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Royal  
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# Commissioning better eye care

Clinical commissioning guidance from

The College of Optometrists and The Royal College of Ophthalmologists

## Age-related macular degeneration

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# **Commissioning better eye care: clinical commissioning guide from The College of Optometrists and The Royal College of Ophthalmologists**

This resource is to help those designing and commissioning eye care improve the value of their services.

It was produced by the Colleges using a template provided by the Department of Health's Right Care team led by Professor Sir Muir Gray. In addition to the Right Care team, The Royal College of General Practitioners, the National Association of Primary Care, the UK Vision Strategy and partners in the eye health sector have supported the Colleges to produce this guidance.

It is arranged in to the following sections:

- Summary and recommendations
- Introduction
- What is AMD?
- What are the causes of and scope of prevention for AMD?
- How many people have AMD?
- What are the best value diagnostic tests?
- What are the best value treatments?
- How can individuals and carers be best supported long term?
- How to compare services based on activity, quality and outcome
- What are the elements of a system of care for a population?

## Summary

- Age-related Macular Degeneration (AMD) is a long term condition which is the leading cause of sight loss in the UK. Sight loss often occurs quickly with the exudative (“wet”) form of AMD but can be stabilised or improved in most cases with prompt treatment and timely monitoring. The main objective for an AMD service is to minimise preventable sight loss.
- Patients with wet AMD need ongoing treatment for their vision to remain stable. Monthly monitoring appointments may be required for a considerable time; the length of time patients are in treatment can vary from three months to two years or more. The biggest challenge for an AMD service is to ensure patients receive those follow up appointments on time.
- Innovative service models across the UK are meeting this challenge in different ways (see pages 6-8). However, even with the most efficient use of resources, AMD services will need to continue increasing capacity until longer-acting treatments or treatments that do not require regular intravitreal injection become available.

## Recommendations

- To minimise avoidable delays to starting treatment, patients presenting to community optometrists with suspected wet AMD should be referred **directly and urgently** to a specialist macular clinic where imaging and treatment facilities are available.
- So treatment of confirmed wet AMD can start within 2 weeks of diagnosis and for timely review and re-treatment appointments to occur as close as possible to the intended interval:
  - Electronic referrals should be introduced to improve the speed and quality of referrals.
  - Optometrists and GPs, particularly locums, should receive regular training to recognise the symptoms and signs of wet AMD and should be familiar with the local process for urgent referrals.
  - Services should tailor best practice models from elsewhere (see pages 6-8).
- Patients who have visual loss should have access to services which provide support and visual rehabilitation.

## What is AMD?

Age-related macular degeneration (AMD) is a general term applied to degenerative changes that occur in the macula, the area of the retina responsible for central vision. It is the most common cause of sight loss in the developed world and loss of central vision can have a major impact on quality of life, independence and mental and emotional well being.

In its early stages, AMD is characterised by atrophy of cells in the retina, build up of drusen and pigmentary changes in the macula. In some people AMD progresses very slowly and in others it can advance very quickly. Late AMD takes two forms, both of which cause loss to central vision: late dry AMD where atrophy affects the centre of the macula and late wet (or neovascular) AMD where abnormal blood vessels grow into the macula and leak blood or fluid. Late dry AMD progresses slowly whereas late wet can develop quickly causing sudden sight loss.

Anti-vascular endothelial growth factor drugs (anti-VEGF drugs) are currently the most common treatment for late wet AMD. There is currently no medical treatment for late dry AMD but patients benefit from support, information and rehabilitation to cope with the condition.

Reducing the number of people registering as severely visually impaired as a result of AMD is an objective in the *Public health outcomes framework for England*<sup>1</sup>.

## How many people have AMD?

Overall prevalence of late AMD is estimated at 2.4% (95% credible interval (CrI) 1.7% to 3.3%), equivalent to 513,000 cases (95% CrI 363,000 to 699,000)<sup>2</sup>. The prevalence of late AMD in the UK population aged 50 years or more is thought to be 2.4% (95% CrI 1.7% to 3.3%), increasing to 4.8% (95% CrI 3.4% to 6.6%) in those aged 65 years or more and 12.2% (95% CrI 8.8% to 16.3%) in those aged 80 years or more. The same research predicted that the number of people with late AMD in the UK will rise by a third to 679,000 between 2010 and 2020.

