection of Eye Disease in Minorities and Low Socioeconomics At-Risk Populations. Asia-Pacific journal of ophthalmology (Philadelphia, Pa.), 10(5), 461–472. https://doi.org/10.1097/APO.0000000000000416	Wrong intervention
Alexopoulos, P., Madu, C., Wollstein, G., & Schuman, J. S. (2022). The Development and Clinical Application of Innovative Optical Ophthalmic Imaging Techniques. Frontiers in Medicine, 9, 891369. https://doi.org/10.3389/fmed.2022.891369	Wrong intervention
Anonymous. (2016). The Correlation of the Checkup Vision Assessment System to Standard In Office Visual Assessment. clinicaltrials.gov.	Wrong intervention

Reference	Reason for exclusion
Anonymous. (2018a). Design and Clinical Evaluation of a Smartphone-based Low Vision Enhancement System. clinicaltrials.gov.	Wrong intervention
Anonymous. (2018b). The Effects of Regular Eye-training With a Mobile Device on Adult Patients With AMD. clinicaltrials.gov.	Wrong intervention
Anonymous. (2019). Comparison of Quantitative Metamorphopsia- Measurements in Patients With mCNV. clinicaltrials.gov.	Wrong intervention
Anonymous. (2020). Visual Rehabilitation in Macular Degeneration: a Pilot Study on Biofeedback Training and Home-based Mobile Virtual-reality Stimulation. clinicaltrials.gov.	Wrong intervention
Anonymous. (2025). Research on a New Intelligent Mobile Screening and Diagnosis Pattern for Ocular Diseases. clinicaltrials.gov.	Wrong intervention
Aydindogan, G., Kavakli, K., Sahin, A., Artal, P., & Urey, H. (2021). Applications of augmented reality in ophthalmology [Invited]. Biomedical Optics Express, 12(1), 511–538. https://doi.org/10.1364/BOE.405026	Wrong intervention
Baban, K., Mishra, K., Van Manh, A. L., Esperanza, K., & Brodie, S. E. (2016). Autoamsler: Envisioning secondary prevention through digital health. Investigative Ophthalmology and Visual Science, 57(12), 4971.	Wrong intervention
Balaskas, K., Pontikos, N., Korot, E., Jaber, A., Thomas, P., Sim, D., & Keane, P. (2021). Real-life implementation of smartphone-based home vision monitoring in a high volume intravitreal injection service for patients with neovascular Age-related Macular Degeneration and Retinal Vascular Di. Ophthalmologica, 244.	Wrong intervention
Buechi, R., Faes, L., Bachmann, L. M., Thiel, M. A., Bodmer, N. S., Schmid, M. K., Job, O., & Lienhard, K. R. (2017). Evidence assessing the diagnostic performance of medical smartphone apps: A systematic review and exploratory meta-analysis. BMJ Open, 7(12), e018280. https://doi.org/10.1136/bmjopen-2017-018280	Wrong intervention
Chang, M. L., Chiu, Y. H., Chiu, C. J., & Avoni, L. (2015). Mobile application software (App) for prediction of advanced age-related macular degeneration. Investigative Ophthalmology and Visual Science, 56(7), 4111.	Wrong intervention
A Clinical Trial to Assess the Impact of Home Monitoring to Decrease the Treatment Burden for Neovascular Macular Degeneration (the LIBERTY Study) (	Wrong intervention
The Correlation of the Checkup Vision Assessment System to Standard In Office Visual Assessment (	Wrong intervention
Decentralized Pilot Study to Evaluate MyVisionTrack^TM Home Vision Testing in Patients With Diabetic Macular Edema or Neovascular Age-Related Macular Degeneration Currently Receiving Intravitreal Lucentis® Therapy (	Wrong intervention

Reference	Reason for exclusion
Eichenbrenner, P., Heier, J., Haddock, L., Larney Roper, B., Chakkath, T., Carter, J., & Heggen, C. (2022). AMD.care web apps: A collaborative managed care, provider, and patient approach to support quality outcomes in age-related macular degeneration. Journal of Managed Care and Specialty Pharmacy, 28(10), S81.	Wrong intervention
Farag, S., Szymanska, M., & Abdulhussein, D. (2021). Systematic review of the current availability of mobile applications in patients with non-communicable eye diseases. Ophthalmologica, 244.	Wrong intervention
Fink, W., & Tarbell, M. Investigative Ophthalmology and Visual Science, 56(7), 4110.	Wrong intervention
Gurnani, B., & Kaur, K. (2025). Teleophthalmology-enabled devices: bridging the gap in rural eye care. Expert review of medical devices, 22(11), 1167–1172. https://doi.org/10.1080/17434440.2025.2566741	Wrong intervention
Hartmann, M. (2013). Evaluation of vision auto-testing in patients with AMD using an iPad app. Investigative Ophthalmology and Visual Science, 54(15).	Wrong intervention
Hartmann, M. G. (2014). Home vision auto-testing in patients with AMD using an iPad app. Investigative Ophthalmology and Visual Science, 55(13), 5604.	Wrong intervention
Ho, C. Y. D., Wu, Z., Turpin, A., Lawson, D. J., Luu, C. D., McKendrick, A. M., & Guymer, R. H. (2018). A tablet-based retinal function test in neovascular age-related macular degeneration eyes and at-risk fellow eye. Translational Vision Science and Technology, 7(2), 2. https://doi.org/10.1167/tvst.7.2.2	Wrong intervention
Hogg, R. E., Wickens, R., O'Connor, S., Gidman, E., Ward, E., Peto, T., Burton, B. J. L., Knox, P., Lotery, A. J., Sivaprasad, S., Donnelly, M., Rogers, C. A., & Reeves, B. C. (2024). Inequalities in Uptake and Use of Digital Applications for Home-Monitoring of Neovascular Age-Related Macular Degeneration in an Elderly Visually Impaired Population: The MONARCH Study. Translational vision science & technology, 13(3), 2. https://doi.org/10.1167/tvst.13.3.2	Wrong intervention
Hogg, R. E., Wickens, R., O'Connor, S., Gidman, E., Ward, E., Treanor, C., Peto, T., Burton, B., Knox, P., Lotery, A. J., Sivaprasad, S., Donnelly, M., Rogers, C. A., & Reeves, B. C. (2024). Home-monitoring for neovascular age-related macular degeneration in older adults within the UK: the MONARCH diagnostic accuracy study. Health technology assessment (Winchester, England), 28(32), 1–136. https://doi.org/10.3310/CYRA9912	Wrong intervention
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Santineau, K. R., Samanta, A., Nguyen, D., Kim, I., Park, A., Reppa, C., Porter, M., & Ray, C. (2023). Results from a Real-World Study of Home Visual Acuity Measurement with Phone Applications. Investigative Ophthalmology and Visual Science, 64(8), 3044.	Wrong population
Satgunam, P., Thakur, M., Sachdeva, V., Reddy, S., & Rani, P. K. (2021). Validation of visual acuity applications for teleophthalmology during COVID-19. Indian journal of ophthalmology, 69(2), 385–390. https://doi.org/10.4103/ijo.IJO_2333_20	Wrong population
Thirunavukarasu, A. J., Hassan, R., Limonard, A., Gudiwala, V., & Savant, S. V. (2024). ACCURACY and RELIABILITY of SELF-ADMINISTERED VISUAL ACUITY TESTS: SYSTEMATIC REVIEW of PRAGMATIC TRIALS. Eye (Basingstoke), 38, 184–185. https://doi.org/10.1038/s41433-024-03254-3	Wrong population

