

1 **NATIONAL INSTITUTE FOR HEALTH AND CARE**
2 **EXCELLENCE**

3 **Guideline scope**

4 **Diabetic retinopathy**

5 The Department of Health in England has asked NICE develop a new
6 guideline on diabetic retinopathy.

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

9 **1 Why the guideline is needed**

10 **Key facts and figures**

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

17 The diabetic retinopathy complications that can cause visual impairment and
18 blindness are diabetic macular ischaemia, diabetic macular oedema and
19 proliferative diabetic retinopathy. Approximately 7% of people with diabetes
20 will get these complications. Diabetic macular oedema causes fluid to gather
21 in the macula, which can cause central vision loss. Proliferative diabetic
22 retinopathy is abnormal blood vessels that grow in the optic nerve and/or
23 retina. This can lead to vitreous haemorrhage and can also cause scarring
24 that can lead to tractional retinal detachment and central and peripheral vision
25 loss.

26 There are an estimated 1.93 million people with visual impairment in the UK.
27 Diabetic retinopathy is the cause for 4% of this group. According to the NHS,

1 diabetic retinopathy causes 1,280 new cases of blindness and puts 4,200
2 people at risk of visual impairment each year in England alone.

3 **Current practice**

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

8 The NHS invites people with diabetes aged 12 years or over for screening at
9 least once a year, as part of the [NHS diabetic eye screening programme](#).

10 Closer monitoring in a surveillance clinic can be offered every 3, 6, 9 or 12
11 months, depending on the specific changes to the person's eyes and how
12 quickly this is happening. People are referred to a hospital eye services clinic
13 for further tests and possible treatment if the eye screening shows signs of
14 sight-threatening diabetic retinopathy.

15 **Policy, legislation, regulation and commissioning**

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

19 **2 Who the guideline is for**

20 This guideline is for:

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

24 It may also be relevant for:

- 25 • healthcare professionals in primary care (such as general practitioners)
- 26 • commissioners and providers of ophthalmology and optometry services
- 27 • the NHS diabetic eye screening programme.

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

4 ***Equality considerations***

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

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

9 **3 What the guideline will cover**

10 **3.1 Who is the focus?**

11 **Groups that will be covered**

- 12 • People with diagnosed diabetic retinopathy.

13 Specific consideration will be given to:

- 14 • people from Black and South Asian minority ethnic groups
- 15 • pregnant women with diagnosed type 1 or type 2 diabetes.

16 **3.2 Settings**

17 **Settings that will be covered**

18 All settings where NHS-funded care is provided.

19 **3.3 Activities, services or aspects of care**

20 **Key areas that will be covered**

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

23 1 Monitoring

24 2 Management

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

6 **Areas that will not be covered**

7 1 Areas that are covered by the NHS diabetic eye screening programme:

- 8 • routine annual screening
- 9 • screening in surveillance clinics
- 10 • how to identify referable diabetic retinopathy.

11 2 Management of diabetes - this is covered in the following NICE
12 guidelines:

- 13 • [diabetes \(type 1 and type 2\) in children and young people:
14 diagnosis and management](#)
- 15 • [type 1 diabetes in adults: diagnosis and management](#)
- 16 • [type 2 diabetes in adults: management.](#)

17 **Related NICE guidance**

18 ***Published***

- 19 • [Type 2 diabetes in adults: management](#) (2021) NICE guideline NG28
- 20 • [Type 1 diabetes in adults: diagnosis and management](#) (2021) NICE
21 guideline NG17
- 22 • [AI technologies for detecting diabetic retinopathy](#) (2021) Medtech
23 Innovation briefing MIB265
- 24 • [Diabetes \(type 1 and type 2\) in children and young people: diagnosis and
25 management](#) (2020) NICE guideline NG18
- 26 • [Diabetes in pregnancy: management from preconception to the postnatal
27 period NG3](#) (2020) NICE guideline NG3
- 28 • [Eating disorders: recognition and treatment](#) (2020) NICE guideline NG69
- 29 • [Fluocinolone acetonide intravitreal implant for treating chronic diabetic
30 macular oedema in phakic eyes after an inadequate response to previous
31 therapy](#) (2019) NICE technology appraisal guidance TA613

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- 1 • [Diabetic foot problems: prevention and management](#) (2019) NICE guideline
- 2 NG19
- 3 • [Noctura 400 Sleep Mask for diabetic retinopathy and diabetic macular](#)
- 4 [oedema](#) (2018) Medtech innovation briefing MIB144
- 5 • [Type 2 diabetes: prevention in people at high risk](#) (2017) NICE guideline
- 6 PH38
- 7 • [Glaucoma: diagnosis and management](#) (2017) NICE guideline NG81
- 8 • [Cataracts in adults: management](#) (2017) NICE guideline NG77
- 9 • [Parkinson's disease with motor fluctuations: safinamide](#) (2017) Evidence
- 10 summary ES6
- 11 • [Integrated sensor-augmented pump therapy systems for managing blood](#)
- 12 [glucose levels in type 1 diabetes \(the MiniMed Paradigm Veo system and](#)
- 13 [the Vibe and G4 PLATINUM CGM system\)](#) (2016) NICE Diagnostics
- 14 guidance DG21
- 15 • [Dexamethasone intravitreal implant for treating diabetic macular oedema](#)
- 16 (2015) NICE technology appraisal guidance TA349
- 17 • [Aflibercept for treating diabetic macular oedema](#) (2015) NICE technology
- 18 appraisal guidance TA346
- 19 • [Fluocinolone acetonide intravitreal implant for treating chronic diabetic](#)
- 20 [macular oedema after an inadequate response to prior therapy](#) (2013)
- 21 NICE technology appraisal guidance TA301
- 22 • [Ranibizumab for treating diabetic macular oedema](#) (2013) NICE technology
- 23 appraisal guidance TA274
- 24 • [Type 2 diabetes prevention: population and community-level interventions](#)
- 25 (2011) NICE guideline PH35

