Age-related macular degeneration: diagnosis and management
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Alliance Pharmaceuticals Limited	3	17	**Diabetes mellitus** Diabetes mellitus has been associated as a risk factor for AMD. Will this patient group be considered given that diabetics can also suffer from vision loss through diabetic retinopathy?	Thank you for your comment. The list of risk factors in this section was not meant to be exhaustive. As the scope stands we have listed the risk factors that have been most commonly cited. Should diabetes be found as an important risk factor under the review question: "Which risk factors increase the likelihood of a person developing AMD or progressing to late AMD?" it will receive due consideration by the guideline committee. Persons with diabetic retinopathy will be considered a group in need of special consideration under the term "retinal damage," i.e. "specific consideration has been identified in people with other comorbidities that affect visual function, for example cataracts, glaucoma and retinal damage."
Bayer plc	2	21	The draft scope currently suggests that people *"who have already lost vision in one eye"* are a group requiring specific consideration. We believe that the wording implies complete vision loss, and we recommend that consideration should be given to this group before this stage. We propose a change to *"who have already had loss of vision in one eye".*	Thank you for your comment. The wording you have suggested adds greater clarity to the original intention of the scoping group and the sentence has been reworded**.**
Bayer plc	3	15	We suggest that social care, and costs of social care, related to vision loss should also be included under 'service organisation'.	Thank you for your comment. Social care and the costs of social care would be included in the scope under the key area of "Patient referral pathways, timescales, and service models for triage and diagnosis, treatment and ongoing management," where these services are NHS/PSS funded. This also falls under our main outcome of "resource use and costs."
Bayer plc	4	16	We understand that the guideline should not revisit areas already evaluated under the technology appraisal process. This position	Thank you for your comment. The statement regarding incorporation of TA294 and TA155 has

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			was stated and agreed at the scoping meeting, and was not challenged by attending stakeholders. Technology appraisals have been published assessing the clinical and cost effectiveness of aflibercept solution for injection for treating wet age related macular degeneration (2013) NICE TA294, ranibizumab and pegaptanib for the treatment of age-related macular degeneration (2008) NICE TA155, and photodynamic therapy for age related macular degeneration (2003) NICE TA68. These technology appraisals were assessed as being up to date and were transferred to the static list in July 2014. The recommendations from these technology appraisals should therefore be incorporated verbatim in this clinical guideline. Failure to make this explicit in the scope may cause confusion amongst commissioners.	been reinstated following discussion with the TA team at NICE. TA68 will be updated by the guidance (subject to consultation with the TA team) and this is also now stated in the scope.
Bayer plc	4	23	We suggest that the frequency of administration and indications for stopping treatment of antiangiogenic therapies should be dictated by the licensed regimens as outlined in their respective Summaries of Product Characteristics (SPCs).	Thank you for your comment. The current SPC leaves room for clarification, for instance the SPC for Lucentis reads: "Thereafter, monitoring and treatment intervals should be determined by the physician and should be based on disease activity, as assessed by visual acuity and/or anatomical parameters. If, in the physician's opinion, visual and anatomic parameters indicate that the patient is not benefiting from continued treatment, Lucentis should be discontinued"

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Guidance has been encouraged to help physicians make these decisions consistently and in an evidence-based way.
Bayer plc	4	28	The draft scope currently states *'The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients'*. We suggest that the line could be amended to read: *"The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients and should have due regard to General Medical Council prescribing guidance and the regulatory framework for the supply and use of medicines"* to be consistent with the NICE manual for the development of guidelines (2014).	Thank you for your comment. The wording used is the current standard for all nice clinical scopes involving medicines. The scoping group considered that authoritative prescribing guidance can be found outside of the GMC. As a result the wording you have suggested was not felt to be a necessary addition to the scope.
Bayer plc	5	16	Given that the scope acknowledges that "*no recommendation* [for the use of bevacizumab] *will be made in any case where a licensed alternative is available*." We suggest that carrying out evaluations of this intervention will be of extremely limited value given that there are already two licensed and NICE recommended antiangiogenic therapies, and therefore to carry out such evaluations would be a significant waste of public resources.	Thank you for your comment. Bevacizumab use is unlikely to be recommended while it remains unlicensed for use in the eye. The guideline group must anticipate possible changes to its status in the coming years along with the possible introduction of biosimilars to which our review work could be applied. We also aim to look at the use of bevacizumab outside of current NICE criteria for ranibizumab (i.e. in those with visual acuity greater than 6/12).
Bayer plc	5	22	We suggest that the *"strategies and tools for monitoring"* should be broken down into functional and anatomic monitoring e.g. eye test	Thank you for your comment. The tools for monitoring AMD can be broken down into their types

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			vs OCT.	after consultation with the guideline committee during the development of the review protocol.
Bayer plc	5	26	The draft scope currently excludes training and certification for healthcare professionals. We feel this is an important area for inclusion because many centres have implemented or are considering implementing nurse-led intravitreal injection services, and there is currently a lack of central guidance or agreed training standards.	Thank you for your comment. The guidance will consider competencies of health and social care (HSC) professionals working in this field but it is outside the remit of NICE guidance to offer recommendations on training of HSC professionals and certification. It may be the case, however, that when we review different organisational models of care, some of these will be dependent on having special training of healthcare professionals (for instance, nurse led intravitreal injections). These issues will be addressed when considering the implementation of the guideline.
Bayer plc	7	25	We understand that the guideline should not revisit areas already evaluated under the technology appraisal process. Technology appraisals have been published assessing the clinical and cost effectiveness of aflibercept solution for injection for treating wet age related macular degeneration (2013) NICE TA294, ranibizumab and pegaptanib for the treatment of age-related macular degeneration (2008) NICE TA155, and photodynamic therapy for age related macular degeneration (2003) NICE TA68. These technology appraisals were assessed as being up to date and were transferred to the static list in July 2014. The recommendations from these technology appraisals should therefore be incorporated verbatim in this clinical guideline. Failure to make this explicit in the scope may	Thank you for your comment. The statement regarding incorporation of TA294 and TA155 has been reinstated following discussion with the TA team at NICE. TA68 will be updated by the guidance (subject to consultation with the TA team) and this is also now stated in the scope.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			cause confusion amongst commissioners.	
Bayer plc	8	3	We understand that the guideline should not revisit areas already evaluated under the technology appraisal process. Technology appraisals have been published assessing the clinical and cost effectiveness of aflibercept solution for injection for treating wet age related macular degeneration (2013) NICE TA294, ranibizumab and pegaptanib for the treatment of age-related macular degeneration (2008) NICE TA155, and photodynamic therapy for age related macular degeneration (2003) NICE TA68. These technology appraisals were assessed as being up to date and were transferred to the static list in July 2014. The recommendations from these technology appraisals should therefore be incorporated verbatim in this clinical guideline. Failure to make this explicit in the scope may cause confusion amongst commissioners.	Thank you for your comment. The statement regarding incorporation of TA294 and TA155 has been reinstated following discussion with the TA team at NICE. TA68 will be updated by the guidance (subject to consultation with the TA team) and this is also now stated in the scope.
Bayer plc	8	5	The guideline should clarify that all NICE approved treatment options must be made available to eligible patients in accordance with the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013. Healthcare professionals should be responsible for deciding which NICE approved treatment option is most appropriate for first and second line use.	Thank you for your comment. The statement regarding incorporation of TA294 and TA155 has been reinstated following discussion with the TA team at NICE. TA68 will be updated by the guidance (subject to consultation with the TA team) and this is also now stated in the scope. We believe, however, that it is NICE's responsibility to provide guidance wherever helpful and possible. This includes helping clinicians make decisions such as which treatment option is most appropriate for first and second line use.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Bayer plc	8	7	We suggest that the frequency of administration of antiangiogenic therapies should be dictated by the licensed regimens as outlined in their respective SPCs.	Thank you for your comment. The current SPC leaves room for clarification, for instance the SPC for Lucentis reads: "Thereafter, monitoring and treatment intervals should be determined by the physician and should be based on disease activity, as assessed by visual acuity and/or anatomical parameters. If, in the physician's opinion, visual and anatomic parameters indicate that the patient is not benefiting from continued treatment, Lucentis should be discontinued" Guidance has been encouraged to help physicians make these decisions consistently and in an evidence-based way.
Bayer plc	8	13	We suggest that the indications for stopping treatment of antiangiogenic therapies should be dictated by the licensed regimens as outlined in their respective SPCs.	Thank you for your comment. The current SPC leaves room for clarification, for instance the SPC for Lucentis reads: "Thereafter, monitoring and treatment intervals should be determined by the physician and should be based on disease activity, as assessed by visual acuity and/or anatomical parameters.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				If, in the physician's opinion, visual and anatomic parameters indicate that the patient is not benefiting from continued treatment, Lucentis should be discontinued" Guidance has been encouraged to help physicians make these decisions consistently and in an evidence-based way.
Bayer plc	9	19	Whilst it is understood that the EQ-5D is NICE's preferred measure of health-related quality of life in adults, it has been recognised that it may be relatively insensitive for vision disorders including age related macular degeneration.[1,2] For this reason we suggest that results from other instruments should also be considered in this clinical guideline. 1. Tosh J, et al. A review of generic preference-based measures of health-related quality of life in visual disorders. Value Health 2012;15:118–27. 2. Longworth L, et al. Use of generic and condition-specific measures of health-related quality of life in NICE decision-making: a systematic review, statistical modelling and survey. Health Technol Assess 2014;18:1–224.	Thank you for your comment. The appropriate measure of health related quality of life will be discussed with the committee and stated in the relevant review protocols. We will take your suggestion into account.
Bayer plc	9	20	We suggest that 'follow-up and monitoring' should also be included as important considerations under 'service user experience and outcomes', and the frequency of these should follow the recommendations of the respective SPCs.	Thank you for your suggestion. It is unclear how follow-up and monitoring would be recorded as outcomes. Different models of service organisation for follow up and monitoring will, however, be reviewed