Reference	Reason for exclusion
Thirunavukarasu, A. J., Hassan, R., Limonard, A., & Savant, S. V. (2023). Accuracy and reliability of self-administered visual acuity tests: Systematic review of pragmatic trials. PloS one, 18(6), e0281847. https://doi.org/10.1371/journal.pone.0281847	Wrong population
Thirunavukarasu, A. J., Mullinger, D., Rufus-Toye, R. M., Farrell, S., & Allen, L. E. (2022). Clinical validation of a novel web-application for remote assessment of distance visual acuity. Eye (London, England), 36(10), 2057–2061. https://doi.org/10.1038/s41433-021-01760-2	Wrong population
Tseng, R. M. W. W., Tham, Y.-C., Rim, T. H., & Cheng, C.-Y. (2021). Emergence of non-artificial intelligence digital health innovations in ophthalmology: A systematic review. Clinical & experimental ophthalmology, 49(7), 741–756. https://doi.org/10.1111/ceo.13971	Wrong population
Vahedi, S., Eghrari, A. O., Bishop, R. J., Brady, C. J., Reilly, C. S., Ferris, F. L., Larbelee, J., & Fallah, M. (2016). Implementation and assessment of visual acuity screening of Ebola Virus Disease survivors utilizing the Peek Vision smartphone platform. Investigative Ophthalmology and Visual Science, 57(12), 5537.	Wrong population
Zhao, L., Stinnett, S., & Prakalapakorn, S. G. (2018). Visual acuity assessment in children obtained using a novel cell phone application compared to the clinical examination in a pediatric ophthalmology clinic. Investigative Ophthalmology and Visual Science, 59(9).	Wrong population
Zhao, L., Stinnett, S. S., & Prakalapakorn, S. G. (2019). Visual Acuity Assessment and Vision Screening Using a Novel Smartphone Application. The Journal of pediatrics, 213, 203–210.e201. https://doi.org/10.1016/j.jpeds.2019.06.021	Wrong population
Anonymous. (2015). Erratum: Development and validation of a smartphone-based visual acuity test (peek acuity) for clinical practice and community-based fieldwork (JAMA Ophthalmol (2015) 133:8 (930-937)). JAMA Ophthalmology, 133(9), 1096. https://doi.org/10.1001/jamaophthalmol.2015.3195	Wrong publication type
Faes, L., Islam, M., Bachmann, L. M., Lienhard, K. R., Schmid, M. K., & Sim, D. A. (2021). Correction: False alarms and the positive predictive value of smartphone-based hyperacuity home monitoring for the progression of macular disease: a prospective cohort study. Eye (London, England), 35(11), 3177. https://doi.org/10.1038/s41433-021-01512-2	Wrong publication type
Abdulhussein, D., Abdul Hussein, M., Szymanka, M., & Farag, S. (2022). A systematic review of the current availability of mobile applications in eyecare practices. European journal of ophthalmology, 11206721221131397. https://doi.org/10.1177/11206721221131397	Wrong study design

Reference	Reason for exclusion
Balaskas, K., Drawnel, F., Khanani, A. M., Knox, P. C., Mavromaras, G., & Wang, Y.-Z. (2023). Home vision monitoring in patients with maculopathy: current and future options for digital technologies. Eye (London, England), 37(15), 3108–3120. https://doi.org/10.1038/s41433-023-02479-y	Wrong study design
Hogarty, D., Hogarty, J., & Hewitt, A. (2019). Smartphone applications in ophthalmology. Clinical and Experimental Ophthalmology, 47, 103. https://doi.org/10.1111/ceo.13632	Wrong study design
Keenan, T. D. L., & Loewenstein, A. (2023). Artificial intelligence for home monitoring devices. Current Opinion in Ophthalmology, 34(5), 441–448. https://doi.org/10.1097/ICU.0000000000000981	Wrong study design

NICE National Institute for Health and Care Excellence

Health Tech Programme

HTE10073 Digital technologies to support monitoring of vision change at home for people with age-related macular degeneration

External Assessment Report (EAR) and economic model – company comments and external assessment group responses

