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

Protocol

Produced by: CEDAR (Centre for Healthcare Evaluation, Device Assessment, and Research)

Authors: Samuel Bird (Senior Evaluation Scientist), Megan Dale (Principal Health Economist), Dr Robert Palmer (Senior Evaluation Scientist), Dr Simone Willis (Systematic Reviewer), Rebecca Hughes (Project Support Officer), Dr Elinor MacFarlane (Senior Evaluation Scientist), Ayesha Rahim (Principal Researcher), Kathleen Withers (CEDAR Director)

Correspondence to: CEDAR (Centre for Healthcare Evaluation, Device Assessment, and Research), Cardiff and Vale University Health Board, Cardiff Medicentre, CF14 4UJ

Date completed: 11/02/2026

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.

Table 1 summarises the decision problem to be addressed in this assessment. Further detail on each element can be found in the published scope for the assessment.

Table 1. Summary table of the decision problem

Item	Description
Population(s)	Adults who have advanced dry AMD (geographic atrophy) in one or two eyes that is at high 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, geographic atrophy with previous neovascular AMD (wet) in the fellow eye and specific OCT features.
Intervention(s)	• Alleye • DigiVis DVA • Odysight • OKKO • Peek Acuity
Comparators	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 eligible for inclusion	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 (CVI) 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 the 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.

1.1 Objectives

The purpose of this early use assessment is to summarise and critically appraise existing evidence on the clinical-effectiveness and cost-effectiveness of digital technologies to support monitoring of vision change at home for people with age-related macular degeneration.

The research questions this assessment will aim to answer are:

- What is the clinical effectiveness and cost-effectiveness of digital technologies used to monitor vision at home in people with age-related macular degeneration? This includes the diagnostic accuracy of these technologies for detecting progression to neovascular (wet) AMD.
- What are the risks and safety considerations associated with using these technologies?
- What are the key gaps in the evidence for these technologies, and how might these be addressed?
- What are the practical, cost and resource implications of introducing the technologies into the current care pathway?

The following objectives are proposed to address the research questions:

<u>Clinical Effectiveness</u>

- Identify and assess evidence relating to the use and clinical effectiveness of the included technologies as it pertains to the scope
- For evidence not directly related to the scope, outline the potential generalisability and limitations of the evidence
- Report any potential safety issues

- Report the evidence gaps, highlighting what data may need to be collected to inform these gaps

Cost Effectiveness

- Identify and assess economic evidence relating to the use of the included technologies within the scope
- Report on the technology costs and develop a simple model using available inputs, reporting on the plausibility of cost effectiveness
- Develop a conceptual economic model, or identify a suitable existing model, related to the scope, that can be used to inform future research and data collection
- Report available model inputs and evidence gaps

2. Evidence review methods

An independent search for relevant evidence will be conducted by the EAG. Evidence relevant to the scope will be identified using a combination of databases of published evidence and evidence provided by technology manufacturers through NICE. Rapid review methods will be adopted by the EAG, such as those outlined in the Cochrane Rapid Review Methods Guidance. A full systematic review will not be conducted as this is outside of the scope for an early use assessment as outlined in section 3.2.6 of the NICE HealthTech programme manual (NICE, 2025).

2.1 Inclusion criteria

Table 2 outlines the inclusion and exclusion criteria considered for the evidence identified. If a large volume of evidence is identified, certain evidence may be prioritised for inclusion (see Section 2.3).

Table 2. Inclusion and exclusion criteria

	Inclusion Criteria	Exclusion Criteria
Population	People diagnosed with advanced dry AMD (geographic atrophy) in one or two eyes that is at high risk of	Animal studies will not be included.