Age related macular degeneration (AMD) is a major cause of ocular morbidity in high income countries, accounting for over half of severe visual impairment and visual impairment certifications in the UK<sup>3</sup>. However, the number registered underestimates the number with visual loss caused by the condition, as it excludes those who choose not to be registered or have not been offered registration. Moreover, this figure does not include the appreciable number of those with the condition who do not qualify for registration. The number of people with sight loss from AMD was expected to rise from 223,000 in 2010 to 292,000 by 2020. Of these, 145,697 in 2010 and 189,890 in 2020 were anticipated to be from late wet AMD with the great majority of the remainder caused by late dry AMD<sup>4</sup>.

In 2006, NICE estimated there would be 26,000 new late wet AMD patients in the UK each year<sup>5</sup>. Furthermore, it is estimated that 8-12% of patients with late wet AMD in one eye will develop late wet AMD in the second eye every year<sup>6</sup>. Bearing in mind the ageing demographics of the UK this presents a significant workload for AMD services and will continue to do so for many years to come.

Information on the number of people certified as visually impaired as a result of AMD is published for each area in England as part of the [Public health outcomes framework](#)<sup>7</sup>.

## **What are the causes and scope for prevention?**

Smokers are more than three times more likely to develop AMD than non-smokers<sup>8</sup> as smoking damages the structure of the eye and may reduce the protective effects of antioxidants. All patients with macular degeneration should be advised to stop smoking however smoking cessation services are often not offered in community or hospital eye care. Exposure to UV from sunlight may also contribute to the development of AMD.

A family history of AMD can put patients at higher risk of developing late AMD and some major genes involved in AMD are being recognised (e.g. complement factor H and C3, LOCS 3877, HTRA 1)<sup>9</sup>.

Studies have found that a diet high in monosaturated fats and carbohydrates and low in fibre can increase the risk of developing early AMD<sup>10</sup>.

Many nutritional supplements for eye health are available, but only the AREDS formula is proven to be of benefit. It is able to slow the progression of AMD in some people but not prevent it<sup>11,12</sup>. It is important to note the contraindication of beta-carotene in smokers due to the potential genitourinary side effects in men. The AREDS 2 study has shown a benefit of lutein/zeaxanthin but other supplements, such as omega-3 fatty acids, have not proven beneficial. Patients with early AMD and at high risk of developing late AMD could be recommended to take the AREDS2 supplement but they are not approved by NICE or the Scottish Medicines Consortium.

## **What are the best value diagnostic tests?**

Suspect cases are most commonly identified by optometrists during sight tests for patients who may or may not have reported symptoms.

AMD is diagnosed using a combination of clinical findings and further investigation. Optical Coherence Tomography (OCT) is a non-invasive test which provides high resolution visualization of retinal layers. Fundus fluorescein angiography (FFA) requires the availability of resuscitation facilities and remains the gold standard for diagnosing wet AMD. It provides a sequence of retinal images over a 10 minute period after fluorescein dye is injected in to a vein. Both of these tests can differentiate between the dry and wet types of AMD, therefore identifying those patients suitable for treatment.

Indocyanine green (ICG) is an alternative dye to fluorescein which is used to visualize the choroidal circulation and differentiates conditions that can mimic wet AMD such as polypoidal choroidal vasculopathy and retinal angiomatous proliferation.

Given that around 10 to 15% of people with dry age-related macular degeneration develop wet age-related macular degeneration, patients with dry AMD can monitor themselves using an Amsler chart and should be regularly examined by their optometrist with advice to return in between visits if they notice changes in their vision.

## **What are the best value treatments?**

Only the wet form of AMD is currently reversible and anti-VEGF therapy by intravitreal injection is the treatment of choice<sup>13,14,15</sup>. Patient outcomes improve significantly if the anti-VEGF injections treatment begin quickly and if patients receive follow up treatment on time<sup>16</sup>. Current guidance from the Royal College of Ophthalmologists is that patients should be treated within two weeks<sup>17</sup>.

