

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Diabetic retinopathy: management and monitoring

We conducted a surveillance review of current evidence related to diabetes and identified a need for a new guideline on managing and monitoring diabetic retinopathy.

The guideline will be developed using the methods and processes outlined in [developing NICE guidelines: the manual](#).

1 Why the guideline is needed

Key facts and figures

Diabetic retinopathy is one of the leading causes of visual impairment and blindness in the UK. Within 20 years of diagnosis, most people with type 1 or type 2 diabetes will have some degree of retinopathy. It is a direct consequence of raised glucose levels. High blood pressure and high serum lipids are also important risk factors for diabetic retinopathy (and both are common in people with diabetes).

The diabetic retinopathy complications that can cause visual impairment and blindness are diabetic macular ischaemia, diabetic macular oedema and proliferative diabetic retinopathy. Approximately 7% of people with diabetes will get these complications.

Diabetic macular oedema causes fluid to gather in the macula, which can cause central vision loss.

Proliferative diabetic retinopathy is abnormal blood vessels that grow in the optic nerve and/or retina. This can lead to vitreous haemorrhage. It can also

cause scarring that can lead to tractional retinal detachment and central and peripheral vision loss.

More than 2 million people in the UK have sight loss that is severe enough to significantly impact on their daily lives. Diabetic retinopathy is the cause for approximately 95,000 of these people. It causes 1,280 new cases of blindness, and puts 4,200 people at risk of visual impairment, each year in England alone.

Current practice

Diabetic retinopathy is currently treated when sight-threatening complications (diabetic macular oedema and proliferative diabetic retinopathy) have developed. Treatments include laser treatment, eye injections and eye surgery.

The NHS invites people with diabetes aged 12 years or over for screening as part of the [NHS diabetic eye screening programme \(DESP\)](#). Closer monitoring in a DESP surveillance clinic can be offered every 3, 6, 9 or 12 months, depending on the specific changes to the person's eyes and how quickly these changes are happening. People are referred to a hospital eye services clinic for further tests and possible treatment if the eye screening shows signs of sight-threatening diabetic retinopathy.

Policy, legislation, regulation and commissioning

The [NHS Long Term Plan](#) emphasises the importance of reducing variation in the quality of care for people with type 1 and type 2 diabetes. This guideline will support this goal.

2 Who the guideline is for

This guideline is for:

- healthcare professionals in secondary care
- practitioners in ophthalmology and optometry services
- people using these services, their families and carers.

It may also be relevant for:

- healthcare professionals in primary care (such as general practitioners)
- integrated care systems, commissioners and providers of ophthalmology and optometry services
- the NHS diabetic eye screening programme.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the [Welsh Government](#), [Scottish Government](#), and [Northern Ireland Executive](#).

Equality considerations

NICE has carried out [an equality impact assessment](#) during scoping. The assessment:

- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.

3 What the guideline will cover

3.1 Who is the focus?

Groups that will be covered

- People who have been referred to hospital eye services with diagnosed diabetic retinopathy.

Specific consideration will be given to:

- people from Black and South Asian minority ethnic groups
- people with a learning disability
- pregnant women with diagnosed type 1 or type 2 diabetes.

3.2 Settings

Settings that will be covered

All settings where NHS-funded care is provided.

3.3 *Activities, services or aspects of care*

Key areas that will be covered

We will look at evidence in the areas below when developing the guideline, but it may not be possible to make recommendations in all the areas.

- 1 Management
- 2 Monitoring

Note that guideline recommendations for medicines will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

Areas that will not be covered

- 1 Areas that are covered by the NHS diabetic eye screening programme:
 - routine annual screening
 - screening in surveillance clinics and slit lamp examinations
 - how to identify referable diabetic retinopathy.
- 2 Management of diabetes - this is covered in the following NICE guidelines:
 - [diabetes \(type 1 and type 2\) in children and young people: diagnosis and management](#)
 - [type 1 diabetes in adults: diagnosis and management](#)
 - [type 2 diabetes in adults: management](#).

3.4 *Economic aspects*

We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS perspective, as appropriate.

3.5 Key issues and draft questions

While writing this scope, we have identified the following key issues and draft questions related to them:

1 Management of diabetic retinopathy

1.1 In people who have been referred to hospital eye services, what clinical features predict progression of non-proliferative diabetic retinopathy to vision-threatening:

- proliferative diabetic retinopathy
- diabetic macular oedema
- diabetic macular ischaemia?

1.2 In people who have been referred to hospital eye services, what is the threshold or are the criterium to start treating:

- non-proliferative diabetic retinopathy
- proliferative diabetic retinopathy
- diabetic macular oedema?

1.3 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, considering the following strategies:

- rapid reduction in blood glucose levels
- lipid modification therapies
- antihypertensive medicines
- light therapies (including light-emitting sleep masks)
- anti-vascular endothelial growth factor agents
- intravitreal steroids
- laser photocoagulation (pan-retinal photocoagulation, and macular lasers including micropulse lasers).

1.4 What is the effectiveness, cost-effectiveness and acceptability of different management strategies for treating proliferative diabetic

retinopathy, considering the following strategies (alone or in combination):

- laser photocoagulation (pan-retinal photocoagulation, targeted retinal photocoagulation)
- anti-vascular endothelial growth factor agents
- vitrectomy (surgery).