	progression to neovascular (wet) AMD	
Intervention	• Alleye • DigiVis DVA • Odysight • OKKO • Peek Acuity	Papers that do not report the use of a technology named in the scope will be excluded.
Comparators	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	Comparative evidence where the comparator does not reflect the UK clinical pathway, unless no relevant evidence is identified with comparators relevant to the UK.
Setting	The technologies are for use in the home setting	
Outcomes	Those included in the scope.	Evidence will be excluded if no relevant outcomes are reported. If a subsection of outcomes are relevant to the scope, these alone will be reported.
Study design	Randomised controlled trials, retrospective and prospective observational studies, diagnostic accuracy studies, cross-sectional studies, case series.	Narrative reviews, case reports, editorials, letters.
Publication type	Full-text publications. Abstracts and conference proceedings will only be included if there is sufficient information reported for the purposes of this assessment. Unpublished reports submitted by companies (provided they contain sufficient detail on methods and relevant outcomes).	Abstracts and conference proceedings will be excluded if: - there is an associated full-text paper available for the same study, - there is insufficient information reported for adequate assessment, - there is a large volume of relevant full-text publications available.

2.2 Search strategy

Searches will be developed in Medline ALL (Ovid) by an experienced Information Specialist. Search terms will include free-text terms and controlled terms from

databases (e.g. MeSH). Searches will be structured around population and intervention concepts as detailed in the inclusion criteria (Section 2.1). An example search strategy is provided in Appendix A. The search strategy will be peer-reviewed by a second Information Specialist. The search strategy will be translated to each database.

The following bibliographic databases will be searched:

- Medline ALL (Ovid)
- Embase (Ovid)
- Cochrane Database of Systematic Reviews (CDSR)
- Cochrane Central Register of Controlled Trials (CENTRAL)
- International HTA database (INAHTA)

The following clinical trials registries will be searched for ongoing trials:

- ClinicalTrials.gov
- International Clinical Trials Registry Platform (ICTRP)

Relevant guidelines will be identified by searching:

- NICE Guidance
- Scottish Intercollegiate Guidelines Network (SIGN)
- Health Technology Wales

Where possible, the EAG will identify additional studies from the information provided by companies to NICE. To identify studies that have not been retrieved by the database searches, company websites will be searched for relevant publications. The MHRA alerts and MAUDE database will be searched for any safety notices or adverse events for the technologies.

The EAG anticipates that the main search strategy described above will identify both clinical and economic evidence relevant to the technologies in scope. Where economic evidence is identified as relevant to the wider decision problem, but is not

specific to the technologies, the EAG will consider a brief summary in the final report. Additionally, a targeted literature search may be conducted to update model inputs for this assessment, if necessary. To increase the relevance of the results, filters will be added to this search, such as the economic evaluations and models (CADTH, 2025), health utilities (CADTH, 2025), and the NICE UK geographic filters (Ayiku, 2017).

2.3 Study selection

Retrieved references will be imported into EndNote and deduplicated, after which they will be imported into the screening tool Rayyan, where deduplication will be completed and records screened. The titles and abstracts of the identified studies will be screened by one reviewer and a minimum of 20% of excluded records will be checked by a second reviewer against the pre-specified inclusion and exclusion criteria (see Table 2). The AI screening tool available within Rayyan will not be used and all decisions will be made by the review team. Where a record appears to meet the eligibility criteria, or where a decision cannot be made based on the information provided in the titles and abstracts alone, it will be progressed to the full-text screening stage. The full texts of the articles progressed to this stage will be obtained and screened by one reviewer, with a random 20% of exclusions checked by a second reviewer. Where disagreement occurs between the first and second reviewer, there will be a discussion with involvement of a third reviewer where necessary. Only records where it is made explicit that the examined technology is one of those in scope will be included in the review. A list of studies excluded at the full-text stage, with reasons for their exclusion, will be presented in an appendix in the report.

Where a large volume of evidence is identified, a pragmatic approach to study selection may be taken, in line with the NICE HealthTech programme manual (NICE, 2025). Prioritisation of studies to be included may be based on factors such as study design, sample size, availability of relevant patient-focused outcomes, length of follow up, and extent of generalisability to a UK population. Clinical experts may be consulted to inform these decisions. Any decisions made and approaches taken by the EAG will be flagged with the NICE team for discussion and presented transparently in the final report.