There are several types of anti-VEGF drugs being used in eye care: ranibizumab (Lucentis), bevacizumab (Avastin) and aflibercept (Eylea). NICE has approved ranibizumab for treating wet AMD<sup>18</sup> and has published final draft guidance recommending aflibercept<sup>19</sup>. The Scottish Medicines Consortium has approved ranibizumab and aflibercept for use in NHS Scotland<sup>20</sup>. Bevacizumab is not licensed for the treatment of AMD in any part of the UK.

Ranibizumab is an anti-VEGF drug that is injected into the eye causing new blood vessels to stop leaking and involution. With timely treatment, eyesight improves in a quarter of affected people and, in the majority (90% or more), eyesight does not significantly deteriorate over two years. These results represent a major improvement over previous treatments. It is usually effective for a month after a loading dose of three injections and usually requires repeat injections.

Bevacizumab may be as effective as ranibizumab and is considerably less expensive but is not an approved treatment for any ophthalmic condition. Preliminary results from the first year of a trial comparing the efficacy and safety of bevacizumab and ranibizumab found there was no functional difference in the effects of both drugs and that their effects on preventing vision loss were similar<sup>21</sup>. A study in the US found the two drugs had a similar effect on visual acuity after two years<sup>22</sup>. However the study also found that patients treated with bevacizumab suffered a higher number of adverse events than those treated with ranibizumab but was unable to conclude if this was due to differences between the drugs.

Whereas patients receiving treatment with ranibizumab or bevacizumab require visits every four weeks, aflibercept treatment is initiated with one injection per month for three consecutive doses followed by one injection every two months. So patients might typically require fewer follow up appointments than those treated with ranibizumab or bevacizumab.

With intravitreal injections, there is a small risk of bacterial endophthalmitis which poses a serious threat to the eye and visual function. Good aseptic techniques and using a clean room minimise the risk<sup>23</sup>.

Photodynamic therapy targets abnormal blood vessels with the help of a intravenously injected photosensitive (verteporfin) dye. This can be used in certain AMD lesion types but has largely been superseded by anti-VEGF therapy.

## How can individuals and carers be best supported long term?

Low vision support, rehabilitation and advice at an early stage of sight loss is imperative for patients who have significant sight loss that is unlikely to recover. We have produced guidance on [commissioning low vision services](#).

The Macular Society offers a helpline, signposting, local support networks and counselling. Their phone number is 0300 30301111. The Royal National Institute of Blind People and many local organisations also provides advice and support services.

## What are the elements of a sustainable system of care for a population?

The key objective for an AMD service is to prevent sight loss. Detecting cases of AMD promptly then treating the high and growing numbers of patients within recommended waiting times is key to achieving it.

Demand for AMD treatment is rising at a time when retina clinics are under growing pressure as anti-VEGF drugs are approved to treat a growing number of eye conditions. The Royal College of Ophthalmologists recommends that outcomes for patients treated with ranibizumab will be best when they are seen and treated within two weeks of diagnosis and receive follow up appointments at four weekly intervals<sup>24</sup>.

Delays in treatment worsen patient outcomes. Frequency of follow up appointments for wet AMD patients cannot be safely reduced without compromising outcomes<sup>25</sup>. Delayed appointments was a major patient safety issue found in an analysis of patient safety incidents in England and Wales<sup>26</sup>. Treating AMD patients on time became more challenging in 2013 after NICE approved ranibizumab to treat diabetic macular oedema<sup>27</sup> and retinal vein occlusion<sup>28</sup> which increased the demand for intravitreal injections.

Commissioners are urged to work with managers and clinicians to ensure that their services have rapid access and the capacity to meet demand in a timely manner now and in the future. Innovative services are meeting this challenge in different ways.

### **Innovative service models – improving detection and initial referral times**

Patient groups have highlighted the need to improve patients' awareness of the symptoms of AMD and to streamline referral processes so that treatment can begin within two weeks<sup>29,30</sup>.

Commissioners, community optometrists and GPs should work with hospitals to improve understanding of rapid referral pathways and to tackle issues that can cause delays<sup>31</sup>. Services should allow optometrists to refer patients directly to AMD clinics without going through a GP for example.

