1 2	NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
3	Guideline
4	Type 2 diabetes in adults: management
5	Draft for consultation, November 2021
6	

This is an update to NICE guideline NG28 (published December 2015). We have:

- reviewed the evidence and added new recommendations on continuous glucose monitoring for adults with type 2 diabetes
- updated other recommendations to reflect these changes.

#### Who is it for?

- Healthcare professionals who care for adults with diabetes
- Commissioners and providers of diabetes services
- Adults with type 2 diabetes, and their families and carers

#### What does it include?

- the new recommendations
- related recommendations that have not been updated but are included here for context (shaded in grey and marked [2015] or [2015, amended 2022])
- recommendations for research
- rationale and impact sections that explain why the committee made the 2022 recommendations and how they might affect practice
- the guideline context.

Information about how the guideline was developed is on the <u>guideline's</u> <u>webpage</u>. This includes the evidence reviews, the scope, details of the committee and any declarations of interest.

#### Commenting on this update

We have reviewed the evidence on continuous glucose monitoring for adults with type 2 diabetes. You are invited to comment on the new recommendations. These are marked as **[2022]**.

We have not reviewed the evidence for the recommendations marked **[2015]** or **[2015, amended 2022]** (shaded in grey) and cannot accept comments on them. In some cases, we have made minor wording changes for clarification (shaded in yellow).

Sections of the guideline that have had no changes at all have been temporarily removed for this consultation and will be re-instated when the final guideline is published. See the <u>existing short version of the guideline</u>.

See <u>update information</u> for a full explanation of what is being updated.

Full details of the evidence and the committee's discussion on the 2022 recommendations are in the <u>evidence reviews</u>. Evidence for the 2015 recommendations is in the <u>full version</u> of the 2015 guideline.

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## 1 Contents

2	Contents	3
3	Recommendations	4
4	1.6 Blood glucose management	4
5	Recommendations for research	7
6	Key recommendations for research	7
7	Other recommendations for research	8
8	Rationale and impact	8
9	Continuous glucose monitoring	8
10	Context	11
11	Reasons for the 2015 update	12
12	Reasons for the 2021 update	13
13	Finding more information and committee details	13
14	Update information	13
15	•	

## 1 **Recommendations**

People have the right to be involved in discussions and make informed decisions about their care, as described in <u>NICE's information on making</u> <u>decisions about your care</u>.

<u>Making decisions using NICE guidelines</u> explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

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#### 3 **1.6 Blood glucose management**

4	Self-moni	toring of capillary blood glucose
5	These rec	ommendations relate to self-monitoring by intermittent capillary
6	blood gluc	ose monitoring.
7	1.6.12	Take the Driver and Vehicle Licensing Agency (DVLA)'s Assessing
8		fitness to drive: a guide for medical professionals into account
9		when offering self-monitoring of <mark>capillary</mark> blood glucose levels for
10		adults with type 2 diabetes. [2015, amended 2022]
11	1.6.13	Do not routinely offer self-monitoring of capillary blood glucose
12		levels for adults with type 2 diabetes unless:
13		<ul> <li>the person is on insulin or</li> </ul>
14		<ul> <li>there is evidence of hypoglycaemic episodes or</li> </ul>
15		• the person is on oral medication that may increase their risk of
16		hypoglycaemia while driving or operating machinery <b>or</b>
17		• the person is pregnant or is planning to become pregnant (see
18		the NICE guideline on diabetes in pregnancy). [2015, amended
19		2022]

1 2 3	1.6.14	Consider short-term self-monitoring of capillary blood glucose levels in adults with type 2 diabetes, reviewing treatment as necessary:
4 5 6		<ul> <li>when starting treatment with oral or intravenous corticosteroids or</li> <li>to confirm suspected hypoglycaemia. [2015, amended 2022]</li> </ul>
7 8 9	1.6.15	Be aware that adults with type 2 diabetes who have acute intercurrent illness are at risk of worsening hyperglycaemia. Review treatment as necessary. <b>[2015]</b>
10 11 12	1.6.16	If adults with type 2 diabetes are self-monitoring their capillary blood glucose levels, carry out a structured assessment at least annually. The assessment should include:
13 14 15 16 17 18 19		<ul> <li>the person's self-monitoring skills</li> <li>the quality and frequency of testing</li> <li>checking that the person knows how to interpret the blood glucose results and what action to take</li> <li>the impact on the person's quality of life</li> <li>the continued benefit to the person</li> <li>the equipment used. [2015, amended 2022]</li> </ul>
20	Continuo	ous glucose monitoring
21 22 23 24	1.6.17	Offer intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash') to adults with type 2 diabetes on multiple daily insulin injections if any of the following apply:
25 26 27 28		<ul> <li>they have recurrent or severe hypoglycaemia</li> <li>they have impaired hypoglycaemia awareness</li> <li>they have a condition or disability that means they cannot self- monitor their blood glucose by intermittent capillary blood</li> </ul>