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				under the draft question below: □ How do different organisational models for ongoing treatment and follow up influence outcomes for people with neovascular AMD (for example, disease progression, time to treatment, non-attendance)?
Bayer plc	11	5	The listed NICE technology appraisal guidance should also be incorporated verbatim in this clinical guideline in accordance with the manual for developing NICE guidelines (2014). In the version of the draft scope circulated at the stakeholder workshop it was made clear that this would be the case; however there appears to have been a change to this version of the scope. We suggest that this section should be reinstated to be clear that the guideline development process will not revisit areas already evaluated under the technology appraisal process. Failure to make this explicit in the scope may cause confusion amongst commissioners.	Thank you for your comment. The statement regarding incorporation of TA294 and TA155 has been reinstated following discussion with the TA team at NICE. TA68 will be updated by the guidance (subject to consultation with the TA team) and this is also now stated in the scope.
Bayer plc	16	13	We note that the cited references were published some time ago, and we suggest that current practice may have changed since the introduction of the anti-angiogenic therapies.	Thank you for your comment. While the referenced studies were published back in 2001 and 2008, their results still show that there is an underlying need for information, psychological and emotional support in these patients. The introduction of anti-angiogenic therapies will certainly have helped prevent more people from becoming blind or partially sighted but by

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				no means all patients, AMD remains the most common cause of sight loss in the developed world. Therefore the cited studies are still likely to be relevant.
Department of Health	General	General	NICE and MHRA sponsor team, do not have any substantive comments to make.	Thank you for your comment.
Digital Assessment Service, NHS Choices	General		The Digital Assessment Service welcome the guidance and have no comments on its content.	Thank you for your comment.
Global Organization for EPA and DHA Omega-3s	3	17 26	Currently, omega-3s are listed under "Strategies for reducing the risk of AMD progressing or developing in the unaffected eye" [lines 21-26], but omega-3s should also be considered under "Risk factors for the development and progression of AMD" [lines 18-20]. Data from prospective studies suggesting that higher intakes of n-3 LCPUFAs and fish provide protection against AMD have been consistently positive (Augood et al., 2008; Cho et al., 2001; Christen et al., 2011; SanGiovanni, Agrón, Clemons, et al., 2009; SanGiovanni, Agrón, Meleth, et al., 2009; SanGiovanni et al., 2008; SanGiovanni et al., 2007; Swenor et al., 2010; Tan et al., 2009). In addition, both plasma n-3 LCPUFA and red blood cell EPA+DHA have been shown to be strongly associated with a reduced risk for late AMD (Merle et al., 2014; Merle et al., 2011; Merle et al., 2013).	Thank you for your comment and the information provided. The list was not intended to be exhaustive, although if the risk factors you have mentioned are found to be important following review, the guideline committee will give them due consideration. Screening was outside of the remit for this guidance which is for the diagnosis and management of AMD. The guideline will focus on risk factors for AMD only in so much as will help aid suspicion and diagnosis of the disease. As such we will not be looking at therapies to prevent AMD in the general population although we are interested in reviewing strategies to reduce the risk of developing AMD in the second unaffected eye.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Augood C, Chakravarthy U, Young I, Vioque J, de Jong PT, Bentham G, Rahu M, Seland J, Soubrane G, Tomazzoli L, Topouzis F, Vingerling JR, Fletcher AE. Oily fish consumption, dietary docosahexaenoic acid and eicosapentaenoic acid intakes, and associations with neovascular age-related macular degeneration. Am J Clin Nutr. 2008;88:398-406. Cho E, Hung S, Willett WC, Spiegelman D, Rimm EB, Seddon JM, Colditz GA, Hankinson SE. Prospective study of dietary fat and the risk of age-related macular degeneration. Am J Clin Nutr 2001;73:209-18. Christen WG, Schaumberg DA, Glynn RJ, Buring JE. Dietary ω-3 fatty acid and fish intake and incident age-related macular degeneration in women. Arch Ophthalmol. 2011;129:921-9. Merle BM, Benlian P, Puche N, Bassols A, Declourt C, Souied E. Circulating omega-3 fatty acids and neovascular age-related macular degeneration. Invest Ophthalmol Vis Sci. 2014;55:2010-9.	

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Merle B, Delyfer MN, Korobelnik JF, Rougier MB, Colin J, Malet F, Féart C, Le Goff M, Dartigues JF, Barberger-Gateau P, Delcourt C. Dietary omega-3 fatty acids and the risk for age-related maculopathy: the Alienor Study. Invest Ophthalmol Vis Sci. 2011;52:6004-11. Merle BM, Delyfer MN, Korobelnik JF, Rougier MB, Malet F, Féart C, Le Goff M, Peuchant E, Letenneur L, Dartigues JF, Colin J, Barberger-Gateau P, Delcourt C. High concentrations of plasma n3 fatty acids are associated with decreased risk for late age-related macular degeneration. J Nutr. 2013;143:505-11. SanGiovanni JP, Agrón E, Clemons TE, Chew EY. Omega-3 long-chain polyunsaturated fatty acid intake inversely associated with 12-year progression to advanced age-related macular degeneration. Arch Ophthalmol. 2009;127:110-2. SanGiovanni JP, Agrón E, Meleth AD, Reed GF, Sperduto RD, Clemons TE, Chew EY; Age-Related Eye Disease Study Research Group. ω-3 Long-chain polyunsaturated fatty acid intake and 12-y incidence of neovascular age-related macular	

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			degeneration and central geographic atrophy: AREDS report 30, a prospective cohort study from the Age-Related Eye Disease Study. Am J Clin Nutr. 2009;90:1601-7. SanGiovanni JP, Chew EY, Agrón E, Clemons TE, Ferris FL 3rd, Gensler G, Lindblad AS, Milton RC, Seddon JM, Klein R, Sperduto RD; Age-Related Eye Disease Study Research Group. The relationship of dietary omega-3 long-chain polyunsaturated fatty acid intake with incident age-related macular degeneration: AREDS report no. 23. Arch Ophthalmol. 2008;126:1274-9. SanGiovanni JP, Chew EY, Clemons TE, Davis MD, Ferris FL 3rd, Gensler GR, Kurinij N, Lindblad AS, Milton RC, Seddon JM, Sperduto RD; Age-Related Eye Disease Study Research Group. The relationship of dietary lipid intake and age-related macular degeneration in a case-control study: AREDS Report No. 20. Arch Ophthalmol. 2007;125:671-9. Swenor BK, Bressler S, Caulfield L, West SK. The impact of fish and shellfish consumption on age-related macular degeneration. Ophthalmology. 2010;117:2395-401.	

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Tan JS, Wang JJ, Flood V, Mitchell P. Dietary fatty acids and the 10-year incidence of age-related macular degeneration: the Blue Mountains Eye Study. Arch Ophthalmol. 2009;127:656-65.	
Global Organization for EPA and DHA Omega-3s	7	5	The science supports that low EPA+DHA intake is a risk factor for developing AMD.	Thank you for your comment. Should low EPA+DHA intake exposure be found as an important risk factor under the review question: "Which risk factors increase the likelihood of a person developing AMD or progressing to late AMD?" it will receive due consideration by the guideline committee.
Gloucestershire Hospitals NHS Foundation Trust	2	21	The frequency of second eye involvement with wet AMD is very high (50% of second eyes with good vision are affected within 3 years based on the world's largest collation of real-world evidence, a paper I co-authored). This highlights the importance of preserving vision in the worst seeing eye. Reference: The **neovascular age-related macular degeneration database**: report 2: incidence, management, and visual outcomes of second treated eyes. Zarranz-Ventura J et al. Ophthalmology. (2014)	Thank you for your comment and the information provided. This seems to support our addition of those who have already lost vision in one eye as a "group in need of specific consideration." These patients will need special attention because they may be facing risk of complete blindness. We agree that preserving vision in the worst-seeing eye is important. The treatment of wet AMD in these eyes will be reviewed in the following draft question: □ What is the effectiveness of different anti-angiogenic therapies for the treatment of neovascular AMD?