Electronic referrals improve the speed and quality of referrals by enabling optometrists to share relevant information, such as fundus photographs or OCT scans with hospital clinicians. A service piloted in Scotland allowed optometrists to

send clinical fundus images of patients with potentially serious eye problems directly to ophthalmologists using encrypted email accounts<sup>32</sup>. This enabled swift decisions on appointments and timely follow ups. Each referral was assessed by a consultant ophthalmologist whose telemedicine assessment was based solely on the information and image provided in the referral. The patient and GP were sent a letter informing them whether an appointment in the eye clinic was necessary or not and the optometrists was informed by email. Similar innovations using electronic transfer of OCT images to triage referrals from community optometry services have been developed in Salford<sup>33</sup>. All these services relied on well integrated IT systems, such as allowing community optometrist and hospital eye services access to NHSmail or, where also needed, N3 connections.

### **Innovative service models – improving the efficiency and quality of treatment**

Individual services differ in their structure, size, and patient population, as well as in the specific limitations of the service. The accepted view therefore is that there is no one single solution for all services.

There are broadly two categories of service models. A two stop service with investigation and diagnosis on the first visit and treatment on the second. This allows the service to streamline and maximise the efficiency of each of the two stages. The alternative is a one stop model combining investigation and intravitreal injection treatment in to a single visit which can result in longer but fewer appointments.

An example of a one-stop clinic service is the Gloucestershire model. Here assessment and treatment clinics run in parallel using non-consultant staff, in particular nurse practitioners and optometrists. All clinical data is recorded electronically, allowing clinicians to make rapid treatment decisions for new and returning wet AMD patients using information on patient electronic medical records. If necessary, clinicians can also view previous OCT scans and examine the patient themselves<sup>34</sup>. In Ayrshire, trained nurses examine and image patients under stable review. The nurses flag up any changes to the ophthalmologist who then decides whether or not further treatment is required. Other services use optometrists as clinical assessors to increase capacity.

At the other end of the spectrum, some units have adopted mobile assessment units. Peripheral clinics complement some units at larger teaching hospitals and are said to ease pressure on clinic space at the main hospital eye unit and resulting in a more patient-friendly service. Patients are diagnosed and have their first injection in the main eye unit. They are then booked for injections or follow-up at the peripheral health centre, providing a one-stop service. As more optometry practices acquire OCT instruments it may be possible to develop a hub and spoke model, where accredited and trained community optometrists review patients then refer those who need treatment or advanced investigation to the hospital.

In some parts of the country, non-medical healthcare professionals administer anti-VEGF injections to increase capacity. The Royal College of Ophthalmologists has issued guidance on the conditions services should meet to do this safely<sup>35</sup>.

The above examples are not an exhaustive list of well functioning units, but show how services can be tailored to the specific needs of local populations and resources<sup>36</sup>.

### **Discharging patients**

Patients with dry AMD should be offered low vision support if visual loss is impacting upon their independence and lifestyle. Patients who meet the criteria for a certificate of visual impairment should offered one.

Decisions on when to discharge patients with wet AMD are more complex but should be at clinicians' discretion and based on how stable the condition is and if treatment will bring any further benefits to the patient.

Again, patients should be offered low vision support and a certificate of visual impairment if appropriate.

Care should be taken to explain to all discharged patients that they should see an optometrist or GP urgently if they develop any new symptoms, particularly those patients who have been treated for wet AMD in one eye and develop problems in the other.

### **Service models and training**

Although not within the scope of this document, commissioners are also urged to consider the impact commissioning decisions can have on training opportunities for the medical and non-medical workforce delivering these services. It is hoped that the guiding principles with different examples of delivering AMD services can be used to help commissioners and providers provide the best service for their local needs.

### **How to compare services based on activity, quality and outcome**

At present, few commissioners can compare their AMD service in terms of activity, quality and outcomes. Compiling an annual quality report for AMD is the first step to understanding these issues. Existing software can be incorporated in to clinical services to support this.

