



## EDITORIAL

# The Royal College of Ophthalmologists Commissioning guidelines on age macular degeneration: executive summary

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equivocal scans on OCT-A, partial or poor responders to anti-vascular endothelial growth factor (anti-VEGF) therapy and in patients where any other retinal signs might be confounders. Centres that do not have ICGA facility may need to refer to those with services.

## INTRODUCTION

The Royal College of Ophthalmologists (RCOphth) published the commissioning guidance for AMD services in June 2021 to set out the principles and minimum standards of care for AMD to decrease variations of care across AMD services in England and Wales. It provides information to support the current and future capacity planning of AMD services. It is intended for use by payors, providers, social care and users of the AMD services, including their families and carers. It is based on the best available evidence obtained from the systematic review of the literature and is compliant with the National Institute for Health and Care Excellence (NICE) Clinical Guideline on AMD NG82 dated 23 January 2018, NICE quality standard QS180 dated February 2019 [1, 2]. The document uses the NICE guidelines classification for AMD shown in Table 1. The guidance provides recommendations on minimal standards for diagnosis and management of early and late AMD. The complete guidance can be accessed from <https://www.rcophth.ac.uk/resources-listing/commissioning-guidance-age-related-macular-degeneration-services/>.

## RECOMMENDED STANDARDS FOR DIAGNOSIS OF AMD

These include recording symptoms of AMD, smoking and family history of AMD. Visual acuity (VA) assessment should ideally be done using a logarithm of the minimum angle of resolution (logMAR) chart and recorded in Early Treatment Diabetic Retinopathy Study (ETDRS) letters for all cases of AMD. Snellen VA is acceptable if ETDRS is not available during the first consultation. However, conversion of Snellen VA to logMAR should be avoided due to the high level of inaccuracy [3]. Clinical examination of both eyes should be recorded.

Optical coherence tomography (OCT) is often the first diagnostic test for patients with suspected AMD [4] and it has high sensitivity and specificity in detecting late AMD. Optical coherence tomography–angiography (OCT-A) has become more widely accepted as a rapid, sensitive, and non-invasive imaging test used for confirmation of neovascular AMD (nAMD) that has been detected on OCT [5]. OCT can be employed as a sole investigation to detect nAMD in rare scenarios when there is no ready access to confirmatory tests such as OCT-A or fundus fluorescein angiography (FFA) to avoid delay in receiving first treatment within 2 weeks of diagnosis or due to patient factors such as difficulty in obtaining informed consent, allergy to fluorescein dye or inconclusive OCT-A and/or FFA. FFA is the recommended invasive test but indocyanine angiography (ICGA) may add value to the interpretation especially when there is a suspicion of polypoidal choroidal vasculopathy (PCV) [6, 7]. FFA in combination with ICGA is indicated specifically in cases with

## RECOMMENDATIONS FOR REFERRAL TO AMD SERVICES

Referrals for AMD can come from primary care optometrists, general practitioners (GPs), diabetic retinopathy services, tele-medicine or virtual retinal clinics in hospital eye services (HES) or self-referral to eye casualty by the patient themselves. Referral letters should include history and symptoms, VA and funduscopy findings. Any OCT scans or fundus photographs should be attached to the referral. For referrals from sources other than optometrists, optional referral to optometrists may be made first for diagnostic confirmation but this should not delay treatment. Urgent referrals may be made through a dedicated phone line or secure email service approved for information transfer of clinical information. If the option is available and compatible with local rapid access services, eRS helps optimise dialogue and feedback.

As a result of the COVID-19 pandemic, COVID-19 red flags are incorporated into urgent eye-care service pathways developed by the national outpatient transformation programme of NHS England and NHS Improvement. Please refer to the Community of Practice NHS website for updates (<https://future.nhs.uk/home/grouphome>).

## Referral assessment and refinement in HES

Minimum standards to be met are:

- Medical retina consultant-led service providing governance structure.
- History and symptoms: medical history should include medication and allergies.
- VA assessment preferably in ETDRS letters or logMAR.
- Imaging: structural OCT for the initial assessment. If clinical examination and OCT exclude nAMD, the pathway stops, and patients may be discharged back to optometrists.
- OCT findings are confirmed by OCT-A and/or FFA/ICGA if OCT shows signs of nAMD.
- Assessment and offer of treatment within 2 weeks of the date of referral after discussing the pros and cons of the treatment regimen.