1		glucose monitoring but could use an isCGM device (or have it
2		scanned for them)
3		<ul> <li>they would otherwise be advised to self-test at least 8 times a</li> </ul>
4		day. <b>[2022]</b>
5	1.6.18	Offer isCGM to adults with insulin-treated type 2 diabetes who
6		would otherwise need help from a care worker or healthcare
7		professional to monitor their blood glucose. [2022]
8	1.6.19	Consider real-time CGM as an alternative to isCGM if it is available
9		for the same or lower acquisition cost. [2022]
10	1.6.20	Continuous glucose monitoring should be provided by a team with
11		expertise in its use, as part of supporting people to self-manage
12		their diabetes. <b>[2022]</b>
13	1.6.21	If a person is unable or does not wish to use any real-time CGM or
14		isCGM device, offer capillary blood glucose monitoring. [2022]
15	1.6.22	Ensure continuous glucose monitoring is part of the education
16		provided to adults with type 2 diabetes who are using it (see the
17		section on patient education in the existing guideline) and that
18		people using CGM devices are empowered to do so. [2022]
19	1.6.23	Monitor and review the person's use of continuous glucose
20		monitoring as part of reviewing their diabetes care plan (see the
21		section on individualised care in the existing guideline). [2022]

For a short explanation of why the committee made these recommendations see the <u>rationale and impact section on continuous glucose monitoring</u>.

Full details of the evidence and the committee's discussion are in <u>evidence</u> review A: continuous glucose monitoring in adults with type 2 diabetes.

## 1 **Recommendations for research**

- 2 The Guideline Development Group has made the following recommendations
- 3 for research.

## 4 Key recommendations for research

## 5 1 The effects of stopping or switching drug treatments to control

## 6 blood glucose levels

- 7 In adults with type 2 diabetes, what are the effects of stopping and/or
- 8 switching drug treatments to control blood glucose levels, and what criteria
- 9 should inform the decision? [2015]

## 10 **2** Non-metformin-based drug treatment combinations to control

## 11 blood glucose levels

- 12 In adults with type 2 diabetes, what treatment combinations (for example,
- 13 glucagon-like peptide-1 [GLP-1] mimetics and insulin combination therapy
- 14 with meglitinides) are most effective when initial drug treatment with
- 15 non-metformin monotherapy fails to adequately control blood glucose levels?
- 16 **[2015]**
- 17 **3 Drug treatment for when blood glucose levels are inadequately**

## 18 controlled by 3 oral antidiabetic drugs or insulin combinations

- 19 When blood glucose levels are inadequately controlled by 3 oral antidiabetic
- 20 drugs and/or insulin combinations, which blood glucose lowering therapies
- should be used to control blood glucose levels? [2015, amended 2021]

## 22 4 Self-monitoring of blood glucose levels

- 23 What is the optimal frequency for self-monitoring of blood glucose in adults
- 24 with type 2 diabetes? [2015]
- 25 **5 Glucagon-like peptide-1 receptor agonists (GLP-1) and insulin**
- 26 therapy
- 27 What is the effectiveness and cost effectiveness of GLP-1 mimetics compared
- with insulin therapy in adults with type 2 diabetes? **[2021]**

## 1 Other recommendations for research

#### 2 Long-term outcomes associated with blood glucose lowering

#### 3 agents

- 4 In adults with type 2 diabetes, what are the long-term effects of blood glucose
- 5 Iowering therapies such as dipeptidyl peptidase-4 (DPP-4) inhibitors, sodium-
- 6 glucose cotransporter-2 (SGLT2) inhibitors and meglitinides? [2015]
- 7 Using routinely collected real-world data to assess the
- 8 effectiveness of continuous glucose monitoring
- 9 What is the effectiveness and cost effectiveness of CGM devices to improve
- 10 glycaemic control in adults with type 2 diabetes using routinely collected real-
- 11 world data? [2022]

For a short explanation of why the committee made this recommendation and how it might affect practice, see the <u>rationale section on continuous</u> <u>glucose monitoring</u>.

