Diabetic retinopathy

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Stakeholder	Page no.	Line no.	Comments	Developer's response
Alimera Sciences Europe Ltd	General	General	Question 1 – Are there any cost saving interventions or examples of innovative approaches that should be considered for inclusion in this guideline? **Please see our notes below of the poor implementation of TA301.**	Thank you for your comment.
Alimera Sciences Europe Ltd	001	026	Estimation of visual impairment may be outdated. See Royal National Institute of Blind People (RNIB) and Specsavers (2017) The State of the Nation Eye Health 2017: A year review.	Thank you for your comment and additional information. This section has been updated with estimation figures from this publication.
Alimera Sciences Europe Ltd	002	015	It will be important that the DR guideline references the RNIB See The Light Campaign that has 16 key recommendations for all stakeholders (e.g. SHSCDHSC/HEE/ICS) (see https://www.rnib.org.uk/sites/default/files/See%20the%20light_Improving%20NHS%20eye%20care%20capacity%20in%20England.pdf)	Thank you for your comments. In line with the NICE processes within the NICE guideline manual the guideline will not link to this RNIB report. Published guidelines within the scope of a NICE guideline can be assessed for quality for inclusion in the evidence base.

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Alimera Sciences Europe Ltd	002	016	The NHS Long term plan is referred to regarding reducing of variation of quality care. However, PHE Atlas of Variation vision atlas also needs referencing. (see https://www.rcophth.ac.uk/news-views/vision-atlas-england/) Key points in this reference to consider in NICE DR guideline may be: 1) ethnic variation 2) the backlog new pathways developed to manage the backlogs should be reviewed for their impact on mitigating risk for irreversible disease progression, reducing delays and acceptability to patients use of intravitreal injections etc.	Thank you for your comments. The equality impact assessment includes consideration of equality issues relating to race/ethnicity and these have been included in this assessment. This proposed scope includes consideration of how often those not currently getting treatment and whose care is managed by the hospital eye service, should be reviewed. Consideration of backlogs is not within the remit of NICE.
Alimera Sciences Europe Ltd	003	001	It will be important for the guideline to consider current data from the Atlas of Variation (see https://www.rcophth.ac.uk/news-views/vision-atlas-england)	Thank you for your comment and this additional information.

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Alimera Sciences Europe Ltd	003	010	Diabetic Macular Oedema (DMO) represents an accumulation of fluid within the central portion of the retina, which arises as a consequence of failure of the blood-retinal barrier (BRB). Diffuse oedema is caused by extensive capillary leakage, whereas localised oedema is caused by focal leakage from grouped microaneurysms (MAs). DMO can occur in isolation without other signs of microangiopathy in the fundus; therefore, it merits being classified as a separate entity within this new NICE Diabetic Retinopathy (DR) clinical guideline, and a clear note should be made that DR and DMO may be diagnosed independently of each other, and that the NICE DR guideline will seek address both diagnoses.[i] This is especially important when it comes to choosing pharmacological therapies indicated for treatment of DMO.	Thank you for your comment and additional information. As can be seen in the key issues and draft review questions section this guideline will consider diabetic macular oedema separately where needed in the management questions.

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Alimera Sciences Europe Ltd	006	030	Existing backlogs in Ophthalmology services have been exacerbated by COVID-19. Ophthalmology is a resource heavy NHS service, and recorded the highest level of outpatient activity of all NHS services in 2019-20 with 7.9 million attendances.[ii] Chronic conditions (e.g. cataract development, glaucoma, neovascular age related macular oedema (nAMD) and DMO) have been severely delayed during this prolonged pandemic period leading NHS England leadership to request that all healthcare systems aim for top quartile performance in productivity in high-volume clinical pathways systems with the greatest COVID-19 patient backlogs. Ophthalmology is a key focus for NHS England as it is one of the top 4 priority areas.[iii]	Thank you for your comment and additional information. The review questions in this guideline will consider the clinical and cost effectiveness of treatments. The acceptability of treatments is also being included in these reviews. There is a further question relating to switching or stopping treatments that evidence will be considered for.

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			"Even prior to the pandemic, ophthalmology was the busiest specialty in England with the highest number of attendances for outpatient appointments and delays in hospital eye care services were resulting in permanently reduced vision in some patients. As the most common cause of delay is in regard to follow-up appointments, it is clear that this is an area where improvement needs to be a priority, particularly as an intensive intravitreal regimen has a considerable effect on patients' quality of life and increases the risk of patient non-adherence."[iv] In light of COVID-19 backlogs, it may be beneficial for less clinically burdensome pharmacological options for the treatment of DMO to be prioritised due to the changing clinic environment in real-world practices.[4]	

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			Two key points we would like to emphasise that should be considered in the DR guideline: 1) There is a lack of any robust clinical data that switching from 1 anti-VEGF to another offers additional clinical benefit and a change in class may prove a better option 2) Stopping anti-VEGF and switching to intravitreal corticosteroids is not currently practiced in line with the supporting evidence base or the uptake expected in NICE TA301/TA349 Frequent injections are required with anti-VEGF treatments for the treatment of nAMD as well as DMO (TA274 and TA346). These treatments represent a key area of clinical burden for Ophthalmology services. The NICE DR guideline should consider the	