Table 2 shows the various outcomes for referrals. Feedback on referral must be sent to the referrer and copied to the GP.

## RECOMMENDED CARE PATHWAYS

The recommended care pathways for various stages of AMD are shown in Fig. 1. A set of general recommendations are suggested to be made available to all patients with AMD (Table 3).

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**Table 1.** NICE guidelines-based classification of age-related macular degeneration [1].

AMD classification in NICE guidance	Definition in NICE guidance	Frequently used terminology
Normal eyes	No signs of age-related macular degeneration (AMD) Small ('hard') drusen (less than 63 µm) only	No AMD
Early AMD	<p>Low risk of progression: –medium drusen (63 µm or more and less than 125 µm) or pigmentary abnormalities</p> <p>Medium risk of progression: –large drusen (125 µm or more) or –reticular drusen or –medium drusen with pigmentary abnormalities</p> <p>High risk of progression: –large drusen (125 µm or more) with pigmentary abnormalities or –reticular drusen with pigmentary abnormalities or –vitelliform lesion without a significant visual loss (best-corrected acuity better than 6/18) or –atrophy smaller than 175 µm and not involving the fovea</p>	<p>Early AMD or age-related maculopathy</p> <p>Intermediate AMD</p>
Late AMD (indeterminate)	Retinal pigment epithelial (RPE) degeneration and dysfunction (presence of degenerative AMD changes with subretinal or intraretinal fluid in the absence of detectable neovascularisation) Serous pigment epithelial detachment (PED) without neovascularisation	
Late AMD (wet active)	Classic choroidal neovascularisation (CNV)—Type 2 Occult (fibrovascular PED and serous PED with neovascularisation)—Type 1 Mixed (predominantly or minimally classic CNV with occult CNV) Retinal angiomatous proliferation (RAP)—Type 3 Polypoidal choroidal vasculopathy (PCV)	Neovascular AMD (nAMD) or wet AMD
Late AMD (dry)	Geographic atrophy (in the absence of neovascular AMD) Significant visual loss (6/18 or worse) associated with: –dense or confluent drusen or –advanced pigmentary changes and/or atrophy or –vitelliform lesion	Advanced dry AMD/ geographic atrophy
Late AMD (wet inactive)	Fibrous scar Sub-foveal atrophy or fibrosis secondary to an RPE tear Atrophy (absence or thinning of RPE and/or retina) Cystic degeneration (persistent intraretinal fluid or tubulations unresponsive to treatment) NB: eyes may still develop or have a recurrence of late AMD (wet active)	Advanced wet AMD/ disciform scar
Do not refer to late AMD (wet inactive) as 'dry AMD'		

#### A. Scenarios during the long-term management of nAMD patients

1. **Stability:** it is defined clinically as two to three visits at maximal extension based on the posology of the drug used (12 or 16 weeks) with dry retina and stable VA. After a treatment-free monitoring interval of 12 months, 34% of patients will still reactivate and need to restart treatment in the subsequent 12 months of further monitoring [8]. Self-monitoring using Amsler chart is not a sensitive tool. Home monitoring devices that are used to detect changes in visual function are not validated in the NHS yet [9]. Meanwhile, OCT is the only sensitive monitoring tool for assessing reactivation.
2. **Treatment discontinuation:** anti-VEGF treatment is discontinued when an eye meets the defined criteria of late AMD wet inactive (Table 1) and/or if it is determined that there is no prospect of visual improvement as a result of continued treatment [1]. Premature treatment discontinuation and inefficient

treatment are important causes of visual loss and should be avoided.