Full details of the evidence and the committee's discussion are in <u>evidence</u> <u>review A: continuous glucose monitoring in adults with type 2 diabetes</u>.

## 12 Rationale and impact

- 13 These sections briefly explain why the committee made the updated
- 14 recommendations and how they might affect practice.

## 15 **Continuous glucose monitoring**

16 Recommendations 1.6.17 to 1.6.23

#### 17 Why the committee made the recommendations

- 18 The committee discussed how continuous glucose monitoring (CGM) could
- 19 potentially be useful for many people with type 2 diabetes. They were aware
- 20 of examples from current practice where adults who have insulin-treated type
- 21 2 diabetes and use intermittently scanned CGM (isCGM, or 'flash') have had
- 22 good outcomes. Because of the additional cost associated with CGM and the

large number of adults with type 2 diabetes, the committee used both the
 evidence and their clinical experience to decide who would gain the most

3 benefit from using CGM.

4 There was no evidence that real-time CGM was cost effective for people with 5 type 2 diabetes, so the committee agreed it could not be recommended for all 6 adults with type 2 diabetes. For flash, there was evidence that it was cost 7 effective for adults with type 2 diabetes using insulin, but no evidence for 8 populations not using insulin, so the committee agreed to restrict their 9 recommendations to that subpopulation. They noted, however, that prices of 10 real-time CGM have reduced over the past few years, and if this continues to 11 happen there may come a time when the price is no higher than flash, so it 12 would be appropriate to consider as an alternative.

13 People who have recurrent or severe hypoglycaemic events were identified as 14 one of the groups likely to benefit most from flash, because hypoglycaemic 15 events were considered to be one of the most important and concerning 16 outcomes for adults with type 2 diabetes who are using insulin. The committee 17 decided that the number of hypoglycaemic events was a more effective 18 indicator of someone who would benefit from flash than specific HbA1c target 19 values, because target values can vary between people. The evidence also indicated minimal effects of flash on HbA1c values. 20

21 The committee agreed that people with impaired hypoglycaemic awareness 22 would also benefit from flash, as would people who have a physical or 23 cognitive impairment that restricts their ability to self-monitor blood glucose 24 levels. Providing access to flash for this group means they will no longer have 25 to rely on others to monitor their diabetes, potentially increasing their 26 independence. People who are advised to self-test using capillary blood 27 glucose monitoring more than 8 times a day should also be offered flash, 28 which is similar to the funding requirements for NHS England's flash glucose 29 monitoring: national arrangements for funding of relevant diabetes patients, 30 Although the funding requirements are specifically for people with type 1

31 diabetes, the committee thought that this criterion was also important for

1 people with type 2 diabetes who have to monitor their blood glucose levels

2 multiple times a day.

The committee decided that people who need help from a care worker or 3 4 other healthcare professional to administer their insulin injections should also be offered flash, even if they only use once-daily insulin injections. flash will 5 6 help care workers to record a person's blood glucose levels guickly. And for 7 people who have multiple home care visits per day, blood glucose levels can 8 be recorded at each visit. This should ensure that there are sufficient 9 recordings against which a person's insulin schedule can be adjusted to 10 reduce the risk of hypoglycaemic events between home visits.

11 The committee decided to highlight that CGM should be provided by a team 12 who have expertise in its use. To ensure that CGM is effective, healthcare professionals need to have the skills to interpret and communicate the data 13 14 effectively. As well as healthcare professionals having a clear understanding 15 of CGM, it is also crucial that people with type 2 diabetes who are using CGM 16 have education about the technology. This will increase the likelihood that 17 people will scan and report the results frequently, allowing people to 18 understand and manage their diabetes effectively.

19 Although CGM can have many benefits for the management of type 2

20 diabetes, it is not always a permanent solution. The committee wanted to

highlight the importance of routinely reviewing a person's use of CGM. This

22 will establish whether it is providing clinical benefits and whether the monitor

23 is being used correctly. Making people aware that their use of CGM will be

continually reviewed is important so they know it is not a guaranteed long-term option.