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			current NHS service issues, driven by high clinical burden investigations, treatments, as well as the need for regular and frequent injections of treatments like anti-VEGF. Hence, the impact of treatment options that favour a reduction in patient and NHS service burden should be considered in the clinical pathway. Other useful clinical guidelines have been published recently, including in the EU and UK, which are especially important to consider on the back of the worsened service situation caused by COVID-19 pandemic.[4,10] The NICE DR guideline should be very clear on when to switch from anti-VEGF treatment in eyes considered to be insufficiently responsive to anti-VEGF if they have been given six or more anti-VEGF injections in the preceding 12 months.[v,vi] A number of publications have demonstrated that high clinical burden anti-	

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			VEGF treatments have not been administered or monitored at appropriate levels and this has led to worsening patient outcomes during the pandemic.[vii] Recent consensus guidelines are clearer on this, recommending a switch away from anti-VEGF treatment to a cortico-steroid pathway after benefit is not displayed after greater than, or equal to 6 injections in the preceding 12 months, or where the burden of treatment does not allow anti-VEGF to be injected sufficient frequency to be effective.[4] Whilst in RCTs the anti-VEGF agents have been shown to be effective in controlling macula/intra-retinal fluid in 50-60% of DMO patients who meet the strict inclusion/exclusion criteria in these studies, these results have not proven to be widely replicable in every day clinical practice. The reasons for this are multifactorial and well described in the literature and	

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			fundamentally due to the fact that in many patients with DMO that anti-VEGF levels may not be increased and thus use of anti-VEGF agent may be inappropriate and secondly the ability for Hospital Eye units/providers to deliver the high level of injections due to patient compliance and or capacity constraints in normal working hours of ophthalmology services in NHSE and are well summarised in the following reference: *"Several factors may contribute to suboptimal outcomes among DMO patients treated with anti-VEGF therapy, such as delays in diagnosis and/or treatment, insufficient response to therapy, and more definitively, the impossibility of physicians to administer therapies according to the standard-of-care (SoC) in real-life practice…Factors that have been exacerbated by the current corona virus pandemic and also led to patients fearing*	

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			traveling to and attending clinical appointments to receive therapy."[7] If there had been improved implementation of NICE TA301 and TA349 prior to the COVID-19 pandemic, more patients may have benefitted from long-acting intravitreal corticosteroid treatments that do not require frequent injections and therefore are less onerous on the clinic and the patient. This new guideline should ensure clearer stopping and switching rules for anti-VEGF treatment and when it is appropriate to switch to pharmacological treatments with a different mode of action, such as fluocinolone acetonide (ILUVIEN®)[viii] and dexamethasone intravitreal implant (Ozurdex®).[ix] A recent independent publication highlighted that "*30 to 40% of optimally treated DME patients respond poorly to*	

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			anti-VEGF with transient or incomplete. resolution of fluid. This can be partly explained by the pro-inflammatory state present since the beginning of the disease that plays a pivotal role in the pathophysiology of early DR. As the disease progresses, studies have shown that the expression and secretion of inflammatory cytokines and chemokines increase accordingly, causing inflammation to play a major role in the pathogenesis of chronic DME inducing further resistance to anti-VEGF treatment. Therefore, steroids appear effective at all stages of DME."[x]	
Alimera Sciences Europe Ltd	007	011	How is management of DR/DMO patients going to be future proofed? i.e. the information from the tools and the management of the condition. Connectivity of tools, language to describe biomarkers etc, the decision maker for treatment or switching etc may not be human.	Thank you for your comment. NICE has an ongoing surveillance programme for NICE guidelines. Once published this guideline will be subject to that surveillance programme and will be considered for an update depending on the findings of this surveillance process.

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Alimera Sciences Europe Ltd	007	016	It will be important to consider the site of monitoring, screening and diagnosis. Simple procedures such as monitoring intraocular pressure (IOP) and cataract development might be better managed in local settings by optometrists, assessment hubs and homecare services closer to patient's homes. This may assist in reducing the burden on acute trusts and outpatient services. It may also allow treatments that require less injection frequency and monitoring to be monitored more effectively. At present, many trusts structure services around treatment type (e.g. anti-VEGF) and not around diagnosis, and this can mean that patients stay in high clinical burden pathways, when they could be seen in a different pathway (e.g. long acting steroid pathway – see Downey et al 2021).[4]	Thank you for your comment. This guideline includes settings where NHS funded care is provided. The sites from which services are delivered are likely to be decided at a local level. The review questions in this guideline will consider the clinical and cost effectiveness of treatments. The acceptability of treatments is also being included in these reviews. There is a further question relating to switching or stopping treatments that evidence will be considered for.