1.5 What is the effectiveness, cost-effectiveness and acceptability of different management strategies for treating diabetic macular oedema, considering the following strategies (alone or in combination):

- intravitreal steroids (such as fluocinolone acetonide or dexamethasone)
- laser photocoagulation (micro-pulse subthreshold macular laser or standard threshold macular laser)
- anti-vascular endothelial growth factor agents
- vitrectomy (surgery).

1.6 What are the clinical features or factors that suggest treatment should be switched or stopped for people diagnosed with proliferative diabetic retinopathy or diabetic macular oedema?

1.7 In people being considered for cataract surgery, what are the most effective and cost-effective treatment strategies (before, during and after cataract surgery) for managing:

- non-proliferative diabetic retinopathy
- proliferative diabetic retinopathy
- diabetic macular oedema?

2 Monitoring of diabetic retinopathy

2.1 How often should people diagnosed with non-proliferative diabetic retinopathy, whose care is managed under the hospital eye services but who are not having treatment, be reviewed?

2.2 How often should people diagnosed with proliferative diabetic retinopathy or diabetic macular oedema be reviewed, if they are having treatment or have had previous treatment?

2.3 What tools (for example optical coherence tomography scans and ultra-wide field imaging) are effective and cost-effective for monitoring:

- people diagnosed with non-proliferative diabetic retinopathy, whose care is managed under the hospital eye services, but who are not having treatment?
- people diagnosed with proliferative diabetic retinopathy or diabetic macular oedema, who are having treatment or have had previous treatment?

The key issues and draft questions will be used to develop more detailed review questions, which will guide the systematic review of the literature.

3.6 *Main outcomes*

The main outcomes that may be considered when searching for and assessing the evidence are:

- 1 Best-corrected visual acuity
- 2 Central and peripheral vision
- 3 Macular thickness changes
- 4 Progression of diabetic retinopathy, progression to diabetic macular oedema and progression of proliferative diabetic retinopathy
- 5 Regression of diabetic retinopathy
- 6 Adverse effects
- 7 Quality of life (including loss of driving licence, registering vision impairment, and stress)
- 8 Acceptability of treatment to patients
- 9 Mental health

3.7 **Related NICE guidance**

Published

- [Type 2 diabetes in adults: management](#) (2015, updated 2022) NICE guideline NG28
- [Type 1 diabetes in adults: diagnosis and management](#) (2015, updated 2021) NICE guideline NG17
- [AI technologies for detecting diabetic retinopathy](#) (2021) Medtech innovation briefing MIB265
- [Diabetes \(type 1 and type 2\) in children and young people: diagnosis and management](#) (2015, updated 2020) NICE guideline NG18
- [Diabetes in pregnancy: management from preconception to the postnatal period NG3](#) (2015, updated 2020) NICE guideline NG3
- [Eating disorders: recognition and treatment](#) (2017, updated 2020) NICE guideline NG69
- [Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema in phakic eyes after an inadequate response to previous therapy](#) (2019) NICE technology appraisal guidance TA613
- [Diabetic foot problems: prevention and management](#) (2015, updated 2019) NICE guideline NG19
- [Noctura 400 Sleep Mask for diabetic retinopathy and diabetic macular oedema](#) (2018) Medtech innovation briefing MIB144
- [Type 2 diabetes: prevention in people at high risk](#) (2012, updated 2017) NICE guideline PH38
- [Glaucoma: diagnosis and management](#) (2017, updated 2022) NICE guideline NG81
- [Cataracts in adults: management](#) (2017) NICE guideline NG77
- [Parkinson's disease with motor fluctuations: safinamide](#) (2017) Evidence summary ES6
- [Integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes \(the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system\)](#) (2016) NICE Diagnostics guidance DG21

- [Dexamethasone intravitreal implant for treating diabetic macular oedema](#) (2015) NICE technology appraisal guidance TA349
- [Aflibercept for treating diabetic macular oedema](#) (2015) NICE technology appraisal guidance TA346
- [Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema after an inadequate response to prior therapy](#) (2013) NICE technology appraisal guidance TA301
- [Ranibizumab for treating diabetic macular oedema](#) (2013) NICE technology appraisal guidance TA274
- [Type 2 diabetes prevention: population and community-level interventions](#) (2011) NICE guideline PH35

In development

- [Dexamethasone intravitreal implant for treating diabetic macular oedema in people without a pseudophakic lens](#). NICE technology appraisal guidance. Publication expected September 2022.
- [Faricimab for treating diabetic macular oedema](#). NICE technology appraisal guidance. Publication expected June 2022.
- [Brolocizumab for treating diabetic macular oedema](#). NICE technology appraisal guidance. Publication expected November 2022.

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to diabetic retinopathy:

- [Babies, children and young people's experience of healthcare](#) (2021) NICE guideline NG204
- [Shared decision making](#) (2021) NICE guideline NG197
- [Medicines optimisation](#) (2015) NICE guideline NG5
- [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- [Service user experience in adult mental health](#) (2011) NICE guideline CG136

- [Medicines adherence](#) (2009) NICE guideline CG76

4 Further information

This is the final scope, which takes into account comments from registered stakeholders.

The guideline is expected to be published in April 2024.

You can follow progress of the [guideline](#).

Our website has information about how [NICE guidelines](#) are developed.

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