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The optimisation of existing vision will be addressed in the following draft question: □ What is the effectiveness of support strategies for people with visual impairment and AMD (for example reablement services)?
Gloucestershire Hospitals NHS Foundation Trust	4 5	16 22 1 17	The secretary of state for Health, Jeremy Hunt has recently written to confirm that commissioning bevacizumab services would be contrary to EU law. What is the point of including bevacizumab when this is the Government's decision? Although there might be room to use bevacizumab outside of NICE criteria for ranibizumab, where the licensed drug is not funded by the NHS at present?	Thank you for your comment. Commissioning bevacizumab would be contrary to EU law while it remains unlicensed for use in the eye. The guideline group must anticipate possible changes to its status in the coming years along with the possible introduction of biosimilars to which our review work could be applied. We also aim to look at the use of bevacizumab outside of current NICE criteria for ranibizumab (i.e. in those with visual acuity greater than 6/12)
Gloucestershire Hospitals NHS Foundation Trust	4	23 24	At present there is a large volume of usage of expensive drugs in patients who have persistently poor vision (6/60 or worse) and from the perspective of the public purse it may be worth having stopping criteria for eyes with vision persistently in this range after eg 6 injections if this is their worst-seeing eye	Thank you for your comment. The guideline will consider treatment stopping criteria for people at different levels of visual acuity. Decisions made about the best rationale for stopping treatment will therefore fall out of the evidence reviewed.
Gloucestershire Hospitals NHS Foundation Trust	6	3 18	NICE should look at the current variation of cost-effectiveness of service delivery and use of tariffs. At present there is massive variation with some centres choosing 'day case procedure' tariffs rather than outpatient tariffs and charging twice in both eyes injected (total cost £500-1000 per visit) versus other sites (such as	Thank you for your comment. In any original health economic analysis performed for this guideline we would cost inpatient and outpatient procedures appropriately, using standard NHS Tariff costs. It is beyond the remit of NICE guidelines to advise on

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Gloucestershire where an assessment + injection in both eyes is only charged at £150 but is still profitable for the Trust). NICE has the opportunity to massively reduce the cost of these drugs by changing the price per QALY that they will pay. Why don't they exercise this power? The NHS is one of the largest healthcare purchasing organisations in the world but does not exercise this power sufficiently and this is leading to extreme funding problems.	NHS pricing and use of tariffs.
Gloucestershire Hospitals NHS Foundation Trust	6 7	22 4	This is the key issue. CCGs should purchase care on the basis of knowing the results, which are different in the real-world than in RCTs, but are now well defined with the world's largest dataset in the UK. It is appalling that at present CCGs spend vast sums of money without demanding any knowledge of the quality of service that is delivered. Reference: The **neovascular age-related macular degeneration database**: multicenter study of 92 976 ranibizumab injections: report 1: visual acuity. Writing Committee for the UK **Age-Related Macular Degeneration** EMR Users Group et al. Ophthalmology. (2014)	Thank you for your comment and support of the "service organisation" review questions as stated.
Gloucestershire Hospitals NHS Foundation Trust	8	9 10	The effectiveness of treating before 6/12 both clinically and cost-effectively is now clearly established in UK real-world publications including one using NICE's own health economic model. References previous row plus: The cost-effectiveness of initiating ranibizumab therapy in eyes with **neovascular** AMD with good vision: an economic model using real-world outcomes. Butt T, Lee A, Lee C, Tufail A; UK AMD EMR Study Group.	Thank you for your comment and the information provided. Evidence for the early treatment of wet AMD will be considered under the review question below: ☐ What is the effectiveness of early treatment of neovascular AMD (in people with visual acuity greater than 6/12)?

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			BMJ Open. 2015 May 5;5(5):e006535. doi: 10.1136/bmjopen-2014-006535.	
Gloucestershire Hospitals NHS Foundation Trust	9	19	ICHOM (The International Collaboration on Health Outcome Measurement) on which I served as a UK representative recommend collection of the 'IVI' PROM	Thank you for your comment. The appropriate measure of health related quality of life will be discussed with the committee and stated in the relevant review protocols. We will take your suggestion into account.
Macular Society	1	18 19 20	We believe the scope should also be addressed to those who commission, provide and are practitioners of **low vision services**.	Thank you for your comment. The scope has also stated that the guideline will be relevant to the following subgroups: • Healthcare professionals in primary care. • Healthcare professionals in secondary care. • Social care professionals. • Local authorities. And • Private sector and voluntary organisations. • People working in related services. After consideration, the scoping group agreed that we had adequately covered practitioners and providers of all other low vision services in England. Please also note that we will be recruiting a commissioner onto the guideline committee.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Macular Society	3	11	While this is a clinical rather than a social care guideline we believe it is important that low vision and rehabilitation services are not overlooked in this guideline. If a person with age-related macular degeneration is to receive integrated care along a well thought-out pathway then the move from medical treatment to low vision service needs to be planned and phased. It is not appropriate simply to leave low vision advice until medical options have been exhausted. As low vision services can be provided in both NHS funded settings and non-NHS funded settings we believe the guideline should reflect that and take those settings into account.	Thank you for your comment. We have noted in the section "Who the guideline is for" that the guideline may also be relevant for private sector and voluntary organisations. Furthermore we also consider it important that low vision and rehabilitation services are not overlooked. We have drafted the following related review question: □ What is the effectiveness of support strategies for people with visual impairment and AMD (for example reablement services)? The wording of this question should not preclude the use of low vision services before medical options have been exhausted. Rather support is assumed to begin as soon as a person develops visual impairment.
Macular Society	3	20	The list of risk factors may not have been intended to be exhaustive but might also include diet, hypertension, obesity and exposure to UV radiation.	Thank you for your comment. The list was not intended to be exhaustive, although if the risk factors you have mentioned are found to be important following review, the guideline committee will give them due consideration.
Macular Society	4	8	We believe there is a need to address the information needs of people who may now be identified as have 'early' AMD (drusen) by optometrists with imaging equipment. Only a proportion of these people will go on to develop 'late' AMD (sight loss) but as they are	Thank you for your comment**.** We recognise the need for providing information for persons at the point of diagnosis and this is reflected in the wording of the following draft review question:

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			at risk we believe there is a need to encourage eye care professionals to give life-style advice to these patients.	□ What information do people with suspected or confirmed AMD, and their family members or carers, find useful and in what format (for example written or oral)? We recognise that the information needs of a person will change depending on whether they are suspected of AMD, diagnosed with the early stages, facing treatment or suffering from vision loss. We hope that the broad wording of the review question will allow us to explore available evidence for each of these circumstances. We will also be assessing the usefulness of strategies (such as life style changes) to slow the progression of AMD in those with early AMD. Please see the following draft review question: □ What is the effectiveness of strategies to slow the progression of AMD or reduce the risk of developing AMD in the unaffected eye?
Novartis	3	14 16	The draft scope does not make any specific reference to service provision that includes care closer to home or in the community. Novartis feels that this should be considered in the guidelines due to the burden for some patients travelling to hospitals on a regular	Thank you for your comment. We are aware that there are ways in which organisations are set up that can help minimise the burden for patients travelling to hospitals (such as the one stop model, or even mobile

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			basis that involves significant time / cost.	ophthalmologists), we will consider the evidence on these approaches in our two draft review questions on service organisation: □ How do different organisational models and referral pathways for triage and diagnosis influence outcomes for people with suspected AMD (for example, correct diagnosis, errors in diagnosis, delays in diagnosis, process outcomes)? □ How do different organisational models for ongoing treatment and follow up influence outcomes for people with neovascular AMD (for example, disease progression, time to treatment, non-attendance)? Please also note that we will consider evidence on other support structures, which will include community services, in our questions on information, low vision services and psychological support: □ What is the effectiveness of psychological therapies for AMD? □ What is the effectiveness of support strategies for people with visual impairment and AMD (for example reablement services)? □ What information do people with suspected or

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				confirmed AMD, and their family members or carers, find useful and in what format (for example written or oral)? We have also listed "number of visits to the hospital" as one of our main outcomes.
Novartis	5	4 6	It is very important to clarify that bevacizumab is unlicensed for use in the eye (refer to bevacizumab SPC for licensed indications and routes of administration https://www.medicines.org.uk/emc/medicine/15748). The text in lines 4-6 is incorrect as it implies that it is unlicensed because it needs to be reconstituted.	Thank you for your comment. The section has been reworded to state: "Although bevacizumab is in use in the UK and elsewhere for the treatment of neovascular AMD, the Medicines and Healthcare Products Regulatory Agency regards it as unlicensed for this indication because its use requires the formulation of the licensed product to be divided into separate smaller doses (to produce multiple aliquots) for injection into the eye"
Novartis	5	4 6	Bevacizumab is not reconstituted. The vial is divided into separate doses for injection into the eye.	Thank you for your comment. The section has been reworded to state: "Although bevacizumab is in use in the UK and elsewhere for the treatment of neovascular AMD, the Medicines and Healthcare Products Regulatory Agency regards it as unlicensed for this indication because its use requires the formulation of the licensed product to be divided into separate smaller doses (to produce multiple aliquots) for injection into the eye"
Novartis	5	17	The draft scope states "no recommendation for its use will be made in any case where a licensed alternative is available." The final	Thank you for your comment. After consideration we agree that your proposed wording makes the intended

