NICE National Institute for Health and Care Excellence

HealthTech Programme

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

Draft Scope consultation – Collated Comments

Questions to stakeholders:

1. Does the Royal College of Ophthalmologists classification of AMD (see The Royal College of Ophthalmologists commissioning guidance – age-related macular degeneration services, 2024) follow the order of progression of AMD, or does advanced dry AMD (geographic atrophy) usually develop before neovascular (wet) AMD?
2. Should juvenile macular dystrophy be included as a population in this assessment?
    - If yes, should juvenile macular dystrophy be considered as subgroup or a separate population group?
    - If yes, which conditions should be included as juvenile macular dystrophy?
3. Are there any criteria for defining which people with advanced dry AMD (geographic atrophy) are at high risk of developing neovascular (wet) AMD?
4. Are there any other subgroups that should be included?
5. In England, are people with AMD at risk of progression (for example, because of family history) encouraged to access OCT at primary care appointments?
    - If yes, should OCT be part of the comparator?
6. Are there any outcomes that should be added?
7. Are there any outcomes currently included that should be removed?
8. Are there any technologies missing?

Comment number	Name / Organisation	Page number	Section number	Comment	NICE response
1	Consultee 1	5	3.3	OCT equipment is not a mandatory requirement for community optometry practice, although there is increasing prevalence. In addition, any practice with OCT does not include this within NHS funded primary care eye testing, and any request for	Thank you for the information. We have added some wording to section 3.3 of the scope to explain that there is variation in access to OCT in the community.

Comment number	Name / Organisation	Page number	Section number	Comment	NICE response
				monitoring should include funding within the model.	
2	Company consultee (Tilak Healthcare)	5	3.3	Self-monitoring also concerns people with intermediate AMD, and unilateral wet AMD (even more with arrival of long-acting anti-VEGF)	Thank you for your comment. We recognise that there is a potential use for the technologies to monitor people with intermediate AMD for progression to advanced forms of AMD. The NICE clinical guideline on Age-related macular degeneration does not recommend self-monitoring for people with intermediate AMD and so this use has not been included in the scope for this assessment. We recognise that the technologies could also be used to monitor neovascular AMD (wet) AMD that is being treated. This use case is outside the scope for this assessment.
3	Company consultee (Tilak Healthcare)	6	4 Unmet need	Even with the advent of home OCT, it seems unrealistic to imagine that all high-risk patients can be monitored regularly enough by OCT	Thank you for your comment.
4	Company consultee (Tilak Healthcare)	7	5 intended use	To be completed? … are intended for use by adults who have been diagnosed with intermediate, advanced dry AMD/ geographic atrophy or unilateral wet AMD and are at risk of developing neovascular or wet AMD	Thank you for your comment. Please see response to comment 2.
5	Company consultee (Tilak Healthcare)	9	5.4	The description of OdySight could be completed to be more accurate : OdySight is the combination of a smartphone app for the patient and a dashboard for the	Thank you for the information. The description of OdySight has been updated in the scope.

Comment number	Name / Organisation	Page number	Section number	Comment	NICE response
				medical team. It is prescribed by an ophthalmologist to monitor the visual acuity at home with the aim of improving the monitoring of eye disease and its progression. If offers two vision tests : a visual acuity test (Tumbling E) and a digital Amsler grid. The patient should test himself twice a week, the test takes less than 1 minute. Based on the visual acuity test (not the Amsler Grid), an algorithm detects the change in the vision and alerts both the patient and the ophthalmologist and her team to set up a call or an early appointment. The medical device is completed by a gaming incentive (puzzles designed by optometrists) to help patients observance. Odysight has a class 1 CE mark. It is not currently used in the NHS.	
6	Consultee 2	10	5.7	Perhaps a couple of sentences can be added about how the technologies can also be used to monitor for reactivation of neovascular AMD after patients have completed the intravitreal injection pathway. As patients need to be monitored for up to 2 years following treatment cessation, these technologies can help in adjunct to hospital monitoring (can help reduce frequency of hospital visits).	Thank you for your comment. This use case is outside of the scope for this assessment, as this assessment will focus on detecting progression of advanced dry AMD (geographic atrophy) to neovascular AMD (wet AMD). We have added some information about other potential use cases for the technologies, including this one suggested, for completeness and to clarify the use cases that are included and excluded from the scope.
7	Consultee 3	14	10	The clinical outcomes on table 1 could also include assessment of false positive and false negative responses.	Thank you for your comment. The term diagnostic accuracy is intended to cover all relevant measures including sensitivity, specificity, false positives and false