Section A: Comments on External Assessment Report

Organisat-ion	Comment no.	Page no.	Section no.	Comment	CEDAR response
Oculocare Medical Inc	1	7	Exec. Summary	The statement that there is "little evidence to support the use of Alleye for this decision problem" appears too broad. The report itself shows that the more precise issue is limited direct evidence in the narrowly defined population of advanced dry AMD/GA at risk of conversion to neovascular AMD. A broader Alleye evidence base exists, but multiple studies were excluded as out of scope because they were conducted in related retinal populations rather than the exact target population. Framing this as "limited direct in-scope evidence" would be more accurate and less liable to misinterpretation.	The EAG considers the wording we have included in the report to be accurate. However, we have added in further comments in the report reiterating that the reference to little evidence is with regards to the consideration of the decision problem.
Oculocare Medical Inc	2	7	Exec. Summary	The summary selectively foregrounds the least favourable diagnostic contrast from Schmid et al. (2019), namely dry AMD versus wet AMD with AUROC 0.660. Elsewhere in the report, the same study is described as showing good discrimination for wet AMD versus age-matched healthy eyes (0.845), excellent discrimination for wet AMD versus young healthy controls (0.969), and good discrimination for dry AMD versus young healthy controls (0.799). The paper itself concludes that the test is "highly accurate to detect wet AMD and reasonably accurate to classify dry vs. wet AMD." The current summary therefore risks understating the overall diagnostic signal shown in the study.	The EAG consider this comparison from the study to be the only relevant comparison to the decision problem. The executive summary is summarising the most relevant points of the report, and so the other comparisons have not been included. However, they are included further on in the report in section 5.3

Oculocare Medical Inc	3	7	Exec. Summary	Teo et al. (2021) is described here as one of "2 qualitative studies", but elsewhere in the report it is correctly described as a "good quality observational study". This should be aligned throughout, because Teo is not a qualitative study; it is a real-world observational implementation study addressing uptake and adherence. Misclassification understates the nature of the available evidence.	Thank you for the comment. The report has been updated to refer to Teo et al. (2021) as an observational study.
Oculocare Medical Inc	4	14	2. Technologies, Table 3	The indication for Alleye is listed as "dry AMD, wet AMD, DME, and CRVO". This appears imprecise. The company submission describes a broader retinal-disease indication and refers to RVO rather than specifically CRVO. This should be corrected for accuracy.	Thank you for the comment. The indication for Alleye in the report has been updated to "RVO", rather than "CRVO", as per the RFI submitted by the company.
Oculocare Medical Inc	5	17	1.1 Alleye	The statement that people "are required to have sufficient central visual acuity, e.g. ≥60 ETDRS" appears too absolute. That threshold may reflect particular study settings, but it is not consistently presented as a universal device requirement across the Alleye evidence base. The wording would be more accurate if presented as an example of a study inclusion threshold or practical consideration rather than a general requirement.	Thank you for the clarification. The EAG have added a statement to more precisely reflect the wording in the submitted documents. "People are required to have sufficient central visual acuity (with glasses if needed) to use the app., Optimum results are for patients with corrected visual acuity greater than 60 EDTRS. Patients with corrected visual acuity of less than 35 EDTRS should not use the app.
Oculocare Medical Inc	6	24	4.2 Included and excluded studies	The report states that "two studies were qualitative studies focused on the adherence and use of Alleye". This is not strictly accurate. Dave et al. is qualitative, but Teo et al. is an observational retrospective implementation study. A more accurate characterisation would be: one diagnostic accuracy study, one qualitative usability study, and one observational implementation/adherence study.	The report has been updated to refer to Teo et al. (2021) as an observational study.
Oculocare Medical Inc	7	29	5.1 Quality appraisal of studies	The critique of Schmid et al. (2019) could be framed more precisely. It is reasonable to state that the study does not answer the longitudinal question of conversion from advanced dry AMD/GA	The EAG agrees and the wording regarding Schmid et al. (2019) has been changed to reflect this comment.

				to neovascular AMD. However, describing the design as "introducing bias" may overstate the issue. This is more appropriately characterised as a limitation of applicability to the decision problem rather than a major methodological flaw in an early diagnostic discrimination study. In addition, the report itself notes that the dry AMD group likely included early, intermediate, and advanced dry AMD, so the relevance to advanced dry AMD is limited but not absent.	"However, its cross-sectional design, in addition to using a clinically known population compared to an undiagnosed cohort, does not allow changes to be detected over time limiting it's applicability to the decision problem"
Oculocare Medical Inc	8	29 to 30	5.1 Quality appraisal of studies	The wording around Schmid et al. would benefit from clearer separation of study purpose and decision-problem applicability. Schmid et al. was designed as a cross-sectional diagnostic performance study and should not be judged as though it were intended to provide pathway-level prospective sensitivity and specificity for NHS detection of GA conversion. The main limitation is that it is not a longitudinal conversion study, not that it lacks diagnostic value overall.	The change to the report implemented for comment 7 above also addresses this comment. In addition, it has been acknowledged that the purpose of the study was not designed to answer the decision problem question. "Additionally, although the study demonstrates the ability of the technology, combined with an algorithm, to differentiate between eyes with dry and neovascular (wet) AMD, it does not provide a measurement of sensitivity and specificity of the use of the app as used in practice. It therefore does not reflect the use in the NHS of detecting the conversion of advanced dry AMD (geographic atrophy) to neovascular (wet) AMD. The authors report that their results are not adequate to understand the relationship between changes in the Alleye score and the transition of advanced dry AMD