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			scope should provide clarity for the word "available" as used in this statement since this could be read as either nationally reimbursed or available as it is within the product license. The latter is the appropriate definition of "available" since a national reimbursement restriction does not necessarily constitute the full product label. Preferred wording would be: "no recommendation for its use will be made in any case where *there is* a licensed alternative."	meaning clearer. The section has been reworded accordingly.
Novartis	7	26 27	The ranibizumab label was updated in 2014 – this important update removes the requirement for monthly monitoring as was required historically in the label. Published evidence, both RCT and real world, has evaluated a posology known as treat and extend (T&E), which is within the current UK license and offers promising outcomes with lower resource use versus the original product label (that required monthly monitoring). It would be helpful for evidence of ranibizumab T&E to be included in the section of the guidelines where "anti-angiogenic" therapy is considered.	Thank you for your comment. Different frequencies of administration of anti-angiogenic therapies will be considered as part of the review question: □ What is the effectiveness of different anti-angiogenic regimen for the treatment of neovascular AMD? This will include any evidence there may be on "treat and extend" monitoring.
Novartis	8	5 6	There is an opportunity to define treatment failure/suboptimal response or true non response. Currently there is no guidance or consensus on this important definition and how this might impact clinical management.	Thank you for your comment. Wording for the draft review question below leaves enough room to examine when it is appropriate to stop treatment, either permanently or to switch to second line therapy: □ What factors indicate that treatment should be discontinued for neovascular AMD?
Novartis	8	7	The ranibizumab label was updated in 2014 – this important update removes the requirement for monthly monitoring as was required	Thank you for your comment. Different frequencies of administration of anti-angiogenic therapies will be

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
		8	historically in the label. Published evidence, both RCT and real world, has evaluated a posology known as treat and extend (T&E), which is within the current UK license and offers promising outcomes with lower resource use versus the original product label (that required monthly monitoring). This ranibizumab posology should be included within the guidelines.	considered as part of the review question: □ What is the effectiveness of different anti-angiogenic regimen for the treatment of neovascular AMD? This will include any evidence there may be on "treat and extend" monitoring.
Novartis	8	9 10	Novartis agrees that it would be very helpful to understand the relative effectiveness of treating patients earlier (with vision >6/12). It would also be helpful to understand the cost effectiveness of treating this patient population as it represents an area of unmet clinical need not currently covered by existing NICE guidance.	Thank you for your comment. Evidence for the effectiveness and cost-effectiveness of early treatment for wet AMD will be considered under the review question below: □ What is the effectiveness of early treatment of neovascular AMD (in people with visual acuity greater than 6/12)?
Novartis	9	6	There should be clarification on what outcome measure will be used to determine health related quality of life. It should be noted that the standard measurement tool, EQ-5D, is reported in the literature as being insensitive to changes in vision and thus a disease specific quality of life tool such as NEI-VFQ would be more sensitive at delineating treatment effects on quality of life. For economic modelling consistency with previous technology appraisals, utility has been commonly derived from best corrected visual acuity (BCVA).	Thank you for your comment. The appropriate measure of health related quality of life will be discussed with the committee and stated in the relevant review protocols. We will take your suggestion into account.
Novartis	9	20	There are important elements of service user experience which are	Thank you for your comment.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
		23	not currently included in the scope. These are: ➢ Improved patient experience of the service ➢ Shorter clinic waiting times ➢ Improved patient journey e.g. treatment closer to home as the burden for some patients travelling to hospitals on a regular basis involves significant time / cost . ➢ Increased access to equitable and consistent care ➢ Provision of help and information for newly diagnosed blind and partially sighted people such as is provided by Eye Clinic Liaison Officers (page 16, lines 11-20 refer to the need for this and it should be included as an outcome in the scope)	1) Improved patient experience will be considered under the outcomes: patient satisfaction, impact on carers and health related quality of life. 2) Speed of diagnosis and speed of treatment will be considered under "time to diagnosis" and "time to treatment" which will take into account the benefit of shorter waiting times. 3) A new outcome "number of visits to hospital" has been added to the scope in order to help assess the travel burden of different organisational models on the patient. 4) It is not clear how the outcome "increased access to equitable and consistent care" would be measured. Therefore it may not be appropriate as one of the main outcomes. 5) Provision of help and information for newly diagnosed blind and partially sighted people will be addressed under the review questions below: □ What information do people with suspected or confirmed AMD, and their family members or carers, find useful and in what format (for example written or oral)? □ What is the effectiveness of psychological therapies for AMD? □ What is the effectiveness of support

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				strategies for people with visual impairment and AMD (for example reablement services)? The main outcomes listed will help us to address these important issues.
Optical Confederation	3	14 16	We note that one of the areas covered in the guidance will be service organisation including patient referral pathways, timescales, and service models for triage and diagnosis, treatment and ongoing management. This seems inconsistent with the statement in page page 5 line 24 and 25 that reducing the risk of AMD will not include "Access to optometrist services, emergency services and general practitioners". We do not believe that service organisation can ignore how patients access primary care (including optometric and dispensing optician services) and emergency services.	Thank you for your comment. Although we recognise the importance of the problem of access to first line services we also see that this is an issue that would not be adequately answered in the macular degeneration guideline. The issue of how patients access first line services and the barriers that prevent this from happening has implications beyond the macular degeneration population and will likely be a topic of interest in future public health guidelines. We will, however, be considering referral from the point at which a person initially presents to health services and is suspected of having AMD. Initial presentation could be at the optometrist, emergency services or the GP.
Optical Confederation	3	21 22	This section indicates the guideline will cover "strategies to reduce the risk of AMD progressing or developing in the unaffected eye". We believe this section should describe strategies for risk reduction in all people not just those who already have AMD in one eye.	Thank you for your comment. Screening was outside of the remit for this guidance which is for the diagnosis and management of AMD. The guideline will focus on risk factors for AMD only in so much as will help aid suspicion and diagnosis of the disease. As such we will not be looking at therapies to prevent

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				AMD in the general population although we are interested in reviewing strategies to reduce the risk of developing AMD in the second unaffected eye.
Optical Confederation	4	11 13	Add reference to optimising existing visual performance.	Thank you for your comment. "Strategies for optimising existing visual performance" has been added to the interventions of interest for early and intermediate AMD.
Optical Confederation	5	24 25	We are concerned that if the guideline does not cover "Access to optometrist services, emergency services and general practitioners" it will be difficult to assess different referral pathways and also difficult to make recommendations about best practice in care pathways identified as a key issue on page 6 line 23-25.	Thank you for your comment. Although we recognise the importance of the problem of access to first line services we also see that this is an issue that would not be adequately answered in the macular degeneration guideline. The issue of how patients access first line services and the barriers that prevent this from happening has implications beyond the macular degeneration population and will likely be a topic of interest in future public health guidelines. However, we will be considering referral from the point at which a person initially presents to health services and is suspected of having AMD. Initial presentation could be at the optometrist, emergency services or the GP.
Optical Confederation	5	23 25	The exclusion of community optometric services conflicts with the stated aim on page 3 line 11 which says that all settings in which NHS funded care is provided will be covered. We are concerned that it will be both difficult to assess different referral pathways and difficult to make recommendations about best	Thank you for your comment**.** Although we recognise the importance of the problem of access to first line services we also see that this is an issue that would not be adequately answered in the macular degeneration guideline. The issue of how patients

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			practice in care pathways if the guideline will not cover "Access to optometrist services, emergency services and general practitioners." The care pathway surely starts with the identification of cases (often through optometric examination) and can end with the provision of low vision services (through optometrists and dispensing opticians)	access first line services and the barriers that prevent this from happening has implications beyond the macular degeneration population and will likely be a topic of interest in future public health guidelines. We will, however, be considering referral from the point at which a person initially presents to health services and is suspected of having AMD. Initial presentation could be at the optometrist, emergency services or the GP.
Optical Confederation	6	13	Costings from a "personal social services perspective" should include non HES eye-care costs such as GOS and community schemes.	Thank you for your comment. We will include such costs where it is appropriate to do so and where reference costs are available.
Optical Confederation	6	22-26	We are concerned that it will be difficult to assess how different organisational models and referral pathways for triage and diagnosis influence outcomes if optometrist services, emergency services and general practitioners are not included in the scope of this guidance – given that these services are the route by which most patients are identified.	Thank you for your comment. Although we recognise the importance of the problem of access to first line services we also see that this is an issue that would not be adequately answered in the macular degeneration guideline. The issue of how patients access first line services and the barriers that prevent this from happening has implications beyond the macular degeneration population and will likely be a topic of interest in future public health guidelines. However, we will be considering referral from the point at which a person initially presents to health services and is suspected of having AMD. Initial presentation could be at the optometrist, emergency

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				services or the GP.
Optical Confederation	7	1 4	We are concerned that it will be difficult to advise on best practice when assessing how different organisational models for ongoing treatment and follow up influence outcomes for people with neovascular AMD if access to community optometric and dispensing optician services is not included in the scope of the guidance.	Thank you for your comment. Although we recognise the importance of the problem of access to first line services we also see that this is an issue that would not be adequately answered in the macular degeneration guideline. The issue of how patients access first line services and the barriers that prevent this from happening has implications beyond the macular degeneration population and will likely be a topic of interest in future public health guidelines. However, we will be considering referral from the point at which a person initially presents to health services and is suspected of having AMD. Initial presentation could be at the optometrist, emergency services or the GP.
Optical Confederation	7	5 9	We are concerned that it will be difficult to assess how the risk of AMD can be reduced if the role of community optometrists, and access to optometric services, is not included in the scope of the guidance, given that optometrists are well placed to identify and advise patients at risk of AMD.	Thank you for your comment. Although we recognise the importance of the problem of access to first line services we also see that this is an issue that would not be adequately answered in the macular degeneration guideline. The issue of how patients access first line services and the barriers that prevent this from happening has implications beyond the macular degeneration population and will likely be a topic of interest in future public health guidelines. However, we will be considering referral from the point at which a person initially presents to health