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			Publications have cited that this service structure means prescribing and treatment practices that are more relevant to nAMD diagnosis, where there are limited pharmacological treatments other than anti-VEGF treatment, results in patients remaining on these high clinical burden intravitreal injection when they may not be administered frequently or they are not effective.[4] As recommended in other publications, it is very important for clear stopping and switching rules for anti-VEGF treatment in DMO and a clear clinical measures to be outlined on exactly when to switch away from these treatments in DMO, rather than switching to another anti-VEGF which may have similar patient and clinician burden of injection, and a very similar mode of action on only VEGF mediators of DMO. There is no reliable RCT data to support this current and frequent practice of anti-VEGF switching in DMO.[4,xi] Second line	

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			steroid treatments such as fluocinolone acetonide and dexamethasone intravitreal implant have been recommended in NICE TA301 and NICE TA349, respectively. These reviews identified that intravitreal corticosteroid treatments offer similar visual and retinal oedema benefits to anti-VEGF treatments and may be useful when DMO was insufficiently responsive to available therapies. Second line intravitreal corticosteroid treatments are very important to consider as DMO pathology is often multi-factorial including anti-inflammatory and anti-VEGF mediators in its aetiology. Anti-VEGF treatments only address the latter mediator. Despite this, the uptake of these cortico-steroid treatments has not been in line with the budget impact models discussed in TA301 and TA349, and as a result patient outcomes may have been impacted where	

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			patients have persisted on anti-VEGF treatment when it may not address the underlying mediators of their DMO. This may have also been at significant cost for suboptimal patient outcomes.	
Alimera Sciences Europe Ltd	007	026	There will be a need to include eye health indicators, service quality assurance and report outcomes of treatment for quality assurance of services. Whilst these are likely to be the subject of departmental audit and discussion, wider reporting and review locally (place) and at ICS level would provide assurance on the quality of services delivered for the population at risk. The outcomes proposed in the Portfolio of Indicators for Eye Health and Care (Indicator 7) based on data collected during routine clinical care, are a useful starting point and should not incur additional burden for data collection.	Thank you for your comment. Quality assurance of services or service audit is not in the remit of this guideline.

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			GPs and practice nurses in primary care as well as primary care pharmacists should also be engaged in auditing DMO patients to ensure they receive the evidenced based treatment, at the correct frequency, for DMO as they are very much involved in the care of diabetes patients. They should be engaged in signposting these patients back into the system alongside GP's particularly to ensure they are monitored and treated in line with the evidence base.	
Alimera Sciences Europe Ltd	008	022	Consideration around cost-effectiveness needs to go beyond cost per QALY and look closely at service provision, and the issues with anti-VEGF prescribing, which may continue despite poor outcomes, and may not be administered in line with RCT study protocols due to the burden of this treatment approach on NHS services. Long-acting intravitreal corticosteroids may reduce the burden of treatment (i.e., injections and visits) and lower both	Thank you for your comment. Any economic analyses conducted for this guideline will be done according to the reference case specified in the NICE guideline manual, which specifies NICE's preferred perspectives for both costs and outcomes. The committee may also take into account a range of other factors, such as implementation or service delivery issues, when making recommendations, and the points you have raised will be considered by

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			pharmaceutical costs and health care costs. This practical service impact approach may prove more realistic than applying complex cost effectiveness analysis modelling, especially as RWE demonstrates consistent outcomes that are aligned to RCTs when using a long-acting steroid implant.	the committee when they are planning the economic work to be undertaken for this guideline.
Alimera Sciences Europe Ltd	009		Additional outcomes should include: 1) Clinic burden of intravitreal injection (i.e., treatment number and visits) 2) Patient/carer burden of intravitreal injection 3) Mean average BCVA (area under the curve – what are the fluctuations in vision over the treatment period and what is the consistency of the quality of vision) 4) Mean average CST (area under the curve – as above, what are the fluctuations in CRT over the	Thank you for your comment. The outcomes in the proposed guideline scope include those that are likely to be included when searching for and assessing the evidence. For the review questions review protocols will be developed by the guideline committee which will specify what the review will include. These will be agreed by the guideline committee and will include more details on the outcomes specific to that review question.

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			treatment period and what is the impact on the quality of vision) 5) Switch/stopping rules to optimise outcomes in non-responders or those who do not receive the correct frequency of anti-VEGF treatment 6) Ability for NHS to deliver injections according to RCT defined protocol(s) 7) Qualitative assessment of imaging i.e. biomarkers Points 3 & 4 are important measures to consider as the frequency of both intravitreal anti-VEGF and short-acting corticosteroid injections may acutely improve BCVA and CST, but their effects may deteriorate prior to re-injection and will not be sustained over the long-term.	
Anglia Ruskin University	General		Could the literature suggesting more frequent screening be examined for people with higher risk of sight threatening	Thank you for your comment. Screening for diabetic retinopathy is included in the NHS diabetic eye screening programme and is therefore not within the

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			retinopathy – for example people with high BMI, and ethnic groups?	remit of this guideline. The scope for this guideline does include considering how often those with retinopathy, who are under the care of hospital eye services, are reviewed.
Anglia Ruskin University	001	013	The draft scope could perhaps include something like 'The risk is higher in people whose diabetes is not controlled adequately and also if the uptake of retinal screening is poor.'	Thank you for your comment. This has not been added as this section reflects why the guideline is needed. Screening and attendance at screening is outwith the remit of this guideline.
Anglia Ruskin University	001	021	The draft scope could perhaps include 'Proliferative diabetic retinopathy is due to new unstable abnormal blood vessels that can leak causing sight loss.	Thank you for your comment. This has been included already in this section.
Anglia Ruskin University	006	007	The draft scope currently does include the work done within the community: Non-proliferative retinopathy that is not under hospital eye services (reviewed by community) should also be considered based on risk factors ?	Thank you for your comment. This is in the remit of the NHS diabetic eye screening programme and outwith the remit of this guideline.