3. Non-responders: a non-responder is defined as a patient whose VA declines due to the persistent activity of the neovascular complex despite an optimally delivered treatment regimen.
  - a. Re-evaluate diagnosis with additional imaging with FFA and/or ICGA angiography where applicable.
  - b. The most common cause for non-response is inadequate therapy due to protocol deviations. A re-loading followed by treat and extend protocol may be required in such cases [10]. Failsafe processes should be available to track patients with poor compliance.
  - c. A switch to another anti-VEGF agent is recommended in cases of allergy or presumed tachyphylaxis and for practical reasons.
  - d. As new treatments emerge it would be worth evaluating the effectiveness based on efficacy (improved visual or anatomical outcomes) or decrease in treatment burden.

**Table 2.** Various outcomes for referrals to AMD services.

Outcome	Action
No AMD	Discharge
Early AMD	Follow recommendations for early AMD care pathway
Late indeterminate AMD	Monitoring with visual acuity and OCT assessment; treatment initiated if nAMD is confirmed
nAMD present and symptomatic presenting VA better 6/96 or better	Follow the recommendation for nAMD care pathway
nAMD with or without disciform scar and poor visual potential (presenting visual acuity Snellen 6/96 or worse or ETDRS letters less than 25 letters)	Clinicians' discretion to initiate treatment or monitor. NICE guidance advises only consider treatment if the patient's visual function could improve, e.g., if the better-seeing eye is affected. Discharge if no treatment is expected. Refer to support services if indicated
Geographic atrophy (late dry AMD)	Follow recommendations for late dry AMD care pathway
Non-AMD causes fluid at macula	Referral to Medical or Surgical Retina Service for diagnosis confirmation and appropriate treatment
Other pathology	Refer to subspecialty depending on pathology identified

AMD age-related macular degeneration, ETDRS early treatment diabetic retinopathy study, nAMD neovascular age-related macular degeneration, NICE National Institute for Health and Care Excellence, OCT optical coherence tomography.

### B. Special scenarios

1. Submacular haemorrhage: the current evidence is to initiate anti-VEGF therapy on a monthly basis until the haemorrhage clears or the futility of treatment is established [11]. A referral to vitreo-retinal team is recommended for possible pneumatic displacement and/or recombinant tissue plasminogen activator (tPA). Some patients may benefit from vitrectomy with subretinal tPA and air tamponade [12, 13].
2. PCV: photodynamic therapy may be offered if there is an insufficient response to anti-VEGF therapy.
3. Retinal pigment epithelium rip: intravitreal injections need to be continued unless there is foveal involvement of rip with no potential for VA improvement as per the decision of the treating clinician.

### C. Complications

#### Endophthalmitis

The risk of endophthalmitis after anti-VEGF therapy is approximately 0.02–0.09% and the cumulative risk per individual increases with increasing number of injections [14–16].

1. The precautions to avoid endophthalmitis include use of topical povidone iodine 5% pre-injection as the most effective step, supported by surgical hand disinfection with use of sterile gloves (changed for each injection) and a 'no lid touch' technique. The use of a lid speculum and face mask is mandatory. Bilateral cases can be treated but separate equipment must be used for each eye and preferably different drug batches. Peri-operative or take-home topical antibiotics are not recommended. Intravitreal injections should be performed in a designated clean room compliant with RCOphth standards [17].
2. Services should report each endophthalmitis case to the service risks management team as part of an incident reporting system so that early recognition of clusters of cases is undertaken [17]. Collective annual incidence should also be reported as part of an audit pathway.

#### Cataract

Patients undergoing anti-VEGF may have an increased risk of age-related cataracts with frequent injections. A very rare complication is an iatrogenic cataract. Cataract surgery should preferably be

avoided in the first 6 months after initiation of anti-VEGF injections as complications are maximum then [18]. Zonular dehiscence is more common in people with repeated anti-VEGF injections and extra caution should be taken [18, 19]. Iatrogenic cataract is best managed by the vitreo-retinal team.