					(geographic atrophy) to neovascular (wet) AMD."
Oculocare Medical Inc	9	33	5.3 Diagnostic test accuracy	The interpretation in this section is more balanced than in the executive summary and should be reflected consistently elsewhere. The report acknowledges good discrimination for wet AMD versus age-matched healthy eyes and higher diagnostic performance versus young healthy controls. This fuller summary should be used consistently to avoid undue emphasis on the single dry-versus-wet contrast.	See the response to comment 2 above.
Oculocare Medical Inc	10	33 to 34	5.4 User adherence to home monitoring	Teo et al. should not be dismissed solely on the basis that AMD represented 12% of the overall invited cohort. In absolute terms, the study still included 330 participants with non-neovascular AMD, of whom 138 signed up and 80 met adherence criteria, and across the programme 245 patients completed 11,592 tests. These are meaningful implementation data and are directly relevant to NICE outcomes on usability and adherence, even if the study is not specific to the exact NICE target population.	The EAG considers the wording in this section to be an accurate representation of the study, and do not agree that the study has been dismissed based on only 12% of the sample having AMD.
Oculocare Medical Inc	11	34	5.5 User acceptability and user experience	The limitations of Dave et al. are fairly described, but the report could acknowledge more explicitly that the study still addresses outcomes that NICE itself lists as relevant, namely acceptability, reassurance, practical barriers, and support needs. The concern about digital exclusion may also be stronger than the currently available UK real-world evidence supports, given later data suggesting that digital exclusion risk and social deprivation were not significantly associated with adherence to Alleye home monitoring.	The EAG considers the report to provide an accurate representation of how the study addresses acceptability, reassurance, practical barriers of Alleye.
Oculocare Medical Inc	12	35 to 36	5.7 Clinical evidence summary and interpretation	The conclusion that there is "very limited, moderate-quality evidence" for Alleye again risks conflating a narrow scope problem with a broader evidence problem. A more balanced conclusion would be that direct evidence in the precise target population is limited, while broader supporting evidence for Alleye exists in related retinal and AMD populations but was excluded as out of scope. Appendix C supports this interpretation by listing several Alleye studies excluded for wrong population, including studies on	The EAG have included statements here, and elsewhere in the report, reiterating that the lack of evidence is when considering the decision problem of this assessment.

				false alarms, clinical actionability, long-term usability, visual outcomes, and digital inclusion.	Included at the start of this section: "when considering the decision problem of this assessment"
Oculocare Medical Inc	13	36 to 37	5.8 Out of scope evidence	This section could be strengthened by acknowledging more explicitly that excluded Alleye studies collectively provide important context on usability, adherence, false-alarm performance, and implementation feasibility. Even if not directly generalisable to advanced dry AMD/GA, they materially inform the plausibility and operational relevance of the technology.	The criteria used to determine which evidence to include here was agreed with NICE, and clinical experts indicated that usability and adherence were the most relevant outcomes we could generalise to dry AMD from wet AMD. The included studies refer to the findings regarding usability and adherence for Alleye.
Oculocare Medical Inc	14	105 to 106	Appendix C: Excluded studies	Appendix C demonstrates that the apparent sparseness of the included Alleye evidence base is driven in substantial part by the narrow scope of the decision problem rather than an absence of published evidence. This should be acknowledged more clearly in the narrative sections to avoid readers concluding that Alleye has only minimal supporting evidence overall.	The EAG have acknowledged the broader evidence base in the report, and that it is out of the scope of this assessment. The scope is determined by NICE following consultation, and the EAG are required to adhere to this.
Oculocare Medical Inc	15	36 to 37	5.8 Out of scope evidence	The criteria used to summarise out-of-scope evidence appear unnecessarily restrictive. The report states that only studies in which the majority of participants had AMD and where outcomes related to usability and adherence were summarised. However, the NICE decision problem also includes clinician experience, implementation, costs/resource use, and change in functional test scores. Restricting discussion of out-of-scope studies to majority-AMD usability/adherence studies alone may therefore exclude important contextual evidence that is directly relevant to several outcomes listed in scope.	See the response to comment 13 above. The EAG have not made any changes in this section.
Oculocare Medical Inc	16	108	Appendix C: Excluded studies	The exclusion of Eppenberger et al. (2021) as "wrong study design" is not self-explanatory from the report. This is particularly important because the EAG separately asked the company whether Eppenberger et al. 2021 could be shared as AIC if it included patients with advanced dry AMD/geographic atrophy, and the company response states that the "Eppenberger et al draft under consideration" was attached. This suggests that the study had at	The EAG have updated the exclusion reason for this study to be due to "wrong population". It was not clear if this study was relevant or not when it was requested, and it wasn't until reading the full text that it became clear

				least potential relevance. A fuller justification for the exclusion category would therefore be helpful.	it does not explicitly include dry AMD as part of the study sample.
Oculocare Medical Inc	17	105 to 106	Appendix C: Excluded studies	The “wrong population” label may have been applied too strictly to UK implementation studies such as Huemer et al. (2024) and Mendall et al. (2024). Although these studies were not conducted in the exact target population of advanced dry AMD/geographic atrophy, they address issues directly relevant to the decision problem, including adherence, clinical outcomes, and digital exclusion. Mendall et al. found no association between higher digital exclusion risk or social deprivation and adherence to hyperacuity home monitoring, which is relevant to generalisability and implementation in NHS populations.	The EAG has only selected studies that include a population that are relevant to the decision problem. These two studies do not include a population that is relevant.
Oculocare Medical Inc	18	105 to 106	Appendix C: Excluded studies	The exclusion of Faes et al. (2021) and Islam et al. (2021) as “wrong population” may be too conservative for pathway-level interpretation. These studies do not address the exact advanced dry AMD/geographic atrophy conversion question, but they directly inform whether Alleye alarms are clinically actionable and whether false-alarm rates are acceptable. This is relevant because the report itself describes the intended value of these technologies as improving detection of change and prompting urgent clinical review. Such studies may therefore merit explicit contextual discussion rather than simple exclusion.	The EAG has been lenient with regards to the scope and included studies evaluating the progression of any dry AMD to wet AMD (rather than specifically advanced dry AMD with geographic atrophy). However, these two studies do not evaluate this population, meaning that it is accurate to exclude them based on being the wrong population for the scope.
Oculocare Medical Inc	19	67 to 68	7. Integration into the NHS and 8.1 Ongoing studies	There appears to be some inconsistency in how population heterogeneity is handled across the report. On page 67, the report acknowledges that previous implementations of these technologies have typically been in specialist clinic settings for people with neovascular AMD. On page 68, an OKKO study including both dry and wet AMD is considered relevant as an ongoing study. By contrast, several mixed-population Alleye studies were excluded outright as “wrong population.” This suggests that the treatment of mixed cohorts may not have been fully consistent across technologies.	The EAG only included studies that explicitly included a population of dry AMD patients. The EAG are not aware of any mixed-population studies with Alleye as the intervention, where people with dry AMD are explicitly part of the sample, that have been excluded based on wrong population. The OKKO study included explicitly mentions the inclusion of dry AMD as an inclusion criterion.

