NHS
Nottingham and Nottinghamshire

Continuous Glucose Monitoring in Patients with Diabetes Mellitus Policy

April 2023

Version Control Record:

Version No.	Description of Change	Author	Date
1.0	New policy developed in response to the release of updated NICE Guidance (NG17, NG18, NG28) published March 2022.	Laura Stokes-Beresford, Senior Commissioning Manager for Diabetes	August 2022
2.0	Minor changes to formatting	Laura Stokes-Beresford, Senior Commissioning Manager for Diabetes	November 2022
3.0	Removal of reference to intermittently scanned and 'flash' continuous glucose monitoring	Laura Stokes-Beresford, Senior Commissioning Manager for Diabetes	August 2023

Contributors/Reviewers:

Name	Last Date of Review	Versions Reviewed
Dr Rahul Mohan, GPwSI Diabetes	December 2022	1.0, 2.0, 3.0
Laura Catt, Prescribing Interface Advisor	December 2022	1.0, 2.0, 3.0
Diabetes and Technology Task and Finish Group	December 2022	1.0, 2.0, 3.0
Nottingham and Nottinghamshire Area Prescribing Committee	November 2022	1.0

	This document is part of a suite of policies that the ICB uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.
1	**Policy Criteria**
1.1	**Continuous Glucose Monitoring**
1.1.1	For Type 1 patients and children with any form of diabetes, real time Continuous Glucose Monitoring (rtCGM) must be initiated by Specialists with special interest in Diabetes (Diabetologists, Paediatricians, Diabetes Specialist Nurses) where patients are attending specialist diabetes mellitus care, as part of strategies to optimise a patients Hba1c level and reduce the frequency of hypoglycaemic episodes. For patients with Type 2 Diabetes who meet the eligibility criteria for initiation of CGM and where CGM devices are available on FP10 these may also be initiated and prescribed by a Primary Care clinician. The initiating clinician must have received appropriate training on the initiation and use of rtCGM devices.

1.1.2	**<u>Type 1 Diabetes</u>** For patients with Type1 Diabetes, real-time continuous glucose monitoring (rtCGM) will be commissioned in accordance with NICE NG3, NG17 and NG18. rtCGM will be offered to all children, young people and adults with Type 1 Diabetes based on individual preferences, needs characteristics and the functionality of the devices available. rtCGM will be offered to all pregnant women with Type 1 Diabetes based on individual preferences, needs characteristics and the functionality of the devices available. When choosing a rtCGM device: • Use shared decision making to identify the person's needs and preferences, and offer them an appropriate device suitable for their clinical needs • If multiple devices meet their needs and preferences, offer the device with the lowest cost.

	<u>Type 2 Diabetes, non-type 1, non-type 2 Diabetes caused primarily by (near-) absence of insulin production, or patients with any form of Diabetes on haemodialysis</u> rtCGM will be commissioned in accordance with NICE NG28 for adults with Type 2 Diabetes. rtCGM will be considered for adults (aged 18 years and over) on multiple daily insulin injections (two or more injections per day) with Type 2 Diabetes or insulin treated non-type 1/ non-type 2 patients with (near) absence of insulin or with any form of diabetes on haemodialysis if it is available at the same or lower cost and if any of the following apply: • They have recurrent or severe hypoglycaemia • They have impaired hypoglycaemia awareness • They have a condition/disability that means they cannot self-monitor blood glucose using capillary blood glucose monitoring but could use rtCGM • They would otherwise be advised to self-measure 8 times a day • The rtCGM device can be obtained at the same or lower acquisition cost compared to a Flash device **<u>Any form of Diabetes in Pregnancy</u>** rtCGM will be offered to pregnant patients in accordance with the above recommendations for pregnant patients. rtCGM for pregnant patients will be initiated and prescribed by Specialists with special interest in Diabetes (Diabetologists, Diabetes Specialist Nurses) where patients are attending specialist diabetes mellitus care. Additionally, and in accordance with NICE NG3, rtCGM will be offered to pregnant patients who are on insulin therapy but do not have Type 1 diabetes, if they have unstable blood glucose levels that are causing concern despite efforts to optimise glycaemic control.
1.1.3	Monitor and review the person's use of rtCGM as part of reviewing their diabetes care plan. If there are concerns about the way a person is using the rtCGM device or a child or young person is not using the device 70% of the time: • ask if they are having problems using their device • look at ways to address any problems and concerns to improve their use of the device, including further education and emotional and psychological support.