The production of an annual quality report as a collaborative initiative between commissioners, providers and other stakeholders such as patients is one way to ensure that there is an effective and safe population-based framework for the AMD. Commissioners can then use the report to inform commissioning decisions.

### **Objectives and outcomes in a high value system of care**

This section recommends objectives for a system of AMD care and how they should be measured with a view to being published in an annual report for the service.

<b>Objectives:</b>	<b>Criteria:</b>	<b>Outcomes:</b>	<b>Standards:</b>
Minimise sight loss due to wet AMD	Number of people in the local population being certified as visually impaired (CVI) where wet AMD is the primary cause, as reported by Public Health England for the Public Health Outcomes Framework. <sup>37</sup>	Number of people in the local population being certified as visually impaired (CVI) where AMD is the primary cause.  Number of people in the local population being certified as severely visually impaired (CVI) where AMD is the primary cause.	It is not possible to set a standard for CVI registrations. The trend in CVI registrations and performance against services with similar populations are useful indicators when assessing performance.
Minimise sight loss due to wet AMD	Patients begin anti-VEGF treatment promptly.	Periodic audit of patient records to measure the percentage of patients who receive anti-VEGF treatment beginning treatment within two weeks being referred.	<b>Baseline:</b> 85% of patients treated within two weeks of referral.  <b>Good:</b> 95% of patients treated within two weeks of referral.  <b>Excellent:</b> 98% of patients treated within two weeks of referral.
Minimise sight loss due to wet AMD	Patients receive follow up anti-VEGF treatment on time.	Periodic audit of patient records to measure the percentage of patients receiving follow up treatment on time (in line with guidance from NICE or RCOphth).	<b>Baseline:</b> 85% of follow up appointments on time  <b>Good:</b> 95% of follow up appointments on time.  <b>Excellent:</b> 98% of follow up appointments on time.
The service is patient-centred	Patient satisfaction with the service is high.	Patient satisfaction, as measured by a recognised tool, such as the friends and family test.	Standards will depend on the tool used to measure patient satisfaction.
Patients have emotional and practical support to cope with their condition	Services should help AMD patients adapt to their condition and improve visual functioning and well being. Examples, include Eye Care	Periodic audit of patient records to measure the percentage of patients who have access to a support service.	<b>Baseline:</b> 70% of patients have access to support service.  <b>Good:</b> 85% of patients have access to a support service.

	Liaison Officers (ECLO) and/or a Low Vision service		Excellent: 100% of patients have access to a support service.
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## Acknowledgements and feedback

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For this version of the guidance, the working group was co-chaired by:

Mr Richard Smith	Professional Standards Committee	Royal College of Ophthalmologists
Dr Cindy Tromans	Chair, Board of Trustees	College of Optometrists

The members of the working group were:

Mr Wagih Aclimandos	Royal College of Ophthalmologists
Dr Susan Blakeney	College of Optometrists
Mr Paul Carroll	College of Optometrists
Mr Andy Cassels-Brown	Royal College of Ophthalmologists
Dr Derek Hopper	National Association of Primary Care
Ms Anita Lightstone	Vision 2020UK and UK Vision Strategy
Mr Simon Kelly	Royal College of Ophthalmologists
Mr David Parkins	College of Optometrists
Dr David Paynton MBE	Royal College of General Practitioners
Mr Trevor Warburton	College of Optometrists

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Mr Douglas Newman  
Mr Jeremy Parkes  
Mr Chris Steele  
Ms Angela Whitaker  
Mr Nicholas Wilson-Holt  
Mr Yit Yang

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Professor Sir Muir Gray  
Dr Anant Jani  
Dr Mehrunisha Suleman

**The Colleges would welcome feedback on the guidance and suggestions for revised versions. To discuss any aspect of the guidance, please contact:**

Stuart Holland  
Public Affairs  
The College of Optometrists

Beth Barnes  
Head of Professional Standards  
The Royal College of Ophthalmologists

Email: [stuart.holland@college-optomerists.org](mailto:stuart.holland@college-optomerists.org)

Email: [beth.barnes@rcophth.ac.uk](mailto:beth.barnes@rcophth.ac.uk)

Tel: 020 7766 4383

Tel: 020 7935 0702

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