The evidence review aims to identify the most relevant evidence relating to the decision question defined in the scope. If no evidence directly relevant to the technologies in scope is available, a broader evidence base may be evaluated. This will be decided upon in conjunction with NICE and transparently reported by the EAG.

2.4 Data extraction strategy

Where available, the following data will be extracted from studies: study information (i.e., author, year), study design, study dates, intervention characteristics (i.e., intervention name), comparator, participant characteristics (i.e., demographics, comorbidities) and participant outcomes which are relevant to the scope. Data extraction will be conducted by one reviewer using Microsoft Word and checked by a second.

2.5 Quality assessment strategy

A full critical appraisal of all studies and outcomes using validated checklists will not be conducted, in line with the expectations outlined in section 3.2.7 of the NICE HealthTech programme manual (NICE, 2025). A narrative summary of the key strengths and limitations of the evidence will be presented in the final report. This summary will highlight potential biases in individual studies, discuss how these impact on the certainty of the results and outline how this might impact generalisability to NHS clinical practice.

2.6 Methods of synthesis and analysis

The EAG will consider meta-analysis methods to synthesise relevant clinical evidence. However, due to the nature and purpose of an early use assessment, it is not anticipated that there will be enough data available to conduct a meta-analysis.

Results for both clinical and economic literature will therefore be presented in a suitable tabular format accompanied by a narrative synthesis of the data, considering available evidence relating to all aspects of the scope (for example, population, setting, comparators). Methodological issues with included studies will be noted along with any identified risks of bias which may impact study results. A discussion outlining the applicability of the evidence to the scope of the early use assessment

will be included, as well as consideration of the generalisability of evidence to clinical practice in the NHS.

3. Economic analysis methods

The scope of the economic analysis will depend on data availability. If data allows, an early economic model will be developed, to compare costs and outcomes of all technologies in the scope. An appropriate time horizon will be used to capture costs and outcomes, based on available evidence. Existing models will be identified, prioritising models used in NICE guidance. These models will be assessed to determine their suitability as the basis for the conceptual model. A simplified early economic model may be developed to reflect limitations in data currently. Clinical expert validation will be sought to assess the face validity of the EAG early economic model and any model modifications of the conceptual model. However, if data are not sufficient to populate the early economic model, a simple cost comparison model may be developed to assess costs, staff time and time to detect changes in vision between technologies.

3.1 Model development

The economic analysis will be performed in line with the NICE reference case. The perspective of NHS and Personal Social Services will be undertaken. Costs will be expressed in 2024 prices and where applicable, costs will be inflated using NHS Cost Inflation Index (NHSCII). If sufficient data are available, quality-adjusted life years (QALYs) will be the primary outcome in the economic analysis, calculated using utility values for each intervention. All costs and outcomes will be discounted at 3.5% per annum.

A simple decision analytic model will be developed in Microsoft Excel to consider technologies to support monitoring of vision change at home as an adjunct to standard care, compared to standard care alone, for the monitoring of advanced dry AMD (geographic atrophy). Where possible, the impact of these technologies would be considered for: user engagement, adherence to monitoring and staff time to support monitoring at home and to respond to detected changes. The diagnostic performance of each intervention (sensitivity, specificity and other relevant diagnostic accuracy outcomes) will be included, and the impact of false positives and negatives

on healthcare resource use and clinical outcomes considered. Where possible, downstream costs and QALYs will be modelled, including time to diagnosis and start of treatment, as well as maintenance of functional eyesight. One-off costs and QALYs of each diagnostic outcome may be applied. Where sufficient clinical evidence is available, a longer-term model may be considered to capture the impact of earlier detection of change and improved care.

The model inputs will be informed by evidence identified from the EAG search, published literature, company submissions and consultation with clinical experts and patient representatives. If necessary, additional targeted searches may be considered to update model inputs. Resource use and costs for each intervention will be estimated, including technology costs, training costs, NHS staff costs. Resource use and costs associated with managing advanced dry AMD (geographic atrophy), or subsequent development of neovascular (wet) AMD will be obtained from relevant clinical guidelines, published literature and clinical expert inputs. Model assumptions will be clearly described and informed by evidence or advice from clinical experts. Where possible, other relevant outcomes will be reported. This may include the need for additional equipment or support to enable use of the technologies under consideration, timeliness of diagnosis, time to initiation of treatment, and the proportion of false positive and false negative cases.