Although many people will choose the option of CGM, there are some people who either cannot be offered it or do not wish to use the device. Because it is still important for these people to monitor their blood glucose levels, the committee added a recommendation to reinforce the importance of offering capillary blood glucose monitoring instead. 1 The committee also made a <u>recommendation for research on using routinely</u>

2 <u>collected real-world data to examine the effectiveness and cost effectiveness</u>

- 3 of CGM. They agreed that this has the potential to show the direct effects of
- 4 the technology used by people with type 2 diabetes instead of interpreting it
- 5 through the results of clinical trials. Increased monitoring of routine healthcare
- 6 data including registries and audits would ensure that findings from a broader
- 7 population are captured.

#### 8 How the recommendations might affect practice

9 The recommendations are likely to increase the number of adults with type 2

- 10 diabetes who are offered CGM, particularly those who have issues with
- 11 hypoglycaemia, and this will have associated cost implications. An increase in
- 12 the number of people using CGM may have some time-saving benefits for the
- 13 NHS, because healthcare professionals do not have to meet people who are
- 14 using CGM as often as they do with people who are self-monitoring. There
- 15 should also be fewer hypoglycaemic events that need to be managed.
- 16 The committee did not expect a significant resource impact related to
- 17 education and monitoring for the CGM devices.

#### 18 Return to recommendations

#### 19 **Context**

- 20 Type 2 diabetes is a chronic metabolic condition characterised by insulin
- 21 resistance (that is, the body's inability to effectively use insulin) and
- 22 insufficient pancreatic insulin production, resulting in high blood glucose levels
- 23 (hyperglycaemia). Type 2 diabetes is commonly associated with obesity,
- 24 physical inactivity, raised blood pressure, disturbed blood lipid levels and a
- 25 tendency to develop thrombosis, and therefore is recognised to have an
- 26 increased cardiovascular risk. It is associated with long-term microvascular
- 27 and macrovascular complications, together with reduced quality of life and life
- 28 expectancy.
- In 2013, over 3.2 million adults were diagnosed with diabetes, with prevalence
  rates of 6% and 6.7% in England and Wales respectively. It is estimated that

about 90% of adults currently diagnosed with diabetes have type 2 diabetes.

2 Type 2 diabetes is more common in people of African, African-Caribbean and

3 South Asian family origin. It can occur in all age groups and is increasingly

4 being diagnosed in children.

5 Multiple vascular risk factors and wide-ranging complications make diabetes 6 care complex and time consuming, and many areas of healthcare services 7 must be involved for optimal management. Necessary lifestyle changes, the 8 complexities and possible side effects of therapy make patient education and 9 self-management important aspects of diabetes care. Diabetes care is 10 estimated to account for at least 5% of UK healthcare expenditure, and up to 11 10% of NHS expenditure.

12 This guideline contains recommendations for managing type 2 diabetes in

13 adults, and focuses on patient education, dietary advice, managing

14 cardiovascular risk, managing blood glucose levels, and identifying and

15 managing long-term complications. The guideline does not cover diagnosis,

16 secondary diabetes, type 1 diabetes in adults, diabetes in pregnancy and

17 diabetes in children and young people.

#### 18 Reasons for the 2015 update

19 Since the publication of the 2009 guideline, availability of new evidence and 20 several key developments have prompted an update in the following areas: 21 managing blood glucose levels, antiplatelet therapy and erectile dysfunction. 22 In particular, reasons included safety concerns surrounding some blood 23 glucose lowering medicines, new evidence on new dipeptidyl peptidase-4 24 (DPP-4) inhibitors, sodium-glucose cotransporter-2 (SGLT2) inhibitors and glucagon-like peptide-1 (GLP-1) receptor agonists, new indications and 25 26 licensed combinations for licensed class members and the potential impact of 27 drugs coming off patent on health-economic issues. In addition, new evidence and safety issues relating to the off-label use of antiplatelet therapy (aspirin 28

and clopidogrel) in the primary prevention of cardiovascular disease motivated

30 an update of this review.

#### 1 Reasons for the 2021 update

- 2 Since the publication of the 2015 guideline a key development has been the
- 3 publication of new evidence from cardiovascular outcomes trials, which have
- 4 looked at DPP-4 inhibitors, SGLT2 inhibitors, GLP-1 receptor agonists and a
- 5 sulfonylurea and thiazolidinedione, and how they affect major adverse
- 6 cardiovascular outcomes such as cardiovascular mortality, myocardial
- 7 infarction and stroke.