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				services and is suspected of having AMD. Initial presentation could be at the optometrist, emergency services or the GP.
Optical Confederation	7	11 13	We are concerned that it will be difficult to have any full assessment of the signs and symptoms which should prompt a healthcare professional to suspect AMD in people presenting to healthcare services without including those healthcare services which are most likely to spot those signs and symptoms – optometrists, GPs and emergency services.	Thank you for your comment. Although we recognise the importance of the problem of access to first line services we also see that this is an issue that would not be adequately answered in the macular degeneration guideline. The issue of how patients access first line services and the barriers that prevent this from happening has implications beyond the macular degeneration population and will likely be a topic of interest in future public health guidelines. However, we will be considering referral from the point at which a person initially presents to health services and is suspected of having AMD. Initial presentation could be at the optometrist, emergency services or the GP. Any recommendations that the committee make about signs of symptoms will be applicable to all healthcare professionals, regardless of setting.
Optical Confederation	8	16	This should include community eye care services that seek to maximise residual vision.	Thank you for your comment. Support strategies delivered by community eye care services that seek to maximise residual vison will be included under this question should evidence be available.
Optical Confederation	8	26	We are concerned that an assessment of what strategies and tools are useful for monitoring people with AMD will be difficult without	Thank you for your comment. Although we recognise the importance of the problem of access to first line

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
		27	including community optometric services in the scope of the guidance, given how well-placed optometrists are to play a role in any monitoring	services we also see that this is an issue that would not be adequately answered in the macular degeneration guideline. The issue of how patients access first line services and the barriers that prevent this from happening has implications beyond the macular degeneration population and will likely be a topic of interest in future public health guidelines. However, we will be considering referral from the point at which a person initially presents to health services and is suspected of having AMD. Initial presentation could be at the optometrist, emergency services or the GP.
Optical Confederation	16	16	Should recognise that where the HES does not provide information to the patient, community optometry practices do.	Thank you for your comment. The guideline will take into the account that the information and support needs of the patient may be met by different healthcare professionals. A review will be performed to ascertain the standard of information that patients and carers find helpful and should receive.
Optical Confederation	16	21	Add in community low vision services.	Thank you for your comment. The scope has stated that the guideline will be relevant to the following subgroups: • Healthcare professionals in primary care. • Healthcare professionals in secondary care. • Social care professionals. • Local authorities.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• Commissioners of ophthalmic and optometric services. • Providers of ophthalmic and optometric services. • Practitioners in ophthalmic and optometric services. And • Private sector and voluntary organisations. • People working in related services. After consideration, the scoping group agreed that we had adequately covered practitioners and providers of all low vision services in England. Please also note that we will be recruiting a commissioner onto the guideline committee.
RCGP	General		It seems inappropriate to set aside bevacizumab when the indications are it will be adopted nationally once licence issues are resolved.	Thank you for your comment. We agree that the status of bevacizumab may change while the guideline is being developed, and this is why it has been included in the scope at all. While the scope can pre-empt the future it must also recognise bevacizumab's current status as an unlicensed drug for wet AMD.
RCGP	General		We would be pleased to see GP involvement in the production of these guidelines.	Thank you for your comment. We are currently in the process of recruiting a GP for the guideline.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
RCGP	General		The scope and statements made other than the above seem appropriate throughout the document.	Thank you for your comment.
RNIB	General	N/A	**About the RNIB:** Royal National Institute of Blind People (RNIB) is the UK's leading charity providing information, advice and support to almost two million people with sight loss. We are a membership organization with over 13,000 members throughout the UK and 80 percent of our Trustees and Assembly members are blind or partially sighted. We encourage members to get involved in our work and regularly consult them on matters relating to Government policy and ideas for change. As a campaigning organisation we act or speak for the rights of people with sight loss in each of the four nations of the UK. We also disseminate expertise to the public sector and business through consultancy on products, technology, services and improving the accessibility of the built environment. RNIB is pleased to have the opportunity to respond to this consultation	Thank you for your comment.
RNIB	General	N/A	**Equalities Act 2010:** We believe that all NICE work should reflect the duties of public bodies under the Equalities Act 2010, not just in relation to	Thank you for your comment. Equality issues are taken into consideration throughout the development of the guideline. An equality impact assessment form is filled out at multiple stages to assess equality

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			communication and accessible information, but in relation to non-discriminatory treatment. We would expect NICE to take steps to meet their legal obligations. This not only requires public bodies to have due regard for the need to promote disability equality in everything they do - including the provision of information to the public - but also requires such bodies to make reasonable adjustments for individual disabled people where existing arrangements place them at a substantial disadvantage.	issues as they emerge and determine how they may impact on guideline development. The guideline Chair in conjunction with the NICE technical team will also ensure that the guideline committee take equality considerations into account as they make recommendations based on the evidence presented and their clinical expertise.
RNIB	General	N/A	**Accessible information:** We believe this guideline should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English." The Equality Act expressly includes a duty to provide accessible information as part of the reasonable adjustment duty. Online information on websites should conform to the W3C's Web Accessibility Initiative Web Content Accessibility Guidelines (WCAG) 1.0, level AA, as required by the NHS Brand Guidelines and the Central Office of Information. With regard to the accessibility of print materials, including downloadable content such as PDF files, we would request that wherever possible they comply with our "See it Right" guidelines:	Thank you for your comment and the information provided. We will work with the Public Involvement Programme at NICE and the committee to ensure that we make our guidance as accessible as possible. NICE's online content follows the guidelines for UK government websites and aim to support W3C's WCAG 2.0 Guidelines Level AA level. NICE also carry out user-testing with a wide range of people and this helps to improve the user-experience for everyone.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			http://www.rnib.org.uk/professionals/accessibleinformation/Pages/see_it_right.aspx	
RNIB	2	35	The age of adults suspected of having macular degeneration or diagnosed with macular degeneration should not be restricted to 50 years and older but instead 18 years and older	Thank you for your comment. The scoping group agrees that including adults 18 years and older is appropriate for this guideline.
RNIB	2	41	We welcome the following subgroups which have been identified as needing specific consideration. However we would like to see: • Diabetic macular oedema patients covered within co-morbidity subgroup • A subgroup for those living in care homes	Thank you for your comment. The term "retinal damage" was used in this section to cover many different problems that can affect the retina. This was to avoid having to list many different types of retinal disease. It is understood that diabetic macular oedema will be included under this term. Those living in care settings have been added to the list of people who may have difficulty accessing care and therefore need specific consideration. The sentence now reads: Who have difficulty in accessing care such as those with impaired cognitive function (for example, dementia and learning disabilities), living in care settings or with impaired mobility.
RNIB	2	51	We would like to see this guideline include adults from 18 years and older when considering preventative strategies and risk factors for developing macular degeneration	Thank you for your comment. This seems in agreement with the wording of the current scope document.
RNIB	3	66	We welcome the criteria for referral and specialist services: specifically the referral of a patient from the optometrist, accident	Thank you for your comment. This seems in agreement with our intentions for the two service

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			and emergency departments or GP to the ophthalmologist. However we would like this section to include • Who provides confirmation of diagnosis and the time frame for referral to confirmation of diagnosis. This timeframe is critical so as to avoid unnecessary delay and treatment (if any), which could otherwise lead to irreversible sight loss, especially where there is uncertainty about the type of AMD. • Methods for rapid referral	organisation draft review questions: □ How do different organisational models and referral pathways for triage and diagnosis influence outcomes for people with suspected AMD (for example, correct diagnosis, errors in diagnosis, delays in diagnosis, process outcomes)? □ How do different organisational models for ongoing treatment and follow up influence outcomes for people with neovascular AMD (for example, disease progression, time to treatment, non-attendance)? These reviews will cover time frames for diagnosis and treatment as well as methods and models for rapid referral. Out of these reviews may also fall "who should provide confirmation of diagnosis?" however the guideline committee may consider it more appropriate to define the skill set and competency required to diagnose AMD correctly. This approach may be wise in order to make the guideline future proof (especially if the role of optometrists and specialist nursing/technical staff could change dramatically in the upcoming years).
RNIB	3	70	We welcome this section, however, we would like it to include: • Access to practical and emotional support through an	Thank you for your comment. While issues of support may fall out of the topic area that you have identified,