1.1.4	**Self-Funded Patients** The ICB will not commission continuation of continuous glucose monitoring commenced in the private sector (self-funded) either in the UK or abroad. However, exceptions are permissible when NHS funded treatment would normally be made available to NHS patients within the terms detailed in this policy. The following statement(s) must apply:

	• the patient must have demonstrably satisfied the initiation criteria detailed in this policy at the time of commencing the self-funded continuous glucose monitoring (rtCGM) as confirmed and documented by the specialist clinician through a review of the patient's medical history. • At the point of device renewal, the patient must satisfy the continuation eligibility criteria above and have previously satisfied the initiation criteria at the time of commencing use of the continuous glucose monitoring (rtCGM) device.
1.1.4	**Insulin Deficiency Conditions** The scope of this policy includes requests for continuous glucose monitoring devices for adults and children of any age with a confirmed diagnosis of Type 1, Type 2 diabetes mellitus or non-type 1, non-type 2 diabetes patients caused primarily by (near-) absence of insulin production (e.g. cystic fibrosis-related diabetes, post-pancreatic destruction, post-pancreatectomy diabetes) where these patients fulfil NICE TA151 criteria in every regard other than having Type 1 diabetes.
1.2	**Insulin Pumps** For insulin pump patients unable to achieve targets for glycaemic control measures as defined by the current local insulin pump policy and technology panel approval processes, the decision to discontinue the insulin pump; or trial an insulin pump with integrated continuous glucose monitoring (where insulin pump patients are not already using continuous glucose monitoring) should be made by the responsible specialist clinician in conjunction with the patient. Continuous glucose monitoring (rtCGM) should only be continued in patients if they demonstrate the additional benefits defined in policy sections 1.1.3.
1.3	**Other requirements** 1. Education on Continuous Glucose Monitoring has been provided (online or in person) 2. Patients agree to regular reviews with the local clinical team. 3. Previous attendance, or due consideration given to future attendance, at a Type 1 or Type 2 diabetes structured education programme (DAFNE, DESMOND) or completion of digital education via MyDESMOND,MyType1Diabetes, Healthy Living.
2	**Scope and definitions**

2.1	This policy is based on the ICBs' Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted).
2.2	Type 1 Diabetes Mellitus is a chronic metabolic disorder caused by the destruction of insulin-producing cells in the pancreas that lead to a lack of hormone and subsequent loss of blood glucose control. Treatment of Type 1 Diabetes Mellitus is by insulin therapy to achieve blood glucose control. Type 2 Diabetes mellitus is a chronic metabolic condition characterised by insulin resistance (that is, the body's inability to effectively use insulin) and insufficient pancreatic insulin production, resulting in high blood glucose levels (hyperglycaemia) Patients with Type 2 Diabetes mellitus may initially be managed with lifestyle and dietary changes alone, although due to the progressive nature of the disease patients will require interventions with medicines including insulin as glycaemic control deteriorates. To help maintain control of blood glucose levels, NICE guidelines recommends that Type 1 patients self-monitor their blood glucose levels between 4 and 10 times a day. NICE guidelines do not recommend routine self-monitoring in type 2 patients, (except in patients using drug treatments such as sulphonylureas and insulins). Currently most patients self-monitor using blood glucose testing strips. For those patients who are not satisfactorily managed with self-blood-glucose testing, continuous glucose monitoring is an alternative glucose monitoring method. Continuous glucose monitoring systems (rtCGM) measure interstitial fluid glucose levels and automatically transmit readings to a receiver every minute if using a smartphone, or when scanned if using a reader. Continuous glucose monitoring devices may be fitted with alarms to alert patients when blood glucose levels are too high or low and can be integrated into continuous subcutaneous insulin infusion devices (insulin pumps) to allow real time adjustment of insulin doses or suspend insulin delivery following a low glucose warning.
2.3	The scope of this policy does not include the provision of continuous glucose monitoring for adults and children who do not have a confirmed diagnosis of diabetes mellitus or any other aspects of the management of Type 1 or Type 2 diabetes mellitus or cystic fibrosis-related diabetes.

