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.

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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.