Oculocare Medical Inc	20	27 to 30 and 36 to 37	4.2 Included and excluded studies; 5.1 Quality appraisal of studies; 5.8 Out of scope evidence	The report includes Teo et al. for Alleye despite a mixed retinal population and includes Bonjean et al. for OdySight despite a heterogeneous maculopathy cohort, with the limitations then discussed narratively. A similar approach could have been taken for at least some excluded Alleye studies, particularly where the outcomes were not core efficacy outcomes but implementation, adherence, usability, or operational performance. This would have allowed a fuller and more balanced account of the broader evidence base without implying that the studies directly answer the primary decision problem.	These two studies mentioned are explicit in their inclusion of dry AMD as part of the study sample. The EAG are not aware of any studies excluded based on wrong population, that include dry AMD as part of the study sample.
Oculocare Medical Inc	21	69 to 70	8.2 Evidence gap analysis and 8.3 Key areas for evidence generation	Table 22 explicitly states that it does not reflect evidence available in other populations. Given this acknowledgement, the report could go further in integrating excluded Alleye studies as contextual evidence for AMBER domains such as clinician experience/system implementation, costs/resource use, and patient usability/acceptability. Several excluded studies appear relevant to exactly these domains, even if not directly relevant to progression from advanced dry AMD/geographic atrophy to neovascular AMD.	The evidence gap analysis only includes gaps with regards to the decision problem. The EAG have included some out of scope evidence as an aside, but will not be including any more. The EAG have included a comment in this section regarding NHS studies in different populations that were not included: “For some of the technologies there were studies demonstrating implementation in the NHS, but that did not meet the inclusion criteria for the main body of the report, or for the out of scope information. For Alleye, there were 4 studies (Eppenberger et al. 2021; Huemer et al. 2024; Islam et al. 2021). For OKKO for AMD, there were 2 (Campbell et al. 2022; Campbell et al. 2024). For DigiVis DVA, there were 2 (Thirunavukarasu et al. 2022; Nct, & Cambridge University Hospitals. 2020).

					There were none for Peek Acuity or OdySight."
Cambridge Medical Innovation Ltd	22	14	Table 3	Time taken: mean time taken is 7.8 minutes	Thank you for this information, it has been added to the table
Cambridge Medical Innovation Ltd	23	17	1.2	Although not directly relevant to this clinical issue, it is important to state that DigiVis DVA is also suitable for use in clinical, community and commercial settings, where it can also be configured as a self-testing Kiosk. As well as use prior to telephone consultations, DigiVis DVA can be used between face to face visits or during video consultations.	An additional sentence has been added to stated: "DigiVis DVA can also be used during appointments, and also configured as a self testing kiosk device to enable community testing and use in clinics, however this is not included in the current scope."
Cambridge Medical Innovation Ltd	24	41	Table 11	DigiVis DVA additional onsite support is available at up to £900 per day, depending on the requirement and grade of staff involved.	The report accurately states the information supplied in the RFE. No changes have been made
Cambridge Medical Innovation Ltd	25	41	Table 11	Set up time per patient is about 10 minutes.	Thank you for this information, it has been added to the table
Cambridge Medical Innovation Ltd	26	46	Table 13	Minimum implementation costs including staff training is £1500 as training is included in onboarding charge.	The EAG calculated full implementation costs include the time of the NHS staff to attend the training, which results in a slightly higher cost. No changes have been made.
Cambridge Medical Innovation Ltd	27	67	Para 2	DigiVis DVA – we do not provide technical support directly to patients, other than in the course of investigating a technical issue or safety event.	Thank you for the clarification, it has been removed from the description.

Section B: Comments on the economic model

Organisation	Issue	Description of problem	Description of proposed amendment	Result of amended model or expected impact on the result (if applicable)	CEDAR comment
Oculocare Medical Inc	1	The model structurally captures costs up to diagnosis, but not most of the benefits that home monitoring is intended to generate. The EAG states that the pathway ceases at initial diagnosis, that utilities and the costs of early or delayed treatment are excluded, and that earlier diagnosis is expected to improve outcomes and quality of life but that this cannot be quantified with current evidence. The report also notes that this structure makes it unsurprising that monitoring technologies appear cost-incurring.	Add a scenario or extended model that goes beyond diagnosis and captures downstream consequences of earlier detection, such as earlier treatment initiation, reduced vision loss, and utility effects. Even if this must initially be scenario-based, it would be more aligned with the decision problem, which explicitly includes time to first treatment, functional vision, and quality-of-life outcomes.	Expected impact: the model would likely become materially more favourable to monitoring, because it would start to count the benefits that the current structure omits. At minimum, the current conclusion that monitoring remains cost-incurring even in the best case would become less definitive.	There is insufficient available evidence to model the potential impact of early diagnosis for this population, even as a scenario. This is made clear and explained within the report. The EAG have however added a sentence to reiterate this in both the summary of the economic evidence and the executive summary. 6.6: “The model does not capture the pathway beyond diagnosis, and therefore does not include any potential consequences of earlier diagnosis.” Exec summary:”…and considered events only up to the point of diagnosis without capturing subsequent consequences”