26 ***In development***

- 27 • [Dexamethasone intravitreal implant for treating diabetic macular oedema in](#)
- 28 [people without a pseudophakic lens](#). NICE technology appraisal guidance.
- 29 Publication expected September 2022.
- 30 • [Faricimab for treating diabetic macular oedema](#). NICE technology appraisal
- 31 guidance. Publication expected June 2022.

- 1 • [Type 2 diabetes in adults: management \(medicines update\)](#). NICE
2 guideline. Publication expected February 2022.
- 3 • [Type 2 diabetes in adults: management \(glucose monitoring update\)](#). NICE
4 guideline. Publication expected March 2022.
- 5 • [Type 1 diabetes in adults: diagnosis and management \(glucose monitoring
6 and diagnosis update\)](#). NICE guideline. Publication expected March 2022.
- 7 • [Diabetes \(type 1 and type 2\) in children and young people: diagnosis and
8 management \(glucose monitoring update\)](#). NICE guideline. Publication
9 expected March 2022.
- 10 • [Brolocizumab for treating diabetic macular oedema](#). NICE technology
11 appraisal guidance. Publication date to be confirmed.

12 **NICE guidance about the experience of people using NHS services**

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

- 16 • [Babies, children and young people's experience of healthcare](#) (2021) NICE
17 guideline NG204
- 18 • [Shared decision making](#) (2021) NICE guideline NG197
- 19 • [Medicines optimisation](#) (2015) NICE guideline NG5
- 20 • [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- 21 • [Service user experience in adult mental health](#) (2011) NICE guideline
22 CG136
- 23 • [Medicines adherence](#) (2009) NICE guideline CG76

24 **3.4 Economic aspects**

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

1 **3.5 Key issues and draft questions**

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

4 1 Monitoring of diabetic retinopathy

5 1.1 How often should people diagnosed with non-proliferative diabetic
6 retinopathy, whose care is managed under the hospital eye services but
7 who are not having treatment, be reviewed?

8 1.2 How often should people diagnosed with proliferative diabetic
9 retinopathy or diabetic macular oedema be reviewed, if they are having
10 treatment or have had previous treatment?

11 1.3 What tools (for example optical coherence tomography scans and
12 ultra-wide field imaging) are useful for monitoring:

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

19 2 Management of diabetic retinopathy

20 2.1 In people who have been referred to hospital eye services, what
21 clinical features predict progression of non-proliferative diabetic
22 retinopathy to vision-threatening:

- 23 • proliferative diabetic retinopathy
- 24 • diabetic macular oedema
- 25 • diabetic macular ischaemia?

26 2.2 In people who have been referred to hospital eye services, what is
27 the threshold or criteria to start treatment of:

- 28 • non-proliferative diabetic retinopathy
- 29 • proliferative diabetic retinopathy
- 30 • diabetic macular oedema?

1 2.3 What strategies are effective and cost-effective in preventing or
2 reducing the risk of progression of non-proliferative diabetic retinopathy
3 to vision-threatening proliferative diabetic retinopathy, diabetic macular
4 oedema or diabetic macular ischaemia, considering the following
5 strategies:

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

14 2.4 What is the effectiveness, cost-effectiveness and acceptability of
15 different management strategies for treating proliferative diabetic
16 retinopathy, considering the following strategies (alone or in
17 combination):

- 18 • laser photocoagulation (pan-retinal photocoagulation, targeted
19 retinal photocoagulation)
- 20 • anti-vascular endothelial growth factor agents
- 21 • vitrectomy (surgery).

22 2.5 What is the effectiveness, cost-effectiveness and acceptability of
23 different management strategies for treating diabetic macular oedema,
24 considering the following strategies (alone or in combination):

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

- 1 2.6 What are the clinical features or factors that suggest treatment
2 should be switched or stopped for people diagnosed with proliferative
3 diabetic retinopathy or diabetic macular oedema?
4 2.7 In people being considered for cataract surgery, what are the most
5 effective and cost-effective treatment strategies (before, during and after
6 cataract surgery) for managing:
- 7 • non-proliferative diabetic retinopathy
 - 8 • proliferative diabetic retinopathy
 - 9 • diabetic macular oedema?

10

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

13 **3.6 Main outcomes**

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

- 16 1 Best-corrected visual acuity
- 17 2 Central and peripheral vision
- 18 3 Macular thickness changes
- 19 4 Progression of diabetic retinopathy, progression to diabetic macular
20 oedema and progression of proliferative diabetic retinopathy
- 21 5 Regression of diabetic retinopathy
- 22 6 Adverse effects
- 23 7 Quality of life (including loss of driving licence and stress)
- 24 8 Acceptability of treatment to patients

25 **4 Further information**

This is the draft scope for consultation with registered stakeholders. The consultation dates are 18 January to 15 February 2022.

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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