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			ECLO	we are going to review issues of low vision and psychological support in the management section of the guideline. The following two review questions have been drafted: □ What is the effectiveness of psychological therapies for AMD? □ What is the effectiveness of support strategies for people with visual impairment and AMD (for example reablement services)? We also recognise the role that ECLOs can offer in providing information for patients pre and post-diagnosis. The information needs of a person with AMD will be considered in the following draft review question: □ What information do people with suspected or confirmed AMD, and their family members or carers, find useful and in what format (for example written or oral)? We hope that this approach will help us to effectively assess the support needs of a person with AMD. However this is a separate issue to how, and through

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				who, this need will be met. This will be addressed when considering implementation of the guideline.
RNIB	3	74	While we welcome the section on interventions and advice for delaying onset or progression of macular degeneration, it is important to note there is limited robust data pertaining to the clinical effectiveness of such interventions. To date there is the AREDS trial.	Thank you for your comment. While the AREDs trial is likely to be a major source of evidence for this review question you will appreciate the need to systematically look for other potential important sources of evidence in this rapidly changing field. Even finding no evidence on certain preventative strategies may be useful in order to produce recommendations against their use for this purpose.
RNIB	3	80	We welcome the section on signs and symptoms of macular degeneration. We would like it to include: • General symptoms and signs that should prompt an ophthalmologist to suspect age-related macular degeneration • General symptoms and signs that should prompt an ophthalmologist to suspect geographic atrophy (Dry AMD) • General symptoms and signs that should prompt an ophthalmologist to suspect neovascular age-related macular degeneration (wet AMD)	Thank you for your comment. We agree that this is a sensible approach to splitting the evidence for the signs and symptoms of AMD. However this level of detail is usually fleshed out in the review protocol after consultation with the guideline committee rather than in the scope.
RNIB	4	81	We welcome the section on risk factors, however, we would like it to include: • Sunlight exposure	Thank you for your comment. The list of risk factors in this section was not meant to be exhaustive. As the scope stands we have listed the risk factors that have been most commonly cited. Should sunlight exposure be found as an important risk factor under the review question: "Which risk factors increase the likelihood of

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				a person developing AMD or progressing to late AMD?" it will receive due consideration by the guideline committee.
RNIB	4	84	We welcome the section on diagnosis and investigation of macular degeneration , however, we would like it to include: • Amsler Grid. This particularly important aid for patients with early, intermediate AMD or those who are not on treatment. It provides a way to identify symptoms they would not necessarily acknowledge. • Who should carry out the investigation/procedure i.e. ophthalmologist, optometrist, specialist nurse • Monitoring- for activity of disease and for detecting progression from dry to wetAMD • Genetic profiling	Thank you for your comment. 1) We will be reviewing the use of Amsler grid as part of the review question: □ What strategies and tools are useful for monitoring people with AMD? 2) Within the guideline we intend to define the skillset and competency required to perform treatments or investigations. We do this in preference to defining the role of a particular healthcare professional. This is important because roles of optometrists and specialist nurses may change dramatically in the coming years and the guidance will need to be futureproof. 3) Monitoring will be reviewed in the following draft review questions: □ How often should people with early AMD or geographic atrophy be reviewed? □ How often should people with early AMD or

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				geographic atrophy have their non-affected eye reviewed? □ How often should people with wet AMD be reviewed before active treatment can begin? □ How often should people with wet AMD have their non-affected eye reviewed? 3) Genetic profiling is not explicitly excluded from the scope since there may be evidence pending on its use, however it is not yet commonly used in UK practice. It may be considered as part of the question above on tools for monitoring patients with AMD if good evidence is found.
RNIB	4	91	We strongly welcome the section on information and support for people with macular degeneration, their carers and their families. However we would like to see information specifically on: • Eye Clinic Liaison Officer (ECLO) • Information preferences, formats and accessibility • Information about the eye condition, how will it affect their sight and every-day living, high risk groups • Information on signs and symptoms • Information on regular screening tests • Point of contact for patients if something goes wrong • How glasses can help • Low vision assessments	Thank you for your comment**.** We recognise the need for providing information for persons suspected of AMD and beyond diagnosis. The information needs of people with AMD will be assessed in the following draft review question: □ What information do people with suspected or confirmed AMD, and their family members or carers, find useful and in what format (for example written or oral)? The evidence that falls out of this review will direct the recommendations made.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			• Amsler Grid • Information about treatment options such as a patient decision aid • Information on organisations that can help i.e. RNIB • Patient compliancy/patient empowerment • A subgroup for those whose first language is not English	A number of products to support implementation of the guidance will also be produced. For example, Information For The Public is an easily understood guide to the recommendations, provides information on organisations which can help and also lists helpful questions for patients and carers to think about asking health and social care professionals ie. about points of contact and how visual aids can help. Cross-reference to Patient experience in adult NHS services (2012) NICE CG138. Also appears in the scope document, which gives instruction on providing NHS services to those without English as their first language.
RNIB	4	94	We welcome the section on management. However we would like to see information on: • Optimal and timely treatment. Making sure people get injections in clinically appropriate timeframes • Management of Dry AMD- regular follow-ups, sign posting to further sources of support and registration/certification • With regards to wet AMD-Switching treatments when patients are unresponsive • With regards to wet AMD-Fixed treatment • With regards to wet AMD-Treat and extend	Thank you for your comment. 1) The provision of optimal and timely management of AMD (including one stop services) will be covered by the review questions for service organisation: □ How do different organisational models and referral pathways for triage and diagnosis influence outcomes for people with suspected AMD (for example, correct diagnosis, errors in diagnosis, delays in diagnosis, process outcomes)?

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			• With regards to wet AMD-Stopping rules • Management before treatment • Management for those who do not meet NICE recommendations • Patient discussion and consent • Reporting adverse events • One-stop services • ECLO	How do different organisational models for ongoing treatment and follow up influence outcomes for people with neovascular AMD (for example, disease progression, time to treatment, non-attendance)? 2) Management of Dry AMD and information/support needs (possibly delivered by an ECLO) will be covered by the draft review questions: What information do people with suspected or confirmed AMD, and their family members or carers, find useful and in what format (for example written or oral)? What is the effectiveness of psychological therapies for AMD? What is the effectiveness of support strategies for people with visual impairment and AMD (for example reablement services)? How often should people with early AMD or geographic atrophy be reviewed? How often should people with early AMD or geographic atrophy have their non-affected eye reviewed? 3)Management of Wet AMD will be covered by the

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				draft review questions: □ What is the effectiveness of different anti-angiogenic therapies for the treatment of neovascular AMD? □ What is the effectiveness of switching therapies for neovascular AMD where first-line therapy is contraindicated or has failed? □ What is the effectiveness of different frequencies of administration of interventions for the treatment of neovascular AMD? □ What is the effectiveness of early treatment of neovascular AMD (in people with visual acuity greater than 6/12)? □ What factors indicate that treatment should be discontinued for neovascular AMD? Please note the questions: □ What is the effectiveness of early treatment of neovascular AMD (in people with visual acuity greater than 6/12)? □ How often should people with neovascular AMD be reviewed before starting active treatment? Are attempting to answer the issue of how to manage those who do not meet NICE recommendations (for treatment of wet AMD). Otherwise, NICE guidance is

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				intended to be guidance that is appropriate for the majority of patients with a particular condition and cannot replace clinical judgement for patients with different complications or comorbidities that may not meet NICE recommendations. 4) The reporting of adverse events and patient consent are broad issues that are beyond the remit for this guideline.
RNIB	5	130	We welcome the section on monitoring and review of both affected and unaffected eye.	Thank you for your comment.
RNIB	5	136	We believe the following area should be covered: • Access to optometrists- Shared care arrangements maybe set up in number of areas during the development of these guidelines and should therefore be covered • Training, certification and competency for healthcare professionals. This should be included as there is an interest to train nurse injectors for anti-VEGF treatments.	Thank you for your comment. Although we recognise the importance of the problem of access to first line services (such as optometrists) we also see that this is an issue that would not be adequately answered in the macular degeneration guideline. The issue of how patients access first line services and the barriers that prevent this from happening has implications beyond the macular degeneration population and will likely be a topic of interest in future public health guidelines. That said, we will be considering referral from the point at which a person initially presents to health services and is suspected of having AMD. We will also consider models of service organisation which may involve optometrists in triage roles or specialist

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				nurses within treatment roles, but this is not the same as offering guidance on how a professional should be trained or certified. The guidance will consider competencies of health and social care (HSC) professionals working in this field but it is outside the remit of NICE guidance to offer recommendations on training of HSC professionals and certification.
RNIB	8	219	We welcome the outcomes listed in this section. However we would like to see: • The outcomes split for prevention, Dry and wetAMD • Information on ability to drive, read medical labels under functional capacity	Thank you for your comment. Since there is much overlap in the applicability of the main outcomes to either wet or dry AMD. The list does not lend itself to being split in the manner you suggested. There is room for us to further define the outcomes of interest and prioritise outcomes for wet and dry AMD in the relevant review protocols, after consultation with the guideline committee. Ability to drive may be recorded under "functional capacity, independence and ability to carry out activities of daily living" but may not need stipulation here. The issue of ability to drive also relates to the persons CVI status. Reading speed and other measures of reading were not included here since they were found to be