Oculocare Medical Inc	2	The base-case pathway may overstate costs for an Alleye-type deployment by relying on a community/primary-care referral route, while Alleye's actual service model is a stand-alone dashboard plus telephone triage and urgent macula slot when needed. The EAG base case assumes that after an alert the user contacts a community eye-care professional, while the alternative scenario models a secondary-care dashboard and telephone triage. The EAG also recognises that previous implementations for Alleye-type systems have used specialist clinic dashboards and virtual triage. Company submissions state that Alleye can be implemented initially as a stand-alone dashboard with no bespoke EPR build and no separate major integration cost for basic adoption.	Replace or supplement the base case with an Alleye-informed operational scenario: stand-alone dashboard, routine remote review, telephone triage, and use of existing PAS/rapid-access retina pathways, with optional deeper integration treated separately rather than implicitly embedded.	Expected impact: likely lower implementation and triage costs for Alleye relative to a more cumbersome community-first pathway, with a more realistic representation of how the technology is actually deployed.	Thank you for the comments, however no changes have been made. The EAG have already include a scenario that considers implementation in secondary care.
Oculocare Medical Inc	3	[redacted]	Add a contracted-price / basic-deployment scenario for Alleye that combines stand-alone dashboard implementation with realistic local pricing assumptions, rather than allowing list-price and maximal implementation	Expected impact: would likely reduce incremental cost and improve cost per early diagnosis, especially because the best-case scenario in the EAG model is already sensitive to lower cost inputs.	Thank you for the comments, however no changes have been made. The EAG model is not based on any single technology due to the lack of sufficient evidence that was within the

		[redacted]	assumptions to dominate interpretation.		scope. The sensitivity analysis included a range of 50% higher and lower than the base case price, and this would encompass the Alleye range of prices.

NICE National Institute for Health and Care Excellence

Medical Technologies Advisory Committee Interests Register

Topic: Digital technologies to support monitoring of vision change at home for people with age-related macular degeneration

NICE's declaration of interest policy can be accessed here

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Dr Jacob Brown	Chair (scoping workshop and committee prep)	N/A	Nothing to declare	-	19/3/2026	-	No further action
Prof Neil Hawkins	Chair MTAC 1	Financial Interest	I am a director of a company providing HTA consultancy services to pharmaceutical, biotechnology, and medical technology companies. No services have been provided to any	-	7/5/2025	Ongoing	Declare and participate
Mr Abdullah Pandor	Committee Member	Financial interest	I have delivered online workshops on rapid reviews at international conferences (ISPOR) for which I received an honorarium.	November 2021 and August	16/10/2025	-	Declare and participate
Mr Abdullah Pandor	Committee Member	Financial interest	I am an expert evaluator for Horizon Europe (EU Research and Innovation programme grant). I received payment for this role.	May/June 2022 and May/June 2023	16/10/2025	-	Declare and participate

Mr Abdullah Pandor	Committee Member	Non financial professional and personal interests	I am a standing member of the NICE Medical Technologies Advisory Committee (MTAC).	2018	16/10/2025	Ongoing	Declare and participate
Mr Abdullah Pandor	Committee Member	Non financial professional and personal interests	I am a standing member of the NIHR Health Technology Assessment General Funding Committee	2022	16/10/2025	Ongoing	Declare and participate
Mr Abdullah Pandor	Committee Member	Non financial professional and personal interests	I am a standing member of the NIHR Decarbonising the Health and Social Care System Funding Committee	2025	16/10/2025	Ongoing	Declare and participate
Mr Abdullah Pandor	Committee Member	Non financial professional and personal interests	I am currently employed by the University of Sheffield whose job description includes bringing in research grant income primarily from sources such as the NIHR, Industry, Charitable Institutions, and other agencies (NICE and the Ministry of Health in Singapore)	-	16/10/2025	Ongoing	Declare and participate
Mr Abdullah Pandor	Committee Member	Non financial professional and personal interests	I am also engaged in major academic research collaborations with various organisations (see https://www.fundingawards.nihr.ac.uk/ for detailed list of academic collaborators)	-	16/10/2025	Ongoing	Declare and participate

Mr Abdullah Pandor	Committee Member	Non financial professional and personal interests	My spouse is an academic at the University of Sheffield. She has a similar research profile to mine and is also tasked with generating research grant income from sources such as the NIHR, Industry, Charitable Institutions, and other government agencies.	-	16/10/2025	Ongoing	Declare and participate
Mr Abdullah Pandor	Committee Member	Non financial professional and personal interests	I am a co-director of a research consultancy company (from 9 March 2026 to present) that provides health technology assessment services to the NIHR, pharmaceutical and biotech companies and other agencies. I have no personal involvement in, and am not aware of, any work undertaken by the company for stakeholders involved in the current appraisal or related to the technology under consideration	-	5/5/2026	Ongoing	Declare and participate Updated 8 May 2026
Dr Andrew Sims	Committee Member	Financial Interest	I am an employee of The Newcastle upon Tyne Hospitals NHS Foundation Trust	-	29/4/2026	Ongoing	Declare and participate
Mr Alex Williams	Committee Member	N/A	Nothing to Declare	-	21/5/2026	-	No Further Action
Dr Andrew Sims	Committee Member	Non financial professional	Co-director, NIHR Health Tech Research Centre in	-	29/4/2026	Ongoing	Declare and participate