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Diabetes UK	General	General	**Guideline** Diabetes UK welcome the signposting to NICE's shared decision making and patient experience guidelines within this scope but feel it should consider the emotional aspects of diagnosis further given the potential psychological impacts of a sight loss diagnosis. We hear from many people living with diabetes who have experienced retinopathy complications and shared their challenging emotional journey from receiving an uncertain diagnosis, being fearful of treatments, concerned about further deterioration and how this will affect their ability to fulfil key commitments in their life like employment and caring for loved ones. We feel that the guidelines could be more explicit in providing further information on how to emotionally support those who are	Thank you for your comment. The proposed key issues and review questions within this guideline scope include the acceptability of different management strategies. Evidence, and committee discussion of this evidence and their expertise, will be used to develop the guideline recommendations. This guideline committee will, as all NICE committees do, have patient representative members. There are existing NICE guidelines, such as those on 'Patient experience in adult NHS services' (CG138) and 'Shared decision making' (NG197), that may be linked to in this guidance.

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			referred for retinopathy treatment, such as including recommendations about the provision of eye clinic liaison officers to support people as they are referred and receive treatment.	
Diabetes UK	General	General	**EIA** We agree that extra consideration should be given to the higher risk of retinopathy complications in the groups listed in the Equality Impact Assessment but feel that consideration must also be given to the impact of the pandemic on appointments and backlog of eye checks. Whilst this guidance does not cover the screening service, delays in checks will have an effect on referrals to hospital eye services and adjustments will have to be made to ensure everyone, and particularly the groups identified with having potential equality issues, can access these equitably.	Thank you for your comment. Consideration of backlogs is not within the remit of NICE. As noted, the guideline will not cover screening as this is included in the NHS diabetic eye screening programme.

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Diabetes UK	002	008 - 009	This should be updated to reflect the proposed changes in the NHS Diabetes Eye Screening Service criteria that those with no retinopathy or maculopathy should be invited for biennial routine screenings.	Thank you for your comment and additional information. This has been updated to remove the annual timeframe for screening to allow for proposed changes in the service.
Diabetes UK	003	024	We would like to raise a research recommendation with the committee regarding the need for research to find a treatment for retinal ischaemia and for retinal fibrosis, especially in people with proliferative diabetic retinopathy, as neither have a treatment at present.	Thank you for your comment. During guideline development the committee will consider where there may be gaps in the evidence and will consider research recommendations in these areas.
Diabetes UK	007	011	We agree that optical coherence tomography scans are a useful tool for monitoring people who are being treated for proliferative retinopathy and diabetes macular oedema as they provide an accurate 3D picture of the retina for assessment.	Thank you for your comment. The use of tomography within the screening service and referral from the screening service is outwith the remit of this guideline as the NHS diabetic eye screening programme is not in the remit of NICE.

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			It is vital however that the use of optical coherence tomography in hospital eye services is aligned with the criteria for using it within the Diabetes Eye Screening service. Currently, it is not mandatory for the screening service in England to use optical coherence tomography, although this has been recommended, and, if used within the screening program, approximately 80% of referrals for treatment would not require treatment upon further inspection. A clear pathway for referrals including optical coherence tomography will reduce the rate of false positive referrals to hospital eye services. This would significantly improve the experience of people with diabetes who may be alarmed by a false positive referral or repeatedly go-between eye screening and hospital eye services	

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			because of the differences in imaging tools used.	
Diabetes UK	008	001 - 013	We are concerned that newer monoclonal antibody drugs are not included in this scope, particularly as the monoclonal antibody treatments Faricimab and Brolucizumab for diabetic macular oedema are currently being assessed by NICE in technology appraisals that are due to be published later this year. If these appraisals result in positive recommendations there is a risk that these guidelines will be out of date when they are set to be published in 2024. We would therefore request clarity on why monoclonal antibody treatments aren't included in the scope and whether there are plans to incorporate them into these guidelines.	Thank you for your comment. NICE technology appraisals will be incorporated into this guideline where they are relevant to the included review questions. This will include relevant technology appraisals that may be published during the development of this guideline.

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Diabetes UK	008	006	We welcome mention of rapid reduction in blood glucose levels as a risk of progression. This risk factor is already well noted in pregnancy and it is important to be clear about the risk for the wide range of people with diabetes who may experience a rapid reduction in HBa1c such as those who are diagnosed late with type 2 diabetes, people utilising new technologies to support self-management and those who have had bariatric surgery. Reference: https://pubmed.ncbi.nlm.nih.gov/29217386/	Thank you for your comment and additional information. The evidence in this area will be reviewed in this guideline and recommendations considered.
Diabetes UK	009	001	When considering this wider question we feel there should be a focus on how to optimise the treatment of diabetic macular oedema with anti-vascular endothelial growth factor agents. In particular, how to determine a lack of response and when treatment should be stopped within specific	Thank you for your comment. The review questions in this guideline will consider the clinical and cost effectiveness of treatments. The acceptability of treatments is also being included in these reviews.