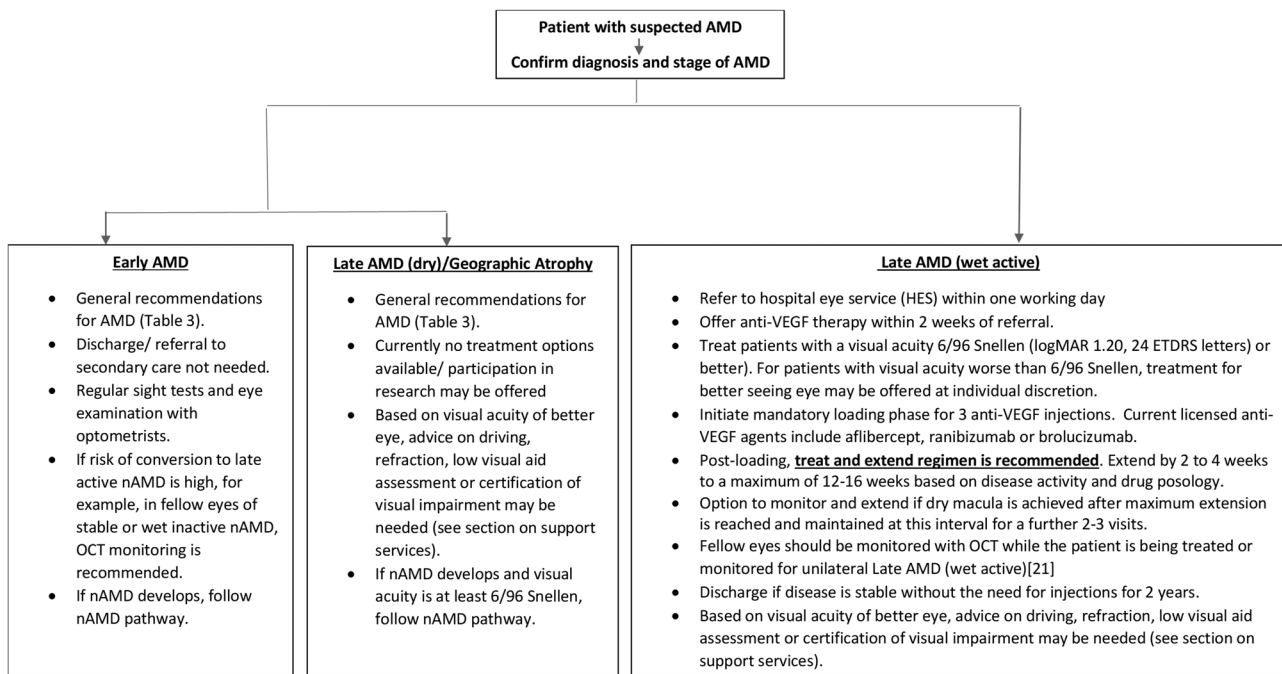
#### Glaucoma

There is a risk of ocular hypertension with increasing number of injections [20]. Eyes with ocular hypertension or glaucoma should have controlled IOP prior to injections. Post injection all patients get an initial spike in IOP; however, only a small percentage may get a sustained rise in IOP requiring treatment. Patients with persistent ocular hypertension should be referred to the glaucoma team for further management. Routine IOP testing post injection is not recommended but annual IOP monitoring is required to identify sustained IOP rise from repeated injections.

### RECOMMENDATIONS ON MONITORING

1. Do not routinely monitor people with early AMD or late AMD (dry) at HES unless in clinical research.
2. Patients with late dry AMD, or people with AMD who have been discharged from HES should:
  - a. Consult their eye-care professional as soon as possible if their vision changes.
  - b. Continue to attend routine sight tests with their primary care optometrist.
  - c. OCT is the most sensitive monitoring tool. For community provision, OCT should be used to monitor patients that are at high risk of new nAMD or being monitored for stable nAMD.
  - d. Be provided information about sources of support for living with sight loss including local and national charities. This would include advice on certification of visual impairment (CVI).
  - e. For people being monitored for late AMD (wet active), both eyes should be assessed at their monitoring appointments [21].

- Patients with coexistent pathology like glaucoma or diabetic retinopathy must continue their follow-up in respective services.



**Fig. 1** Flowchart showing care pathways for patients diagnosed with various stages of age-related macular degeneration. AMD age-related macular degeneration, anti-VEGF anti-vascular endothelial growth factor, ETDRS early treatment diabetic retinopathy study, logMAR logarithm of the minimum angle of resolution, nAMD neovascular age-related macular degeneration, OCT optical coherence tomography.