		and personal interests	Diagnostic and Technology Evaluation Deputy Director, NIHR Health Tech Research Centre Network				
Dr Avril McCarthy	Committee Member	N/A	Nothing to Declare	-	30/10/2025	-	No Further Action
Mr Darren Kell	Committee Member	Financial Interest	Employed by ScubaTx Ltd, a start up medical device company developing a transplant organ preservation device	June 2024	24/4/2026	31 May 2026	Declare and participate
Dr Devavrata Joshi	Committee Member	Financial Interest	Senior clinical lecturer, Brunel Medical School, Brunel University	01.11.2023	19/10/2025	Ongoing	No further action
Dr Devavrata Joshi	Committee Member	Financial Interest	General practitioner, NHS (multiple practices)	07.12.2022	19/10/2025	Ongoing	No further action
Dr Devavrata Joshi	Committee Member	Financial Interest	GP ENT Clinical Lead, East of England, NHS England	01.01.2025	19/10/2025	Ongoing	No further action
Dr Devavrata Joshi	Committee Member	Financial Interest	MRCGP Examiner (SCA), Royal College of General Practitioners (Examiner for the Simulated Consultation Assessment part of the MRCGP qualification)	12.11.2024	19/10/2025	Ongoing	No further action
Dr Devavrata Joshi	Committee Member	Financial Interest	Shield Therapeutics – shareholdings	06.01.2021	19/10/2025	Ongoing	No further action

			(Pharmaceutical company – a commercial stage specialty pharmaceutical company with a focus on addressing iron deficiency with one compound, ferric maltol)				
Dr Elizabeth-Ann Schroeder	Committee Member	N/A	Nothing to Declare	-	20/10/2025	-	No Further Action
Dr Jennie Walker	Committee Member	N/A	Nothing to Declare	-	3/3/2026	-	No Further Action
Dr Jihad Malasi	Committee Member	Indirect Interest	ICB Clinical lead for Mental Health	Sept 2023	6/3/2026	Current	Declare and participate
Dr Jihad Malasi	Committee Member	Indirect Interest	NHSE GP Tutor	2020	6/3/2026	Current	Declare and participate
Dr Jihad Malasi	Committee Member	Indirect Interest	Current Salaried GP (Invicta Health)	January 2026	6/3/2026	Current	Declare and participate
Dr Jihad Malasi	Committee Member	Indirect Interest	Member of British Medical Association	Nov 2023	6/3/2026	Current	Declare and participate
Dr Katherine Boylan	Committee Member	Non financial professional and personal interests	My employing organization has a long standing strategic relationship with Roche Diagnostics for research and innovation for which I am the operational lead. However to date, this has not extended to the pharma side of Roche, and there has been no joint work around anything linked to the clinical indication or technology being discussed in this MTAC meeting.	April 2020	2/3/2026	Ongoing	Declare and participate

Mrs Kiran Bali	Committee Member	N/A	Nothing to Declare	-	20/5/2025	-	No Further Action
Mr Michael Kolovetsios	Committee Member	Financial Interest	Medtronic employee	November 2019	2/3/2026	Ongoing	Declare and participate
Mr Michael Kolovetsios	Committee Member	Indirect Interest	Medtronic employee	November 2019	2/3/2026	Ongoing	Declare and participate
Mr Manu Thomas	Committee Member	N/A	Nothing to Declare	-	13/5/2026	-	No Further Action
Mr Osman Najam	Committee Member	N/A	Nothing to Declare	-	8/5/2026	-	No Further Action
Dr Philip Crilly	Committee Member	N/A	Nothing to Declare	-	20/10/2025	-	No Further Action
Dr Richard Packer	Committee Member	N/A	Nothing to Declare	-	2/3/2026	-	No Further Action
Ms Sharon Foxwell	Committee Member	N/A	Nothing to Declare	-	2/3/2026	-	No Further Action
Stacey Chang-Douglass	Committee Member	Financial Interest	I am a full-time employee of Clarivate, as head of Health Economics in the consulting department since August 2024. Clarivate is a publicly traded analytics company that provides bibliometrics, business intelligence, and competitive profiling for pharmacy and biotech, patents, and regulatory compliance. 27 August 2024 Not applicable My company provides research and consulting support to pharmaceutical companies	27 August 2024	19/10/2025	Not applicable	Declare and participate

			at various stages of their product development, including NICE submissions. However, I am not involved in any work associated with medical or diagnostic devices or medical technologies or digital health. This COI arose since my employment with Clarivate in August 2024				
Dr Stacey Chang-Douglass	Committee Member	Financial Interest	I am a part-time employee of Evidera, a health economic and outcome research consultancy, since January 2023. Evidera is part of PPD, which is a business entity of Thermo Fisher Scientific. However, research and consulting activities conducted by Evidera are independent of its parent organisations and other entities within the business. My company provides research and consulting support to pharmaceutical companies at various stages of their product development, including NICE submissions. However, I am not involved in any work associated with medical or diagnostic devices or	August 2015	19/10/2025	Not applicable	Declare and participate

			medical technologies. This COI arose since my employment with Evidera in January 2023. My employment with Evidera ends on 31 July 2024.				
Dr Stacey Chang-Douglass	Committee Member	Indirect Interest	I am the founding director of a charitable organisation, Pro Bono Health Economist Network, which provides research and training support to other health charities, which could be patient groups directly or indirectly involved in NICE recommendations. However, currently we are not involved in any work with any patient group. Additionally, we do not receive funding from any pharmaceutical or medical device manufacturers.	December 2021	19/10/2025	Not applicable	Declare and participate
Dr Stacey Chang-Douglass	Committee Member	Indirect Interest	I have been a professional reviewer (health economist) for National Institute for Health August 2015 Not applicable Interests form (advisory committees) October 2022 4 of 5 Research (NIHR) since August 2015. I provide independent comments on NIHR funding proposals and Health Technology	August 2015	19/10/2025	Not applicable	Declare and participate