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			populations who are not responding to treatment.	There is a further question relating to switching or stopping treatments that evidence will be considered for.
Diabetes UK	009	023 - 024	Diabetes UK strongly support the inclusion of quality of life and acceptability of treatment to patients in main outcomes to be assessed.	Thank you for your comment.
Liverpool University Hospitals NHS Foundation Trust	007	004	(Monitoring of DR) What are the safe limits of patient number, appointment time, training of health professionals, and quality assurance procedures for patients seen in either virtual clinics or in-person clinics which allows competent assessment of retinal pathology? (Addresses threat to services from 'race to the bottom' with independent providers delivering a minimal service).	Thank you for your comment. This guideline includes settings where NHS funded care is provided. Quality assurance of services in not in the remit of this guideline. The guideline will include frequency of review, it will not include the details of delivery at the individual clinic level.
Liverpool University	007	004	(Monitoring of DR) What is the role of clinical decision support software in the monitoring of patients with	Thank you for your comment. Clinical decision support software is not specific to diabetic retinopathy and is not

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Hospitals NHS Foundation Trust			DR and diabetic macular oedema (DMO), now and in the future? What are the criteria for safe implementation? What regulatory and governance arrangements are required?	included in the proposed scope for this guideline.
Liverpool University Hospitals NHS Foundation Trust	007	005	How should be people with no diabetic retinopathy (DR) or non-proliferative diabetic retinopathy (NPDR) in the hospital eye service with co-pathology preventing adequate photography be monitored? How frequently? By whom? With what clinical/imaging tools?	Thank you for your comment. The proposed scope includes the monitoring of those with non-proliferative retinopathy and the frequency of review for this group. Those with no diabetic retinopathy will be in the NHS diabetic eye screening programme which is outwith the remit of NICE.
Liverpool University Hospitals NHS Foundation Trust	007	020	What is the definition of vision threatening DR?	Thank you for your comment. This draft review question considers features that may predict progression of non-proliferative diabetic retinopathy to those which may be vision threatening, such as proliferative retinopathy, macular oedema or macular ischaemia.

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				Review protocols will be developed by the guideline committee which will specify what the review will include.
Liverpool University Hospitals NHS Foundation Trust	007	020	How should diabetic macular ischaemia be defined? Should the term 'diabetic foveal ischaemia' be favoured?	Thank you for you comment. Definitions where needed will be included in the terms used section of the published guideline. These will be agreed with the guideline committee and may include noting where terms may be used interchangeably.
Liverpool University Hospitals NHS Foundation Trust	008	001	Does the phenomenon of 'early worsening of diabetic retinopathy' (EWDR) in the context of rapid substantial improvement in glycaemic control occur? Is there a risk of visual loss? What strategies are available for eye care professionals and diabetologists to prevent harm from EWDR?	Thank you for your comment. This question considers strategies that may impact on the risk of progression. The outcomes in this proposed scope include visual outcomes and progression or regression of retinopathy. Following the review of the evidence and committee discussion the committee will consider the development of recommendations on possible strategies.

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Stakeholder	Page no.	Line no.	Comments	Developer's response
Liverpool University Hospitals NHS Foundation Trust	008	014 & 022	What is the effectiveness, cost-effectiveness and acceptability of different management strategies for treating proliferative diabetic retinopathy (PDR) and DMO in pregnancy?	Thank you for your comment. People who are pregnant are included in this proposed scope for this guideline and are included in this overall question. Additional subgroup analysis for those who are pregnant will be considered.
Liverpool University Hospitals NHS Foundation Trust	008	014 & 022	What constitutes laser treatment for PDR and centre-involving diabetic macular oedema (CI-DMO)(peripheral scatter and macular laser) in the context of rapidly changing technology and an aging evidence base?	Thank you for your comment. The evidence in this area will be reviewed in this guideline. For the review questions review protocols will be developed by the guideline committee which will specify what the review will include. These will be agreed by the guideline committee. During guideline development the committee will consider where there may be gaps in the evidence and will consider research recommendations in these areas.

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Stakeholder	Page no.	Line no.	Comments	Developer's response
Liverpool University Hospitals NHS Foundation Trust	008	014 & 022	What constitutes surgical treatment for PDR and CI-DMO?	Thank you for your comment. For the review questions review protocols will be developed by the guideline committee which will specify what the review will include. These will be agreed by the guideline committee.
Liverpool University Hospitals NHS Foundation Trust	008	014 & 022	What is the role of clinical decision support software in treatment decision for patients with DR and DMO, now and in the future? What are the criteria for safe implementation? What regulatory and governance arrangements are required?	Thank you for your comment. Clinical decision support software is not specific to diabetic retinopathy and is not included in the proposed scope for this guideline.
Macular Society	General	General	The scope is very comprehensive. We commented as part of the stakeholder discussion session and welcome the inclusion of majority of these comments. However, not all have been considered and it is not really clear why.	Thank you for your comment. All discussions from the stakeholder workshop were considered, not all were identified for inclusion in the scope of this guideline.