2.4	The ICB recognises that a patient may have certain features, such as: • having Type 1 or 2 diabetes mellitus or non-type 1, non-type 2 diabetes patients caused primarily by (near-) absence of insulin production; • wishing to have a service provided for Type 1 or 2 diabetes mellitus or non-type 1, non-type 2 diabetes patients caused primarily by (near-) absence of insulin production; • being advised that they are clinically suitable for a continuous glucose monitoring and; • being distressed by having Type 2 diabetes mellitus or non-type 1, non-type 2 diabetes patients caused primarily by (near-) absence of insulin production. This alone is not sufficient to meet the criteria specified in this commissioning policy. Such features place the patient within the group to whom this policy applies and do not make them exceptions to it.
2.5	Terms and abbreviations used in this policy are explained and defined in Appendix 1. Throughout this policy any term is used with the meaning described in that appendix.
2.6	This policy references the advice of NHS England (NHSE) (published March 2019), the Regional Medicines Optimisation Committee (RMOC) (published in October 2017) and The National Institute for Health and Care Excellence (NICE), in particularly NG17 and NG18 (both updated in March 2022), which relates to adults and to children & young people respectively. Appendix 2 contains statements from the relevant guidelines to support recommendations within the policy.
3	**Appropriate Healthcare**
3.1	The purpose of continuous glucose monitoring devices is to reduce the variability of blood glucose levels. This is achieved by enabling patients to intervene quicker (than would have been possible with finger prick glucose testing) when blood glucose levels deviate from euglycaemia due to more frequent testing and availability of blood glucose data. Improved control of blood glucose levels reduces the likelihood of short-term complications such as episodes of low blood glucose (hypoglycaemia) or life-threatening emergencies such as diabetic ketoacidosis (a consequence of high blood glucose levels).

4	**Effective Healthcare**
4.1	The ICB does not call into question the effectiveness of continuous glucose monitoring and therefore this policy does not rely on the Principle of Effectiveness. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the ICB may consider whether the purpose of the treatment is likely to be achieved in this patient without undue adverse effects before confirming a decision to provide funding.

5	**Cost Effectiveness**
5.1	This policy relies on the Principle of Cost-Effectiveness. The ICB considers that in most patients able to achieve their agreed HbA1c target without disabling hypoglycaemia using alternative methods of self-monitoring of blood glucose, the use of continuous glucose monitoring to improve blood glucose control would not represent a cost-effective use of NHS resources. In determining the circumstances under which continuous glucose monitoring and flash glucose monitoring are cost-effective, the ICB has referenced the guidance of NHSE, the RMOC and NICE clinical guidelines NG17, NG18 and NG28 which relate to adults with Type 1 diabetes mellitus; children and young people with Type 1 and 2 diabetes mellitus; and adults with type 2 diabetes mellitus respectively.
6	**Ethics**
6.1	The ICB does not call into question the ethics of continuous glucose monitoring and therefore this policy does not rely on the Principle of Ethics. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the ICB may consider whether the treatment is likely to raise ethical concerns in this patient before confirming a decision to provide funding.
7	**Affordability**
7.1	The ICB does not call into question the affordability of continuous glucose monitoring and therefore this policy does not rely on the Principle of Affordability. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the ICB may consider whether the treatment is likely to be affordable in this patient before confirming a decision to provide funding.
8	**Exceptions**
8.1	The ICB will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.
8.2	In the event of inconsistency, this policy will take precedence over any nonmandatory NICE guidelines in driving decisions of this ICB. A circumstance in which a patient satisfies NICE guidelines but does not satisfy the criteria in this policy does not amount to exceptionality.
9	**Force**

9.1	This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance relating to this intervention, or to alternative treatments for the same condition.
9.2	In the event of NICE guidance referenced in this policy being superseded by new NICE guidance, then: • If the new NICE guidance has mandatory status, then that NICE guidance will supersede this policy with effect from the date on which it becomes mandatory. • If the new NICE guidance does not have mandatory status, then the ICB will aspire to review and update this policy accordingly. However, until the ICB adopts a revised policy, this policy will remain in force and any references in it to NICE guidance will remain valid as far as the decisions of this ICB are concerned.

10	**References**
	1. NHS England Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients. Available at https://www.england.nhs.uk/wpcontent/uploads/2019/03/National-arrangements-for-funding-of-relevantdiabetes-patients-June-2020-Updated-final.pdf 2. National Institute for Health and Clinical Excellence (2008) Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. Technology appraisal guideline 151 (TA151). Available at https://www.nice.org.uk/guidance/ta151 3. National Institute for Health and Care Excellence (2022) Type 1 diabetes in adults: diagnosis and management. NICE guideline (NG17). Available at https://www.nice.org.uk/guidance/ng17 4. National Institute for Health and Care Excellence (2022) Diabetes (type 1 and type 2) in children and young people: diagnosis and management. NICE guideline (NG18). Available at https://www.nice.org.uk/guidance/ng18 5. National Institute for Health and Care Excellence (2022) Type 2 diabetes in adults: management. NICE guideline (NG28). Available at https://www.nice.org.uk/guidance/ng28 6. Regional Medicines Optimisation Committee (2017) Flash Glucose Monitoring Systems Position Statement. Available at https://www.sps.nhs.uk/wp-