Deterministic and probabilistic sensitivity analyses will be undertaken to identify the key cost drivers and to explore the impact of uncertainty, where possible.

3.2 Conceptual modelling

If available, a suitable existing model will be identified as the conceptual model, and any model modifications for future analysis will be outlined.

Where existing models are not available or not suitable, the EAG will conceptualise the model structure that represents the pathways and parameters needed for this population. This could form the basis for future economic analysis to compare long-term costs and benefits between technologies. However, it is not feasible to develop an executable model and fully populate it. Model inputs that are likely to be key drivers of future cost-effectiveness will be identified.

3.3 Cost of reversing a decision

The cost of reversing a decision will be estimated, which may include any up-front costs to purchase the equipment and setting up the service, training costs and any costs that could not be recouped following their implementation in NHS. This will be explored in a sensitivity analysis, if appropriate.

4. Evidence gaps analysis

Evidence gaps will be identified and summarised in a suitable tabular format. The EAG will use the available evidence base in combination with input from clinical experts to determine where the evidence gaps lie and how these gaps may be addressed. Suggested methods of evidence generation to fill evidence gaps will be summarised in the report and key outcomes that may be required will be identified.

5. Handling information from the companies and other stakeholders

All data submitted by the companies in evidence and information requests by NICE, or data submitted by other stakeholders will be considered by the EAG if received by 27/02/2026. Information arriving after this date will not be considered. If the data included in the information provided meets the inclusion criteria for the review, they will be extracted and quality assessed following the procedures outlined in this protocol. The EAG may seek clarification or additional information from companies and other stakeholders where necessary. All correspondence between the EAG and companies will happen through NICE.

Any 'commercial in confidence' data provided by a company and specified as such will be highlighted in blue and underlined in the assessment report. Any 'academic in confidence' data provided by company(s), and specified as such, will be highlighted in yellow and underlined in the assessment report. If confidential information is included in the economic model, the EAG will provide a copy of the model with 'dummy variable values' for the confidential values (using non-confidential values).

6. Competing interests of authors

None.

7. References

National Institute for Health and Care Excellence (NICE). (2026) Digital technologies to support monitoring of vision change at home for people with age-related macular degeneration: early use assessment [GID-HTE10073]

NICE HealthTech programme manual. (2025) Available from: https://www.nice.org.uk/process/PMG48

Appendix A: Draft search strategy

Ovid MEDLINE(R) ALL <1946 to February 06, 2026>

1	macular degeneration/	20079
2	geographic atrophy/	1358
3	(macula* adj2 (degenerat* or disease* or pathologi*)).tw.	31585
4	Maculopath*.tw.	6294
5	(AMD and macula*).tw.	14424
6	(AMD adj3 (age or advance* or dry or late)).tw.	3117
7	geographic atroph*.tw.	2221
8	or/1-7	41422
9	Smartphone/	12773
10	Mobile Applications/	16545
11	(smartphone* or app or mHealth or mobile*).tw.	216354
12	(web* adj3 application*).tw.	7957
13	"puzzle games".tw.	31
14	(hyperacuity and app).tw.	6
15	or/9-14	225668
16	8 and 15	155
17	alleye.tw.	10
18	DigiVis.tw.	4
19	Odysight.tw.	4

20	OKKO.tw.	0
21	Peek Vision.tw.	7
22	Oculocare.tw,in.	9
23	cambridge medical innovation.tw,in.	0
24	Tilak Healthcare.tw,in.	4
25	Peek Acuity.tw,in.	16
26	"Peek Community".tw.	3
27	or/17-26	47
28	OKKO.tw,in.	75
29	tilak.tw,in.	2752
30	or/28-29	2827
31	8 and 30	1
32	16 or 27 or 31	197
33	exp animals/ not humans.sh.	5422940
34	32 not 33	192