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Macular Society	002	020	The draft scope currently excludes diabetologists, rehabilitation services, ECLOs and local authority sensory assessors which should be considered on this list. These should be included because we know the importance of the communication between the clinicians and other support staff who are managing diabetes and ophthalmic services and this will help to reinforce this. (see below)	Thank you for your comment. These groups are not excluded and are included in the groups identified. This guideline is intended to be specific to the clinical management and monitoring of diabetic retinopathy only.
Macular Society	002	024	The draft scope currently state that this guidance may be relevant for …. We feel that it is **very relevant** for GPs and GPs should be included in the list above (this guidance is for). This is because some patients especially those with type 2 diabetes may only be seen by GP and if they (the GP) don't know about diabetic retinopathy then they cannot help their patients manage their diabetes in a safe way.	Thank you for your comment. As you note GPs are included in those that the guideline may be relevant for. The guideline is directly for those within the group listed under "This guideline is for" as they are most likely to be those acting directly on the guideline recommendations. GPs will know about diabetic retinopathy.

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Macular Society	008	006	We welcome the specific inclusion of this as it is an area where there is a confusion in the message and patient understanding of the impact of this on diabetes and eyes. There is also a challenge in the awareness/ communication between diabetes and ophthalmology around this area. There is very limited specific evidence around strategies. Our survey and feedback from the DMO community tells us that prevention of further damage is key. Education for those that are looking after those with diabetes in primary and secondary care is very important. The rapid reduction of blood glucose levels and the Hba1c is a risk factor to further damage but this is not so well known in the diabetes care sector. To prevent non-proliferative diabetic retinopathy becoming proliferative it is essential that all in the health care sector	Thank you for your comment. The evidence in this area will be reviewed in this guideline and recommendations considered.

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			who look after those with diabetes know the risks and how to prevent further damage. Patients also need to be informed as well as understanding why they need to keep good blood pressure and cholesterol levels.	
Macular Society	008	009	We are cautious about the specific reference to light therapies including light emitting sleep masks. These are not currently "proven" therapies and as a result are not available for use within the NHS – we welcome the inclusion and consideration of future potential therapies but this does need to be balanced with an evidence base compared to the other treatments listed.	Thank you for your comment. The evidence in this area will be reviewed. Following the review of the evidence the committee will consider what recommendations can be made.
Macular Society	009	004	Is the word 'safest' missing from here? Cataract surgery can exacerbate macular oedema and this needs to be taken into consideration.	Thank you for your comment. The review of effective treatment strategies will include outcomes that will identify any adverse effects of the interventions.

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				Further detail on the outcomes for the review question will be included in the review protocol.
Macular Society	009	023	This should also include the word 'employment' or at least 'existing employment' it's not just a driving licence that people with diabetic retinopathy can lose. The impact/ quality of life of the family can also be huge.	Thank you for your comment. These are outcomes that may be considered, so this list is not considered exhaustive. For the review questions review protocols will be developed by the guideline committee which will specify what the review will include. These will be agreed by the guideline committee and will include more details on the outcomes specific to that review question.
NHS England and NHS Improvement	**General**	General	Question 1 – Are there any cost saving interventions or examples of innovative approaches that should be considered for inclusion in this guideline?	Thank you for your comment. The use of digital and mobile interventions is included in other NICE guidance, such as 'Behaviour change: digital and mobile health interventions' (NG183). Other recommendations relating to diabetes

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			• Supported self-management interventions including digital platforms for tracking health status. • Sight-impaired access to nature, physical activity and creative interventions (social prescribing approaches).	behaviour change can be found in the NICE guidelines on diabetes.
NHS England and NHS Improvement	002	024	I suggest removing "it may also be relevant for"	Thank you for your comment. This has not been removed as the guideline is directly for those within the group listed under "This guideline is for" as they are most likely to be those acting directly on the guideline recommendations.
NHS England and NHS Improvement	002	025	I believe some parts of this guidance is of relevance to GP teams who will be required to: code diabetes accurately so patients are invited to eye screening and may also be required to review these patients acutely.	Thank you for your comment. GPs are included in those that the guideline may be relevant for.

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NHS England and NHS Improvement	002	026	With the establishment of Integrated Care Systems and cessation of commissioning organisations I believe this should be altered to reflect the changes.	Thank you for your comment. Integrated care systems have been added.
NHS England and NHS Improvement	003	005	EIA completed which I have read in detail, has a QIA and HEAT also been undertaken?	Thank you for your comment. As you note the equality impact assessment has been completed for this scope. This is in line with the NICE guideline manual, the EIA has been designed for use in NICE guideline development. This is referred to and updated during guideline development. A QIA and HEAT have not been undertaken.
NHS England and NHS Improvement	004	010	"how to identify referrable diabetic retinopathy": I would expect this to be included	Thank you for your comment. This is in the remit of the NHS diabetic eye screening programme and outwith the remit of this guideline.
NHS England and NHS Improvement	007	001 - 018	Agree with these questions, relevant and practical	Thank you for your comment.