# 8 Finding more information and committee details

- 9 To find NICE guidance on related topics, including guidance in development,
- 10 see the <u>NICE webpage on diabetes</u>.
- 11 For details of the guideline committee see the <u>committee member list</u>.

## 12 Update information

- 13 November 2021: This guideline is an update of NICE guideline NG28
- 14 (published December 2015) and will replace it. We have reviewed the
- 15 evidence on continuous glucose monitoring for adults with type 2 diabetes.
- 16 Recommendations are marked **[2022]** if the evidence has been reviewed.
- 17 In recommendations shaded in grey and ending [...amended 2022], we have
- 18 made changes that could affect the intent without reviewing the evidence.
- 19 Yellow shading is used to highlight these changes, and reasons for the
- 20 changes are given in table 1.

#### 21 **Table 1 Amended recommendation wording (change to intent) without**

22 an evidence review

Recommendation in 2015 guideline	Recommendation in current guideline	Reason for change
1.6.12 Take the Driver and Vehicle Licensing Agency (DVLA)'s Assessing fitness to drive: a guide for medical professionals into account when offering self	1. <b>6.12</b> Take the Driver and Vehicle Licensing Agency (DVLA)'s Assessing fitness to drive: a guide for medical professionals into account	Recommendation clarified to make it clear that it applies to adults who are using capillary

monitoring of blood glucose levels for adults with type 2 diabetes.	when offering self monitoring of <mark>capillary</mark> blood glucose levels for adults with type 2 diabetes.	blood glucose monitoring rather than CGM.
<ul> <li>1.6.13 Do not routinely offer self-monitoring of blood glucose levels for adults with type 2 diabetes unless:</li> <li>the person is on insulin or</li> <li>there is evidence of hypoglycaemic episodes or</li> <li>the person is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery or</li> <li>the person is pregnant or is planning to become pregnant (see the NICE guideline on diabetes in pregnancy).</li> </ul>	<ul> <li>1.6.13 Do not routinely offer self-monitoring of capillary blood glucose levels for adults with type 2 diabetes unless:</li> <li>the person is on insulin or</li> <li>there is evidence of hypoglycaemic episodes or</li> <li>the person is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery or</li> <li>the person is pregnant or is planning to become pregnant (see the NICE guideline on diabetes in pregnancy).</li> </ul>	Recommendation clarified to make it clear that it applies to adults who are using capillary blood glucose monitoring rather than CGM.
<ul> <li>1.6.14 Consider short-term self-monitoring of blood glucose levels in adults with type 2 diabetes, reviewing treatment as necessary:</li> <li>when starting treatment with oral or intravenous corticosteroids or</li> <li>to confirm suspected hypoglycaemia.</li> </ul>	<ul> <li>1.6.14 Consider short- term self-monitoring of capillary blood glucose levels in adults with type 2 diabetes, reviewing treatment as necessary:</li> <li>when starting treatment with oral or intravenous corticosteroids or</li> <li>to confirm suspected hypoglycaemia.</li> </ul>	Recommendation clarified to make it clear that it applies to adults who are using capillary blood glucose monitoring rather than CGM.
<ul> <li>1.6.16 If adults with type 2 diabetes are self monitoring their blood glucose levels, carry out a structured assessment at least annually. The assessment should include:</li> <li>the person's self- monitoring skills</li> <li>the quality and frequency of testing</li> </ul>	<ul> <li>1.6.16 If adults with type 2 diabetes are self monitoring their capillary blood glucose levels, carry out a structured assessment at least annually. The assessment should include:</li> <li>the person's self-monitoring skills</li> <li>the quality and frequency of testing</li> </ul>	Recommendation clarified to make it clear that it applies to adults who are using capillary blood glucose monitoring rather than CGM.

<ul> <li>checking that the person knows how to interpret the blood glucose results and what action to take</li> </ul>	<ul> <li>checking that the person knows how to interpret the blood glucose results and what action to take</li> </ul>	
<ul> <li>the impact on the person's quality of life</li> </ul>	<ul> <li>the impact on the person's quality of life</li> </ul>	
the continued benefit to the person	the continued benefit     to the person	
• the equipment used.	• the equipment used.	

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