Comment number	Name / Organisation	Page number	Section number	Comment	NICE response
					negatives. All relevant outcome measures that are reported in the evidence will be included in the assessment.
8	Company consultee (Tilak Healthcare)	14	10 Outcomes and costs	The first Clinical outcomes is the percentage of people that maintained functional vision in the affected eye (measured with ETDRS) => this outcome is very important but needs a lot of time and a lot of patients to be demonstrated, there's no mention of duration to collect the data but with that kind of outcome, you will need at least 3 years.	Thank you for your comment. During the assessment, the external assessment group will search for and review evidence. Duration of follow up for this outcome will be reported in the assessment report.
9	Company consultee (Tilak Healthcare)	14	10 Outcomes and costs	QoL: the EQ-5D-3L is poorly adapted to eye diseases and loss impairment. The interest of this item is probably low. All the other items on the PROMs list are way better to assess the impact.	Thank you for your comment. We have kept EQ-5D-3L in the scope because it is NICE's preferred measure for reporting health-related quality of life. The committee will consider which outcomes are most important for decision making during their consideration of the evidence.
10	Company consultee (Tilak Healthcare)	14	10 Outcomes and costs	A criteria that should be added is the earlier detection of second eye impairment. The bilateralisation of the disease is very frequent and it's interesting to follow up that outcome.	Thank you for your comment. The scope has been updated with an outcome to capture the progression of AMD in the fellow eye.
11	Consultee 2	14	10	Under 'Costs and resource use', need to add cost of any IT infrastructure and other related aspects to facilitate information sharing between apps and hospital systems.	Thank you for your comment. This has been added to the scope.
12	Consultee 3	15	11.1	Lack of resources: dedicated phone line for contacting HES in case of an alert, additional appointments required (virtual of face to face)	Thank you for your comment. We believe that most people with advanced dry AMD (geographic atrophy) alone will not be under the care of hospital eye services. We believe that for this group, the alert would be most likely be sent to the

Comment number	Name / Organisation	Page number	Section number	Comment	NICE response
					optometrist who would make an urgent referral to hospital eye services if progression to neovascular AMD (wet AMD) is detected. We have included the dedicated phone line in the scope and altered the wording slightly to reflect that the alert may not go directly to hospital eye services.
13	Consultee 3	15	11.1	Medicolegal issues (who is responsible in false negative signals)	Thank you for your comment. This has been added to the scope.
14	Company consultee (Tilak Healthcare)	15	11.1	"If people have difficulty using this technologies at home the workload of community eye services could be increased through increased requirement for user training and support" => In France, it's the company that deploys the tool that is in charge of all the support, I don't know if it's transposable in the UK system but clearly the Support Team of the company is Key to help patients using the device since the population is often old.	Thank you for your comment. We will look for data on training costs and requirements during the assessment phase.
15	Company consultee (Tilak Healthcare)	16	11.2	"… their fellow eye will be monitored by hospital eye services": Potentially not really, with the spacing of visits/injections made possible by arrival of new anti-VEGF drugs.	Thank you for your comment.
16	Consultee 4		Q.1	Generally, follows order of progression with early dry gradually progressing to late dry or changing to neovascular AMD; Not all patients with GA develop wet AMD and vice versa	Thank you for your comment. Section 2.1 of the scope has been amended to clarify that the Royal College of Ophthalmologists classification does not necessarily represent a linear progression though each class of AMD.

Comment number	Name / Organisation	Page number	Section number	Comment	NICE response
17	Company consultee (Tilak Healthcare)	17	Question 1	It is rather intermediate AMD that precedes the late forms (geographic or exudative atrophy).	Thank you for your comment. Please see response to comment 16.
18	Consultee 5	2	Q1	• **Does the Royal College of Ophthalmologists classification of AMD (see The Royal College of Ophthalmologists commissioning guidance – age-related macular degeneration services, 2024) follow the order of progression of AMD, or does advanced dry AMD/geographic atrophy usually develop before neovascular AMD or wet AMD?** Neovascular AMD can develop either in early or late-stage AMD.	Thank you for your comment. Please see response to comment 16.
19	Consultee 2		Q.1	*The classification generally follows the order of progression of AMD. Depending on the subtype of Wet AMD, advanced dry AMD/GA does not always have to precede neovascular or wet AMD.*	Thank you for your comment. Please see response to comment 16.
20	Consultee 4		Q.2	No, in my opinion juvenile macular dystrophy is a separate entity to AMD	Thank you for your comment. We have decided not to include juvenile macular dystrophies because they are genetic conditions that are distinct from AMD in terms of disease trajectories, monitoring needs and service pathways.

Comment number	Name / Organisation	Page number	Section number	Comment	NICE response
21	Consultee 1		Q2	Yes – this sub group is especially good for utilising new technology. It should be considered as a separate population group.	Thank you for your comment. Please see response to comment 20.
22	Consultee 2		Q.2	*Yes, they can be included in this assessment. A separate population group.* Best's vitelliform macular dystrophy.	Thank you for your comment. Please see response to comment 20.
23	Company consultee (Tilak Healthcare)	17	Question 2	***Some of the device are not CE mark for people under 18. (It's the case for OdySight, I don't know for the others)***	Thank you for your comment.
24	Consultee 4		Q.3	AREDS severity scale	Thank you for your comment. We have added that the AREDS severity scale and presence of certain clinical factors can be used to identify high risk of progression.
25	Company consultee (Tilak Healthcare)	17	Question 3	Use AREDS classification? (consider also intermediate AMD…)	Thank you for your comment. Please see response to comment 24.
26	Consultee 2		Q.3	*I am not aware of any formal criteria for this. However, a list of clinical signs that describe those at higher risk of developing neovascular AMD can be compiled, which can include signs such as subretinal drusenoid deposits (SRDDs) and confluent soft drusen.*	Thank you for your comment. Please see response to comment 24.
27	Consultee 4		Q.4	Early onset AMD	Thank you for your suggestion. Early onset AMD has been added as a subgroup.
28	Company consultee	17	Question 4	All conditions that may be complicated by subretinal neovascularisation, including high myopia?	Thank you for your comment. The population within the scope of this assessment is people with AMD. We have