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NHS England and NHS Improvement	007, 008, and 009	001 - 030, 001 - 030, and 001 - 012	The following interventions are not in scope as a key issue or questions for the management of Diabetic Retinopathy: Efficacy of supported self-management (SSM) and impact of interventions to address issues with associated constructs of self-efficacy and health literacy, Impact of social prescribing, and Impact of personalised care and support planning (PCSP). These should be in scope as they are part of both the NHS Long Term Plan (LTP) and NHS England and NHS Improvement's Universal Personalised Care (UPC) strategy. Expected outcomes for SSM, PCSP, and Social Prescribing include both biomedical outcomes and quality of life indicators, both of which are in-scope for this guidance. Their absence from the list	Thank you for your comment. The key issues and draft questions within this proposed scope include the acceptability of different management strategies. The main outcomes proposed include quality of life and acceptability. There is existing NICE guidance to support self-efficacy and health literacy such as those on 'Patient experience in adult NHS services' (CG138) and 'Shared decision making' (NG197) that can be linked to in this guidance.

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Stakeholder	Page no.	Line no.	Comments	Developer's response
			of key issues and draft questions is therefore noticeable.	
NHS England and NHS Improvement	008	General	**Strategies** No reference has been made to lifestyle advice, diet and weight management to work alongside therapeutic interventions. Also, referral to social prescribing and community support for individuals can significantly improve outcomes, in a cost-effective way, improving compliance and concordance.	Thank you for your comment. Advice for those with diabetes including education, dietary advice, and individualised care is in the 'Type 2 diabetes in adults: management' and the 'Type 1 diabetes in adults: diagnosis and management' NICE guidelines. These may be linked to within this guideline.
Royal College of Nursing (RCN)	General	General	We do not have any comments on this consultation. Thank you for the opportunity to contribute.	Thank you for your comment.
Royal College of Ophthalmologists	004	006	Section 3.3 What will not be covered. We suggest adding "slit lamp" to screening in surveillance pathway, modify it to	Thank you for your comment. This has been added.

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			"Screening in surveillance and slit lamp pathway" Consider revising lines 20 to 25 using conventional definition of diabetic macular oedema and proliferative diabetic retinopathy.	It is not clear what this refers to.
Royal College of Ophthalmologists	007	004 - 005	Section 3.5 The term 'non-proliferative diabetic retinopathy' encompasses a range of different grades of retinopathy, so we would assume here that you will be referring to follow-up intervals for different levels of severity within that term 'non proliferative'.	Thank you for your comment. The scope identifies the key issues for the topic area. Review protocols will be developed by the guideline committee which will specify what the review will include. This may include subgroups within the overall question.
Royal College of Ophthalmologists	007	011	Section 3.5 Is it worth including aspects relating to staffing groups that may assist in the monitoring of diabetic retinopathy, not just the 'technology' such as ultrawide field imaging/OCT? E.g. graders/shared care	Thank you for your comment. The consideration of the staffing groups will be the decision for a clinical area. This is not within the remit of this guideline.

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			optometrists etc helping out in imaging clinics?	
Royal College of Ophthalmologists	008	007	Section 3.5 Minor point: For the term 'lipid modification therapies' it is worth noting that in terms of 'fibrate plus statin' it is not thought to be directly the 'lipid lowering' effect that may be causing the effect in terms of reduction in retinopathy progression (such as shown in ACCORD Eye study). So, we wonder whether directly using the term 'fibrates/statins here would be technically more correct as that encompasses both the lipid lowering as well as other mechanism(s)of action.	Thank you for your comment and additional information. As these are lipid modification therapies the overall term will be used as this will enable the identification of other evidence that may be published on these therapies.
Royal College of Ophthalmologists	008	007	Section 3.5 For monitoring under 3.5 consider including monitoring by non-medical staff and also scope for machine learning/AI.	Thank you for your comment. Monitoring by non-medical staff and machine learning/AI are not specific to diabetic retinopathy and are not included in the proposed scope for this guideline.

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Stakeholder	Page no.	Line no.	Comments	Developer's response
Royal College of Ophthalmologists	008	008	Section 3.5 2.3 below: not just the pump, but continuous glucose monitoring. 'Follow-up is vital and so use of virtual clinics/AI (as per below as well)/ and non-medical staff competencies need to be included.' Also consider inclusion of management of hyperglycemia with blood sugar monitoring device(s), insulin pump where applicable, management of renal failure.	Thank you for your comment. Staff competencies and virtual clinics/AI are not specific to diabetic retinopathy and are not included in the proposed scope for this guideline. The management of hyperglycaemia and management of renal failure are included in the NICE guidelines 'Type 2 diabetes in adults: management', 'Type 1 diabetes in adults: diagnosis and management', and 'Chronic kidney disease: assessment and management'. These may be linked to within this guideline.
Royal College of Ophthalmologists	009		Section 3.6 • include % patients retaining threshold visual acuity for driving (6/12 or better Include incidence of registration for vision impairment (full and partial sight)	Thank you for your comment. Registration for vision impairment has been added. The outcomes in the proposed guideline scope include those that are likely to be

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				included when searching for and assessing the evidence (this includes loss of driving licence). For the review questions review protocols will be developed by the guideline committee which will specify what the review will include. These will be agreed by the guideline committee and will include more details on the outcomes specific to that review question**.**
Royal College of Paediatrics and Child Health	General	General	We are happy with this guideline scope on diabetic retinopathy.	Thank you for your comment.
Royal College of Paediatrics and Child Health	General	General	We welcome the notes from stakeholders meeting that Paediatric Diabetes consultant is a co-op GC member and Paediatric Ophthalmologist is a GC member.	Thank you for your comment.
Royal National Institute of the Blind (RNIB)	General	General	This comment relates to the impact assessment which says 'Is the proposed primary focus of the guideline a population with a specific communication or	Thank you for your comment. The Accessible Information Standard is applied to our documentation. For further