## SUPPORT SERVICES

- Low vision aid (LVA) service: patients may benefit from LVA especially for reading and should have access to LVA appointments. Option of LVA electronic devices and training for eccentric viewing should be presented to the patient as well.
- Eye Clinic Liaison Officers (ECLO): all ophthalmic departments providing AMD services should have at least one ECLO for provision of ongoing holistic support to patients and signposting to other services.
- Allied health professionals (AHPs) and nurses with specialist role: AHPs including specialist optometrists, ophthalmic nurse specialists and orthoptists may undergo or lead on the training of staff and the development of stable virtual clinics whilst working alongside medical staff at all stages of the patient pathway.
- Patients with Charles Bonnet syndrome/depression/anxiety/learning disabilities: reasonable adjustments in eye care, treatment and surgery should be instituted. All patients with AMD should be signposted to contacts with high-quality information and support, e.g., NHS choices, the Macular Society and Esme's Umbrella [22].

## RECOMMENDED STANDARDS FOR QUALITY ASSURANCE OF SERVICE PROVISIONS

Electronic medical records are recommended for efficient auditing. Standardised data sets and data quality, e.g., the National Ophthalmic database AMD audit, are required to reduce variations in care. It enables data visibility that is consistent and reliable. Suggested audit metrics to assess AMD service performance are shown below:

- Percentage of patients with confirmed late AMD (wet active) being treated (or offered treatment) within 14 days of referral.

Actual interval versus planned interval defined as the time from referral to the first treatment.

- Follow-up delays for ongoing injection appointments.
- VA change following initial three loading doses and at months 12 and 24, with adjustment for baseline VA. Greater stability following initial visual gain is expected if treatment is continued at optimal intervals following loading doses.
- Proportion of patients with a loss of VA of 10 or more ETDRS letters post loading at 12 months and 24 months from initiation of treatment. A change of 10 ETDRS letters is defined as a clinically meaningful change.
- Percentage of eyes with VA better or equal to 70 letters at month 12. This will be strongly influenced by the starting VA of the local population and understanding of the need for urgent presentation and therefore may not directly be within the control of the treating service.
- Outcomes based on drug used and their long-term effectiveness annually.
- Annual incidence of presumed infectious endophthalmitis after intravitreal injection. This will be influenced by patient co-morbidities, e.g., the prevalence of chronic diseases such as blepharitis within a population. Not all these co-morbidities can be controlled and delaying injections in their presence can lead to visual loss.
- Percentage of patients with AMD offered CVI as soon as they become eligible, even if they are still receiving active treatment.
- Monitoring of 'did not attend' and appointment cancellation rates at yearly intervals.
- Percentage of patients that drop off the pathway every year of the patient journey.

## WORKFORCE DEVELOPMENT AND TRAINING

Healthcare professionals (HCP) managing AMD should have the appropriate theoretical knowledge of anatomy and physiology, assessment and examination, disease, investigations and

**Table 3.** General recommendations for patients with AMD.

1. Advice on smoking cessation services and the information on it must be made available to patients by local services.
2. Nutrition and supplements: a healthy diet, rich in fresh fruit, vegetables, eggs and oily fish is recommended. Licensed formulations of multivitamin supplements containing the AREDS2 formulation are not available on prescription within the NHS. Patients may choose to source these over-the-counter supplements independently.
3. Genetic screening is not recommended [23, 24].
4. Need for low vision aids should be assessed in those who meet the definition of low vision at any point throughout the patient journey.
5. Prescription for health: ECLOs, ophthalmic nurses and GPs support is required to promote health-seeking behaviour, physical activity and signposting to other services. Social prescribing is recommended.
6. Screening of fellow eyes: monitoring of fellow eyes with OCT should be done while the affected eye is undergoing treatment or is being monitored (NICE Quality Standard QS180) [2, 21].
7. Whilst patients are undergoing treatment or are being monitored, continued attendance at their regular optometrist should be encouraged. This allows early identification of co-morbidities and correction of refractive errors.
8. Information on natural history and risk factors should be provided to patients.
9. Written information leaflets are recommended either locally developed or sourced from national organisations such as Royal Colleges or patient support charities. Payors need to be clear who will be providing certain essential services, for example: <ul style="list-style-type: none"> <li>•Provision of emotional support for the patient and family;</li> <li>•Rapid referral to counselling or to medical care for depression/anxiety;</li> <li>•Early intervention to avoid falls;</li> <li>•Consistent and timely referral for certification of visual impairment;</li> <li>•Timely referral to low vision support;</li> <li>•Signposting for further information and advice, peer support, free services provided by third-sector organisations.</li> </ul>
10. When patients are discharged to primary care for ongoing monitoring, it is essential that they are discharged with a report of the last findings at discharge, through communication between practitioners to ensure patients receive safe and appropriate care.