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				awkward to record and generally unreliable as a measure of functionality (high variability day to day).
Royal Bolton Hospital NHS Foundation Trust	General	General	We are content with this consultation document as set out	Thank you for your comment.
Royal Bolton Hospital NHS Foundation Trust	General	General	We suggest that more thought be put into the longer term follow up of wet-AMD patients in hospital eye services and based on more recent long term follow up studies and real world outcomes audits from UK. These are different from the key clinical trials used for medication approval studies	Thank you for your comment. The types of evidence that will be included for the questions on service organisation will require careful consideration with the guideline committee. Your suggestion will be taken into account when drawing up the protocols for the above review questions.
Royal College of Nursing	3	23	Omega 3 fatty acids is no longer considered to reduce risk	Thank you for your comment. It may be the case that omega 3 fatty acids are not considered to reduce risk. Should this conclusion be arrived at, following review of the evidence, the guideline committee may be able to make a recommendation against its use for this purpose.
Royal College of Nursing	5	24	It would be good to look at the evidence on how speed or delays in 'access' affect vision outcomes.	Thank you for your comment. Although we recognise the importance of the problem of access to first line services we also see that this is an issue that would not be adequately answered in the macular degeneration guideline. The issue of how patients access first line services and the barriers that prevent this from happening has implications beyond the macular degeneration population and will likely be a topic of interest in future public health guidelines.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				However, we will be considering speed of referral from the point at which a person initially presents to health services and is suspected of having AMD. Issues regarding speed of diagnosis and delays in treatment will be considered in the following two review questions: □ How do different organisational models and referral pathways for triage and diagnosis influence outcomes for people with suspected AMD (for example, correct diagnosis, errors in diagnosis, delays in diagnosis, process outcomes)? □ How do different organisational models for ongoing treatment and follow up influence outcomes for people with neovascular AMD (for example, disease progression, time to treatment, non-attendance)?
Royal College of Nursing]	General	General	Overall a very comprehensive document covering the most important areas of the diagnosis and management of age related macular degeneration.	Thank you for your comment.
Royal College of Nursing]	5	6	Term 'reconstituted' is misleading in this context, should it not be aliquot?	Thank you for your comment. The section has been reworded to state: "Although bevacizumab is in use in the UK and elsewhere for the treatment of neovascular AMD, the Medicines and Healthcare Products Regulatory Agency regards it as unlicensed

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				for this indication because its use requires the formulation of the licensed product to be divided into separate smaller doses (to produce multiple aliquots) for injection into the eye"
Royal College of Ophthalmologists	2	13	Should be adults: 55 years and older (reads 18 y)	Thank you for your comment. The cut off age of 55 was not used since it was noted that AMD can present in younger people. We have, instead, chosen to include all adults with a diagnosis or suspicion of AMD.
Royal College of Ophthalmologists	3	1 7	What is the reference standard to evaluate diagnostic technologies for neovascular AMD? (e.g., OCT? FFA?)	Thank you for your comment. The reference standard to evaluate diagnostic tools for neovascular AMD will be decided after consultation with the guideline committee during the development of the review protocol.
Royal College of Ophthalmologists	4	16	Definition of late wet AMD, perhaps should read manifest wet AMD	Thank you for your comment. In writing the scope of this guideline we recognise that there are different classification systems currently used for AMD. "Late", "intermediate" and "early" are commonly understood ways of defining AMD as well as "wet" and "dry". "Late" AMD can be understood as both "wet" and "dry" forms. We wanted to keep terminology consistent throughout the scope and the introduction of "manifest wet AMD," may raise more questions.
Royal College of Ophthalmologists	5	18 22	When to discharge patients from secondary care? Should be included in this section	Thank you for your comment. The issue of when to discharge people from secondary care relates to the issue of when to stop treatment permanently, which

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				will be covered in the review question below: □ What factors indicate that treatment should be discontinued for neovascular AMD?
Royal College of Ophthalmologists	7	10 19	Is Triage in secondary care useful for people with suspected AMD, and if yes what tools/health care professionals should be used	Thank you for your comment. The usefulness of triage systems will be assessed in the following review question: □ How do different organisational models and referral pathways for triage and diagnosis influence outcomes for people with suspected AMD (for example, correct diagnosis, errors in diagnosis, delays in diagnosis, process outcomes)? The question on tools for triage has been dropped in favour of reviewing all diagnostic tools under the same review question since there will likely be overlap between the tools used for triage and diagnosis: □ What tools are useful for triage, diagnosis and directing treatment in people with suspected AMD? The guideline committee may consider it more appropriate to define the skill set and competency required to triage AMD correctly rather than stipulate the healthcare professional themselves. This

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				approach may be wise in order to make the guideline future proof (especially if the role of optometrists and nursing/technical staff could change in the upcoming years).
Royal College of Ophthalmologists	7 8		What is the impact of frequent visits to hospital and frequent intraocular injections in the quality of life of patients with wet AMD? Should be added	Thank you for your comment. We believe that this is a very important issue however that it can be answered within the review questions drafted on management of wet AMD. Health related quality of life is one of our main outcomes of interest listed in section 1.6 and will be under consideration when we consider frequency of administration for anti-angiogenic therapies. Number of visits to the hospital has also been added to the outcomes of interest as a result of discussion with stakeholders and will help us assess the effectiveness of certain models of service organisation to keep the number of hospital visits required down where possible.
Royal College of Ophthalmologists	General		The Sustainability Working Group has reviewed the scope of the upcoming AMD NICE guideline. We are pleased to note that the scope specifically includes measures to provide guidance on smoking cessation, secondary prevention, when to consider stopping treatment, different service models, the provision of low vision services where possible (within the legal framework) the use of Bevacizumab. We do however think that the scope should be altered by adding to the section on service user experience and outcomes.	Thank you for your comment. Following discussion with the scoping group, and in reference to your previous comment, we consider your suggestion of the addition of "number of visits to the hospital" to be helpful and we have added this outcome to the scope under "service user experience and outcomes."

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal College of Ophthalmologists	9	20 23	The Sustainability Working Group feels this should include "number of visits to the hospital". Many services are currently not operating a one stop model which significantly increases the number of journeys to hospital and time spent by patients and relatives attending hospital. This is a significant cost to the patients and their families and should be specifically considered in the guidelines. This reflects the College's position on sustainability of the service in so far as moving to a one stop model can increase the efficiency of the unit, remove barriers to timely treatment, reduce journeys and costs to patients and improve overall quality. Otherwise we feel the scope is consistent with four of the seven sustainability domains used by the Working Group which are within the scope of the guideline (prevention, productivity, pathways and patient journeys, patient education and empowerment).	Thank you for your comment. Following discussion with the scoping group we consider your suggestion of the addition of "number of visits to the hospital" to be helpful and we have added this outcome to the scope under "service user experience and outcomes."
Royal college of Pathologists	3	19	This might be interpreted as being able to reduce risk of family history. How about something along the lines of 'mitigating genetic risk'? I am not sure what is meant by 'family origin'.	Thank you for your comment. The subheading has been reworded from "reducing the risk of AMD" to "Risk of AMD" since as you have stated some of the risk factors listed would not be modifiable. "Family origin" is the NICE preferred terminology for ethnicity.
Royal college of Pathologists	4	22	Is 'reablement' rehabilitation?	Thank you for your comment. Yes, reablement may be understood as rehabilitation and includes strategies of support for those with visual loss in AMD, and methods for optimising existing visual performance.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal college of Pathologists	5	24	If access to optometry etc is not covered how can referral pathways (2-15) be addressed?	Thank you for your comment. Although we recognise the importance of the problem of access to first line services we also see that this is an issue that would not be adequately answered in the macular degeneration guideline. The issue of how patients access first line services and the barriers that prevent this from happening has implications beyond the macular degeneration population and will likely be a topic of interest in future public health guidelines. However, we will be considering referral from the point at which a person initially presents to health services and is suspected of having AMD. Initial presentation could be at the optometrist, emergency services or the GP.
Royal college of Pathologists	4	7	It is important under 'classification' to be aware that AMD is probably a heterogeneous disease and this will impact on considerations of diagnosis, treatment and monitoring	Thank you for your comment. We agree that this will be an important consideration when choosing the most appropriate classification system for describing AMD. The classification system must provide a clinically useful way to divide persons presenting with AMD. It should help direct management whilst taking into account the heterogeneity found in the population.
Royal college of Pathologists	13	26	It would be clearer if this sentence starts 'Early and intermediate dry AMD', to make it clear that late geographic atrophy is excluded	Thank you for your comment. The statement refers to all kinds of "dry" AMD and the following paragraph refers to all stages of dry AMD from intermediate to advanced "late" AMD. This terminology is based on

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				the classification system described in the Royal College of Ophthalmology Guidance.
SeeAbility	General	General	It would be helpful to understand the rationale for the guideline encompassing adults over 18 and not children and for NICE to indicate if other guidance is planned on young people with sight loss, as the cataract guideline will also exclude the younger age group. For children and young people with learning disabilities any sight issue is heightened by concerns about access, and being able to self report symptoms, which then leads to presenting late for treatment, if at all. We know from our research that children with learning disabilities are 28 times more likely to have serious sight problems than the general population of children, and yet often struggle to get the regular eye care they need.	Thank you for your comment. Age-related macular degeneration (AMD) is a condition that generally affects people over the age of 50, We have chosen to exclude children and young people since the condition will not affect these populations. Since AMD may, in some cases, present earlier that age 50, we have included adults older than 18 years of age. Cataracts is also an age related condition. It is beyond the remit of this scope to state which future guidelines NICE may be commissioned to produce. People with learning disabilities are listed among our "groups in need of special consideration" in section 1.1 of the scope. However young people and children will not be included in this guidance for the reasons outlined above.
SeeAbility	General	7	Under information, and activities, services or aspects of care, it is vital that good, clear easy read information on eye treatment as well as more general information on good eye care is provided to people with learning disabilities throughout their pathway of care. We have a specialist Eye Care and Vision Team dedicated to improving outcomes for people with learning disabilities in looking	Thank you for your comment and the information provided. The information needs of a person will be assessed in the following draft review question: □ What information do people with suspected or confirmed AMD, and their family members or carers, find useful and in what format (for example written or oral)?