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			engagement need, related to disability, age, or other equality consideration? Because people within scope may have visual impairments the Accessible Information Standard should apply. Given that in scope are 'people from black and south Asian communities' their communication needs should also be included here.	information please see https://www.nice.org.uk/accessibility The NICE guideline 'Patient experience in adult NHS services' (CG138) includes recommendations on knowing the patient as an individual, communication and the need to ensure that the patient is able to participate in consultations and care.
Royal National Institute of the Blind (RNIB)	General	General	There is much guidance referred to but I did not find any reference to the problems people with a visual impairment have in managing their diabetes. For example, measuring blood sugar levels and injecting when you have a visual impairment. RNIB has produced guidance on this subject at https://www.rnib.org.uk/eye-health/your-guide-diabetes-related-eye-conditions/managing-diabetes-sight-loss could this be signposted in the guideline.	Thank you for your comment. Managing diabetes is covered in the NICE guidelines 'Type 2 diabetes in adults: management' and 'Type 1 diabetes: diagnosis and management', which include recommendations to take into account any disabilities, including visual impairment, when planning and delivering care. In line with the NICE processes within the NICE guideline manual the guideline will not link to this RNIB report. Published guidelines within the scope of a NICE guideline can be assessed for quality for inclusion in the evidence base.

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Royal National Institute of the Blind (RNIB)	General	General	The section on guidance refers to mental health and NICE guideline CG136 on page 6 line 21 which is good. Given the impact on the mental health of those suffering or diagnosed with visual impairment should the guideline include information about how providing or referring people to mental health services is to be done.	Thank you for your comment. Referral to mental health services is beyond the remit of this guideline. Links to other relevant NICE guidance such as CG136, that include recommendations relating to referral, may be made in this guideline.
Royal National Institute of the Blind (RNIB)	General	General	The non-clinical processes and services in the eye health/sight loss pathway, required for optimum patient outcomes, are not considered in the guideline.	Thank you for your comment. This guideline is intended to be specific to the clinical management and monitoring of diabetic retinopathy only.
Royal National Institute of the Blind (RNIB)	008	006	Rapid reduction in blood glucose levels is mentioned in considering what strategies are effective and cost-effective in preventing or reducing the risk of progression of non-proliferative diabetic retinopathy to vision-threatening proliferative diabetic retinopathy, diabetic macular oedema or diabetic macular ischaemia.	Thank you for your comment. The evidence in this area will be reviewed in this guideline and recommendations considered.

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			RNIB is aware of cases where sight loss has occurred following a rapid reduction in blood glucose levels. If this is a strategy should the risk be recognised in the guideline?	
Royal National Institute of the Blind (RNIB)	009	023	Quality of life (including loss of driving licence and stress) is one of the factors under the heading Outcomes. People losing their sight are more likely to need mental health support. Mental Health/wellbeing should be added as an outcome in the guideline	Thank you for your comment. These are outcomes that may be considered, so this list is not considered exhaustive. Mental health outcomes have been added.
SeeAbility	003	General	People with learning disabilities are not explicitly covered in the scope under the discussion on specific considerations. It is unclear why given those with learning disabilities are at higher risk of diabetes and of having sight problems complicated through being unable to access eye care (sight tests and diabetic eye screening) to	Thank you for your comment and additional information. People with learning disabilities are included in the equality impact assessment that has been completed during this scoping process and will be used during the development of the guideline. This group has also been added within this section of the scope.

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			the same extent as the general population. See for evidence the International Consensus Guidelines for Type 2 diabetes in people with intellectual disabilities https://www.ulster.ac.uk/__data/assets/pdf_file/0007/874420/International-Consensus-Guidelines.pdf and Public Health England guidelines on reasonable adjustments in eye care https://www.gov.uk/government/publications/eye-care-and-people-with-learning-disabilities/eye-care-and-people-with-learning-disabilities-making-reasonable-adjustments and our article for Diabetes UK https://www.diabetes.org.uk/resources-s3/2019-10/Q%26A.pdf and most recently Office for Health Improvement and Disparities Atlas of Eye Health and Vision Variation https://fingertips.phe.org.uk/profile/atlas-of-variation	

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			Although the guideline considers treatment, rather than screening for retinopathy in its scope, the ability to tolerate the treatments outlined in the scope also merit consideration for this population. It could also signpost to existing Royal College of Ophthalmology guidelines for patients with learning disabilities. https://www.rcophth.ac.uk/resources-listing/eye-care-for-adults-with-learning-disabilities-2015/ Please consider adding people with learning disabilities into the scope.	
SeeAbility	004	General	It is unclear why diabetic screening programme is not in scope of the guideline as the guideline covers monitoring as well as management of diabetic retinopathy. Could this be clarified as to why.	Thank you for your comment. National screening programmes such as the diabetic eye screening programme are not within the remit of NICE guidance.

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[ix] NICE TA349, available at: https://www.nice.org.uk/guidance/ta349, accessed 3/3/21

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