Comment number	Name / Organisation	Page number	Section number	Comment	NICE response
	(Tilak Healthcare)				included a subgroup for people that have AMD and another eye condition that may be complicated by subretinal neovascularisation.
29	Consultee 2		Q.4	No, I do not think any other sub-groups should be included.	Thank you for your comment.
30	Consultee 4		Q.5	Yes, OCT should be a comparator	Thank you for your comment. NICE HealthTech assessments use the current standard of care as the comparator. We were unclear whether people with advanced dry AMD (geographic atrophy) are routinely accessing OCT as part of standard care. We have received responses that access to OCT is variable for this group of patients and is not considered standard for monitoring this population, we have amended the scope accordingly. We acknowledge that OCT is the gold standard and so the technologies will be compared with OCT as a reference standard for diagnostic accuracy outcomes.
31	Company consultee (Tilak Healthcare)	17	Question 5	OCT is better than visual acuity tests but is not available at home at the time and costs a lot more. It should not be compared since it's not a possibility for patients nowadays.	Thank you for your comment. Please see response to comment 30.
32	Consultee 2		Q.5	*I do not think they are encouraged to the same level as individuals with family history of other conditions such as Glaucoma. However, I do think these individuals should be encouraged to seek more regular eye examinations with OCT on the day. This is*	Thank you for your comment. Please see response to comment 30.

Comment number	Name / Organisation	Page number	Section number	Comment	NICE response
				especially true for individuals who may only be getting an eye examination every 2 years (this should be altered to a yearly examination). Yes, as OCT is the gold-standard for looking at anatomical changes to ascertain disease activity.	
33	Consultee 5	5	Q5	• **In England, are people with AMD at risk of progression (for example, because of family history) encouraged to access OCT at primary care appointments?** Not all primary care Optometry practices have access to an OCT. Patients in England who have a diagnosis of AMD from either a hospital setting (and discharged) or community Optometry practice should be encouraged to seek OCT within primary care on a regular basis. I would be unsure how regularly this is being encouraged. Most patients would need to pay privately for OCT, and some patients may not be able to do this which then puts them at a disadvantage. Yes, OCT should be part of the comparator.	Thank you for your comment. Please see response to comment 30.
34	Consultee 4		Q.6	Certificate of Visual impairment (CVI) completion or conversion from sight	Thank you for your comment. Proportion of people with a Certificate of Visual

Comment number	Name / Organisation	Page number	Section number	Comment	NICE response
				impaired to severely sight impaired during the course of treatment for AMD	Impairment has been added to the outcomes.
35	Consultee 1		Q6	Is it possible to word another oucome related to patients identified with maula changes/progression in a method other than home monioring – i.e detecting home monitoring false negative.	Thank you for your comment. The term diagnostic accuracy is intended to cover measures including sensitivity, specificity, false positives and false negatives. These outcomes measures will be specified in the protocol.
36	Company consultee (Tilak Healthcare)	17	Question 6	Bilateralisation detection could be added as an outcome.	Thank you for your comment. Please see response to comment 10.
37	Consultee 2		Q.6	*No, I do not think any other outcomes should be added.*	Thank you for your comment.
38	Consultee 4		Q.7	No	Thank you for your comment.
39	Company consultee (Tilak Healthcare)	17	Question 7	I would remove the EQ-5D for QoL.	Thank you for your comment. Please see response to comment 9.
40	Consultee 2		Q.7	*No, I do not think any outcomes should be removed.*	Thank you for your comment.
41	Consultee 4		Q.8	What about ForseeeHome, Notal vision?	Thank you for highlighting these technologies. For NICE HealthTech guidance to be useful and usable, included technologies must have regulatory approval and be available for use in the NHS (or expected to be by the time the guidance publishes). The Notal technologies Foresee Home and Scanly currently have FDA approval but are not

Comment number	Name / Organisation	Page number	Section number	Comment	NICE response
					expected to have regulatory approval for use in UK NHS before the guidance is published. Home OCT has been shared internally within NICE for future consideration.
42	Consultee 2		Q.8	*Ideally, if available, home OCT technologies should be included.*	Thank you for your comment. For NICE HealthTech guidance to be useful and usable, included technologies must have regulatory approval and be available for use in the NHS (or expected to be by the time the guidance publishes). We identified home OCT technologies during scoping but as none of these technologies are anticipated to be available to the UK NHS before this guidance is published, they have been excluded from the scope of this assessment. Home OCT has been shared internally within NICE for future consideration.