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			after their sight, including a project that offers peer to peer support. As part of this work, we have developed a number of resources on helping someone with learning disabilities prepare for eye surgery including an Easy Read Eye Surgery Support Plan, which has been endorsed by Moorfields Hospital. For more information see: https://www.seeability.org/sharing-knowledge/?book=sight-loss-2-eye-operations#eye-surgery-support-plan The scoping document currently omits to include links to consent and mental capacity in this section. We also draw attention to the Royal College of Ophthalmologists guideline in this respect.	People with learning disabilities are listed as one of the groups in need of special consideration when the above review is performed and recommendations are drafted by the committee. The guideline scope refers to the patient experience in the adult NHS service guideline. This document gives instruction on consent and mental capacity issues.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
SeeAbility	General	9	In terms of key outcomes, there is good evidence that supporting people with learning disabilities to access eye care (which would include treatment for AMD) would improve quality of life but ensuring good clinical outcomes is obviously not as straightforward as other patients. It would be helpful if the guideline could focus on the need to be vigilant amongst groups of people with communication difficulties, including those with learning disabilities. Reporting of sight problems is often symptom led (**Leamon, S. et al (2014). Improving access to optometry services for people at risk of preventable sight loss: a qualitative study in five UK locations. *J. Public Health (Oxf).* 1–7.)** so this puts people with communication difficulties at major risk of not getting the eye care they need. Behaviour may be wrongly attributed to the diagnosis of a learning disability, rather than a sight problem (known as "diagnostic overshadowing"). Professionals who know the person best may think they can see perfectly well and yet the person's sight may be at major risk **(Newsam, H et al. Sensory Impairment in Adults With Intellectual Disabilities—An Exploration of the Awareness and Practices of Social Care Providers. Journal of Policy and Practice in Intellectual Disabilities Impact Factor & Information).** There is also evidence that people with learning disabilities are not accessing the care they need and may present	Thank you for your comment and the information provided. Although we recognise the importance of the problem of access to first line services, especially among those with learning disabilities, we also see that this is an issue that would not be adequately answered in the macular degeneration guideline. The issue of how patients access first line services and the barriers that prevent this from happening has implications beyond the macular degeneration population and will likely be a topic of interest in future public health guidelines. However, we will be considering referral from the point at which a person initially presents to health services and is suspected of having AMD. Initial presentation could be at the optometrist, emergency services or the GP. Since people with learning disabilities are listed as one of the groups in need of special consideration. They will receive additional attention when the reviews are performed and recommendations are drafted by the committee.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			late with eye care symptoms. Even dedicated schemes to ensure people with learning disabilities get annual health checks, has found many people were not being told about eye care.(**Codling, M. 'Eye Know': translating needs from annual health checks for people with learning disabilities to demand. British Journal of Learning Disabilities, 41(1), 2013, pp.45-50.)** If there is poor access to eye care, subsequent visual impairment may compound pre-existing disability in some people with learning disabilities (**Evenhuis H M, Does visual impairment lead to additional disability in adults with intellectual disabilities? Journal of Intellectual Disability Research vo 53 No. 1 pp 19-28, 2009**), and increase the risk of self-injurious behaviour (**De Winter C, et al. Physical conditions and challenging behaviour in people with intellectual disability: a systematic review. J Intellect Disabil Res. 2011 Jul;55(7):675-98)**. People with learning disabilities may also at greater risk of accidents and falls, or need more costly packages of support from health and social care.	
The College of Optometrists	General	General	We welcome the development of a NICE clinical guideline on age-related macular degeneration (AMD). AMD is a very common eye condition and the number of people affected is very likely to increase due to an ageing population.	Thank you for your comment.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
The College of Optometrists	General	General	The document should equally focus on prevention, e.g. smoking cessation programmes. In the draft scope, there is a mention of people not being aware of the symptoms of wet AMD, e.g. from low socio-economic groups etc. It will be important to tackle this issue as well, by i.e. national advertising of wet AMD.	Thank you for your comment. Screening was outside of the remit for this guidance which is for the diagnosis and management of AMD. The guideline will focus on risk factors for AMD only in so much as will help aid suspicion and diagnosis of the disease. As such we will not be looking at therapies to prevent AMD in the general population although we are interested in reviewing strategies to reduce the risk of developing AMD in the second unaffected eye. It is likely that the smoking cessation guidance that NICE has already produced will be cross referred to within the guideline, since smoking is cited as being a modifiable risk factor for AMD.
The College of Optometrists	5	26	We are of the opinion that training of healthcare professionals should be included. It is critical to service delivery to involve other professionals e.g. optometrists in the delivery of AMD care and so integral to this is ensuring they are adequately trained. There are economic implications too as other professionals that are an appropriately trained will be more cost-efficient than delivering the service by doctors only.	Thank you for your comment. The guidance will consider competencies of health and social care (HSC) professionals working in this field but it is outside the remit of NICE guidance to offer recommendations on training of HSC professionals and certification. It may be the case, however, that when we review different organisational models of care, some of these will be dependent on having special training of healthcare professionals (for instance, optometrists in triage models). These issues will be addressed when considering the implementation of the guideline.

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
The College of Optometrists	8	18	The guidance should also look at when to discharge those on whom treatment is stopped.	Thank you for your comment. The issue of when to discharge people from secondary care relates to the issue of when to stop treatment permanently, which will be covered in the review question below: □ What factors indicate that treatment should be discontinued for neovascular AMD?
The Royal College of Radiologists	4	21	The Royal College of Radiologists (RCR) welcomes the inclusion of radiotherapy among the management strategies indicated for Late 'wet' Age-related Macular Degeneration (Neovascular). The RCR recommends that the clinical guideline includes a definitive statement on both the historic and potential future role of radiotherapy for treating this condition. Please see reference below. *A Review of the use of radiotherapy in the UK for the treatment of benign clinical conditions and benign tumours.* London: The Royal College of Radiologists, 2015. Ref No. BCFO(15)1 (https://www.rcr.ac.uk/sites/default/files/publication/BFCO%2815%291_RTBenigndisease_web.pdf)	Thank you for your comment and the information provided. On review of the stakeholder comments, the decision has now been made to remove the mention of radiotherapy and submacular surgery from the scope since these practices are no longer commonly used in England. This view is also stated in the evidence that you have cited.
Thomas Pocklington Trust	3	1.3 (1)	We imagine it is part of the service organisation you describe but, in our experience, it is always worth highlighting the importance of support at diagnosis (often provided by eye clinic liaison officers (ECLOs)) in ensuring people receive the support they need post-diagnosis. We are pleased to note this is alluded to later in the document.	Thank you for your comment. While issues of support may fall out of the topic area that you have identified, we are also going to review issues of general and psychological support in the management section of the guideline. The following two review questions have been drafted:

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				□ What is the effectiveness of psychological therapies for AMD? □ What is the effectiveness of support strategies for people with visual impairment and AMD (for example reablement services)? We also recognise the role that ECLOs can offer in providing information for patients pre and post-diagnosis and this will be considered in the following draft review question: □ What information do people with suspected or confirmed AMD, and their family members or carers, find useful and in what format (for example written or oral)? We hope that this approach will help us to effectively assess the support needs of a person at diagnosis.
Thomas Pocklington Trust	3	1.3 2	For reducing the risk, please can you include 'Screening for AMD among people over defined threshold ages' perhaps built into routine health screening programmes.	Thank you for your comment. Screening was outside of the remit for this guidance which is for the diagnosis and management of AMD.
Thomas Pocklington Trust	4	1.3 (5)	Under management strategies, please could you consider why people do not take up or continue with treatment. We are aware there is fall out and later in the scope there is mention of non-attendance but it is important to understand why not in addition to citing that it happens and recognising the cost.	Thank you for your comment. The group has agreed that your suggestion could add value to the current review questions on service organisation. As such the following review question has been drafted in addition:

Macular degeneration
Consultation on draft scope
Stakeholder comments table

08/05/15 to 08/06/15

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				What are the barriers to attendance and uptake of treatment for people with diagnosed AMD?
Thomas Pocklington Trust	General	General	Overall, we think the scoping document covers the major considerations and are glad NICE is developing guidance in this area.	Thank you for your comment.

Registered stakeholders: http://www.nice.org.uk/guidance/indevelopment/gid-cgwave0658/documents