			Assessment reports, which may include research associated with pharmaceutical products or medica devices. However, I am not involved directly in any of the funding decisions.				
Miss Christiana Dinah	Professional Expert	Financial	Employed as Consultant Ophthalmologist and Director of Research at London North West University Healthcare NHS Trust	14 November 2016	12 November 2025	Ongoing	Declare and Participate
Miss Christiana Dinah	Professional Expert	Financial	Director of NIHR London North West CRDC	1 April 2025	12 November 2025	Ongoing	Declare and Participate
Miss Christiana Dinah	Professional Expert	Financial	Ad-hoc consultancy at advisory boards providing advice on clinical trial design, Principal Investigator with funds paid to my organisation Boehringer Ingelheim	1 January 2024	12 November 2025	Ongoing	Declare and Participate
Miss Christiana Dinah	Professional Expert	Financial	Roche Products Advisory board on clinical trial interpretation, conference attendance, speaker at promotional meeting Research grant to my organization and Principal Investigator of trials with funds paid to my organisation	December 2024	12 November 2025	Ongoing	Declare and Participate
Miss Christiana Dinah	Professional Expert	Financial	EyePoint pharmaceuticals	May 2024	12 November 2025	Ongoing	Declare and Participate

			Advisory board providing insight on clinical trial interpretation				
Miss Christiana Dinah	Professional Expert	Financial	Ocular Therapeutix Advisory board on clinical trial interpretation	May 2024	12 November 2025	Ongoing	Declare and Participate
Miss Christiana Dinah	Professional Expert	Financial	Alimera Sciences Advisory board on clinical trial interpretation, speaker at promotional meeting	May 2025	12 November 2025	Ongoing	Declare and Participate
Miss Christiana Dinah	Professional Expert	Financial	Astellas Advisory board on clinical trial interpretation, speaker at promotional meeting	January 2024	12 November 2025	Ongoing	Declare and Participate
Miss Christiana Dinah	Professional Expert	Financial	AbbVie Advisory board member for biomarker on OCT project and speaker at non-promotional meeting	September 2024	12 November 2025	August 2025	Declare and Participate
Miss Christiana Dinah	Professional Expert	Non-Financial Professional and Personal Interest	Oxford Ophthalmological Congress – Council member	December 2024	12 November 2025	Ongoing	Declare and Participate
Miss Christiana Dinah	Professional Expert	Non-Financial Professional and Personal Interest	BEAMS - Chair	April 2025	12 November 2025	Ongoing	Declare and Participate
Miss Christiana Dinah	Professional Expert	Non-Financial Professional and Personal Interest	Siloton – Provided advice on clinical trial design for Siloton, a company developing remote OCT monitoring technology. Unpaid personally or to my organization.	December 2024	12 November 2025	August 2025	Declare and Participate

Mr Jonathan Baker	Professional Expert	Non-Financial Professional and Personal Interest	On-going management of the National Ophthalmology Database (NOD) AMD Audit – on-going interest	-	12 May 2026	Ongoing	Declare and Participate
Mr Jonathan Baker	Professional Expert	Indirect Interest	The RCOphth has historically received funding for its National Ophthalmology Database AMD audit from Bayer and Roche.	1 January 2022	12 May 2026	1 January 2026	Declare and Participate
Mr Mohammed Abid	Professional Expert	Financial Interest	Sponsored by Roche to attend the Royal College of Ophthalmologists Congress in its entirety. Payment also included accommodation and travel. Roche honorarium speaker at a symposium.	19 May 2025	5 November 2025	22 May 2025	Declare and Participate
Mr Nicholas Beare	Professional Expert	Financial Interest	I undertake private practice in general ophthalmology and medical retina. This is not directly relevant.	2010	3 November 2025	Ongoing	Declare and Participate
Mr Nicholas Beare	Professional Expert	Financial Interest	I have led the development of a handheld OCT in collaboration with the Dept of Electrical Engineering as part of a research project funded by Wellcome Trust for which I was chief investigator and grant holder. This device is not	April 2025	3 March 2026	Ongoing	Declare and Participate Updated March 2026

			designed for self use or monitoring, so is not directly relevant.				
Mr Nicholas Beare	Professional Expert	Non-Financial Professional and Personal Interest	Member of the Royal College of Ophthalmologists Scientific Committee	2019	3 November 2025	August 2025	Declare and Participate
Mr Nicholas Beare	Professional Expert	Non-Financial Professional and Personal Interest	Reader and Clinical Academic Lead, Dept of Eye and Vision Science, University of Liverpool.	March 2019	3 November 2025	Ongoing	Declare and Participate
Mr Nicholas Beare	Professional Expert	Non-Financial Professional and Personal Interest	Specialty Co-Lead for Ophthalmology, North-west Coast CRN, NIHR	July 2019	3 November 2025	October 2024	Declare and Participate
Mr Richard Allen	Professional Expert	Financial	Principal Optometrist, East Suffolk and North Essex NHS Trust	2010	30 October 2025	--	Declare and Participate
Mr Richard Allen	Professional Expert	Financial	Education Visitor, General Optical Council	2024	30 October 2025	-	Declare and Participate
Mr Richard Allen	Professional Expert	Indirect Interest	College Of Optometrists representative member of Cataract Audit Advisory Group, National Ophthalmic Database	2024	30 October 2025	-	Declare and Participate
Mr Vasileios Konidaris	Professional Expert	Financial	Private practice, Stoneygate Eye Hospital, Leicester	1 November 2021	3 November 2025	Current	Declare and Participate
Mr Vasileios Konidaris	Professional Expert	Non-Financial Professional and Personal Interest	Principal Investigator for the study: Visual assessments for the enhanced monitoring of macular disease Project Link	28 August 2025	3 November 2025	Current	Declare and Participate

			https://researchapprovals.forms.le.ac.uk/Project/Index/6981 IRAS REF 352853				
Ms Elaine Shaw	Patient Expert	N/A	Nothing to declare	-	9 December 2025	-	No further action
Mrs Pat Edkins	Patient Expert	N/A	Nothing to declare	-	10 December 2025	-	No further action