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7. NICE Medtech Innovation Briefing [MIB 110]: FreeStyle Libre® for glucose monitoring NICE July 2017. Available at https://www.nice.org.uk/advice/mib110
8. ABCD Type 1 Diabetes Clinical Collaborative: Information to help a formulary case for Freestyle Libre System October 2017. Available at https://abcd.care/getting-freestyle-libre-your-formulary
9. ACDC (2017) A Practical Approach to the Management of Continuous Glucose Monitoring (CGM) / Real-Time Flash Glucose Scanning (FGS) in Type 1 Diabetes Mellitus in Children and Young People Under 18 Years. Available at https://www.bsped.org.uk/clinical/docs/CGM-FGS-ACDC-Guideline.pdf
10. Diabetes UK (2017) Diabetes UK Consensus Guideline for Flash Glucose Monitoring.
    Available at https://www.diabetes.org.uk/resources-s3/2017-09/1190_Flash%20glucose%20monitoring%20guideline_SB_V9%5B4%5D.pdf
11. National Institute for Health and Care Excellence (2020) Diabetes in pregnancy: management from preconception to the postnatal period. NICE guideline (NG3). Available at https://www.nice.org.uk/guidance/ng3

11 Appendix 1 – Terms and abbreviations

ICB – Integrated Care Board.

NICE – National Institute for Health and Care Excellence

RMOC – Regional Medicines Optimisation Committee

NHSE – NHS England

Diabetes mellitus – As defined by the World Health Organisation 2006 plasma glucose criteria (fasting plasma glucose ≥ 7.0mmol/l (126mg/dl) or 2–h plasma glucose ≥ 11.1mmol/l (200mg/dl).)

Euglycaemia – Normal concentration of glucose in the blood within an optimal range of 90–130 mg/dl

HbA1c - Glycated haemoglobin measured using methods that have been calibrated according to International Federation of Clinical Chemistry (IFCC) standardisation.

MDI – Multiple daily injections. In this policy this refers to four or more daily injections of insulin.

NG3 – NICE guideline 3 (Diabetes in pregnancy: management from preconception to the postnatal period).

NG17 – NICE guideline 17 (Type 1 diabetes in adults: diagnosis and management).

	NG18 – NICE guideline 18 (Diabetes [type 1 and type 2] in children and young people: diagnosis and management). NG28 – NICE guideline 28 (Type 2 diabetes in adults: management). TA151 – NICE technology appraisal guideline 151 (Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus). Adult – A person over the age of 18 years. Children and young people – People under the age of 18 years as defined by NG18. Children may be defined as people under the age of 12 years and young people defined as people between the ages of 12 and 18 years. (However, the separate definitions for children and young people are not stated in NG18 or TA151). DAFNE – Dose Adjustment For Normal Eating (regimen for patient self-management). DESMOND - Diabetes Education and Self-Management for Ongoing and Newly Diagnosed. Gold Score – A method used to assess impairment of awareness of hypoglycaemia. This comprises a single question “do you know when your hypos are commencing” and a 7-point Likert scale for responses ranging from 1 (always aware) to 7 (never aware). A score of ≥4 implies impaired awareness of hypoglycaemia. Clarke Score – A method used to assess impairment of awareness of hypoglycaemia. This comprises a set of 8 questions relating to hypoglycaemia where patient can score “1” or “0” for each question depending on response. A score of ≥4 implies impaired awareness of hypoglycaemia. Disabling hypoglycaemia – defined by TA 151 as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life. Severe hypoglycaemia – an episode of low blood glucose levels that requires assistance from another person to treat (i.e. a person unable to swallow, convulsing or unconscious). GPwSI in Diabetes – GP with Special interest in Diabetes DKA – Diabetic Ketoacidosis. EQ-5D – Validated Quality of Life measure developed by EuroQol and referenced by NICE. DQoL – Diabetes Quality of Life measure. A validated tool designed by the Diabetes Control and Complications Research Group.

	Intensive monitoring – For the purposes of the policy, patients who perform 8 or more additional blood glucose monitoring tests above the minimum frequency of daily
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