AMD age-related macular degeneration, AREDS2 Age-related Eye Disease Study 2, ECLO Eye Clinic Liaison Officers, GP general practitioner, NHS National Health Service, NICE National Institute for Health and Care Excellence, OCT optical coherence tomography.

management. HCP training and assessment may be undertaken as part of the Ophthalmic Practitioner Training programme (based on Ophthalmic Common Clinical Competency Framework; <https://www.hee.nhs.uk/our-work/advanced-clinical-practice/ophthalmology-common-clinical-competency-framework-curriculum>). Employers are responsible for ensuring practitioners are trained and working at the appropriate level of competence.

## SERVICE MODEL OPTIONS

1. Artificial intelligence: although promising, this technology has not been implemented in clinics yet.
2. Service model utilising virtual clinics: the use of the term 'virtual clinic' with respect to the management of AMD refers to a process where the acquisition of data from the patient (VA measurements and OCT images) occurs at a separate point in time to the assessment of that data to formulate a plan for treatment within secondary care including their diagnostic hubs. Acquisition of data is often done by HCP in a high-throughput clinic and is then commonly followed by a later asynchronous assessment of the data by trained clinicians. It is recommended that the virtual clinics should have HCP or ECLO with appropriate training available to support patients. A similar approach for new patient referrals increases throughput in the same way and ensures that the true positive diagnoses of nAMD can be fast-tracked into the rapid access clinic whilst false positive patients (e.g., with late dry AMD) can still be seen within a service but in a lower priority timescale. Patients should also have access to a mechanism for reporting new symptoms or side effects outside of routine clinic episodes, e.g., a designated telephone number staffed by staff with clinical training to triage patient-reported problems into clinical priority.

## CONCLUSION

This guidance is intended to apply to 80% of patients on 80% of occasions and this recommendation provides details of the optimum pathway for patient benefit. In clinical medicine, there will always be exceptions and uncertainties. It sets out principles and the minimum standards of care, to be moderated by well-informed clinical judgement and common sense for individual patient situations.

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## AUTHOR CONTRIBUTIONS

All authors contributed equally in developing the guidelines. SC and SS were involved in writing the manuscript. All authors read and approved the final manuscript.

## COMPETING INTERESTS

The following interests have been declared by the group: SS has received funding from Boehringer Ingelheim, Novartis, Bayer, Allergan, Roche, Opthea, Optos, Oculus, Oxurion and Apellis for consultancy, research and speaking at symposia. PB has attended Roche Diabetic Eye Disease and neovascular AMD advisory board meetings. LD has been the Principal Investigator for sponsored clinical trials with Bayer, Novartis, Allergan, Roche and Alimera. She has also received fees for speaking at meetings from Bayer and Novartis and sponsorship for attending a meeting from Novartis, Bayer, and Allergan. ZR: the Local Optical Committee Support Unit provides advice on services to primary care providers and commissioners. CY: the Macular Society has received grants from the following companies: Alcon, Allergan (AbbVie), Apellis, Bayer, Novartis, OKKO health, Ox sight, Roche, Vision Express. It has also received consultancy fees from Novartis and an honorarium for her attendance at meetings of the Roche global Retina Patient Forum. SM has been the Principal Investigator for sponsored clinical trials with Bayer, Novartis and Roche. He has also received fees for advisory boards, lecturing and travel grants for meetings from Bayer and Novartis. RC-N has received an honorarium from Bayer for attending a Bayer Ophthalmology Masterclass event. None from other authors.

## ADDITIONAL INFORMATION

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