Lancashire and South Cumbria Integrated Care Board

Policies for the Commissioning of Healthcare

Policy for Continuous Glucose Monitoring and Flash Glucose Monitoring to patients with Diabetes Mellitus

Date of ratification: **30th June 2022**

Date due for review: **30th March 2023**

Date of adoption: **1st July 2022**

This document is part of a suite of policies that the Integrated Care Board (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.

Document control:
Policy for Continuous Glucose Monitoring and Flash Glucose Monitoring to patients with Diabetes Mellitus

Version Date:	Version Number:	Changes Made:
March 2021	2.0	CPDIG agreed to approve the inclusion of all pregnant patients with Type 1 Diabetes in accordance with the ambition set out by NHS England that "every pregnant patient with type 1 diabetes should offered CGM…." by April 2021.
October 2021	2.1	Following feedback from Clinical Engagement (4/10/2021) the following amendments were agreed by CPDIG members: **1.0.** inclusion of criteria aligned with NICE NG3 enabling provision of CGM to pregnant women who are on insulin therapy but do not have type 1 diabetes, if: • they have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia) or • they have unstable blood glucose levels that are causing concern despite efforts to optimise glycaemic control. 2.0 Inclusion of patients with type 2 diabetes mellitus using a basal-bolus insulin regimen 3.0 A change to the review of clearly documented achievement of targets for glycaemic control measures to be undertaken at 6 months rather than 3. 4.0 Any person with diabetes who is eligible for continuous glucose monitoring as defined in section 1.2.2 may be considered for a flash glucose monitoring system if they and their clinician consider that a flash glucose monitoring system would be more appropriate for the individual's specific situation
April 2022	2.2	Following the release of update NICE Guidance and the result of Public Engagement (20/04/2022) CPDIG approved the following changes to the Policy: 1.0 NG28-CGM will be considered as an alternative to isCGM for adults with insulin treated type 2 diabetes or insulin treated non-type 1/ non-type 2 patients with (near) absence of insulin if it is available at the same or lower cost and 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 isCGM They would otherwise be advised to self-measure 8 times a day 2.0. NG17 & NG18- isCGM will be offered to all children aged over 4 years,
July 2022	2.3	Policy adopted by Lancashire and South Cumbria ICB – references to CCG replaced by ICB where relevant

Document control: Policy for Continuous Glucose Monitoring and Flash Glucose Monitoring to patients with Diabetes Mellitus

Version Date:	Version Number:	Changes Made:
July 2022	V2.3	Policy adopted by Lancashire and South Cumbria ICB

1. Policy Criteria

1.1 Continuous Glucose Monitoring

1.1.1 Real-time Continuous glucose monitoring (rtCGM) must be initiated and continually supplied / prescribed by specialist clinicians (Diabetologists, Paediatricians with a special interest in diabetes, GPs with a special interest in Diabetes, Diabetes Specialist Nurses) in limited and controlled settings where patients are attending specialist diabetes mellitus care, as part of strategies to optimise a patient's HbA1c levels and reduce the frequency of hypoglycaemic episodes.

1.1.2 Type 1 Diabetes

For patients with type1 diabetes, real-time continuous glucose monitoring (rtCGM) will be commissioned in accordance with NICE NG 17 and NG 18.

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 (along with isCGM- also known as Flash) will be offered to all adults 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
- If multiple devices meet their needs and preferences, offer the device with the lowest cost.

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

rtCGM will be commissioned in accordance with NICE NG 28 for adults with type 2 diabetes.

Patients with non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production, or with any form of diabetes on haemodialysis will be commissioned under the same arrangements as for patients with type 2 diabetes.

rtCGM will be considered as an alternative to intermittently scanned continuous glucose monitoring (isCGM- also known as Flash) for adults 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 isCGM
- They would otherwise be advised to self-measure 8 times a day

Pregnant patients

rtCGM will be offered to pregnant patients in accordance with the above recommendations for non-pregnant patients.

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.

isCGM may be offered as an alternative to rtCGM for pregnant patients who are eligible for rtCGM as outlined above but are unable to use rtCGM or express a clear preference for isCGM (see 1.2.2)

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 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) or flash glucose monitoring device (isCGM), 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 the continuous glucose monitoring (rtCGM) or flash glucose monitoring device (isCGM).

1.2 Flash Glucose Monitoring (also known isCGM)

1.2.1 Flash glucose monitoring must be initiated by specialist clinicians (Diabetologists, Paediatricians with a special interest in diabetes, GPs with a special interest in Diabetes, Diabetes Specialist Nurses). For patients who do not routinely attend appointments with specialist clinicians flash glucose monitoring devices may be supplied by a clinician responsible for the wider care and management of the patient's diabetes.

The initiating clinician must have received appropriate training on the initiation and use of flash glucose monitoring products and will supply the patient with a scanning device and sensors to cover the initial 2 weeks of use of flash glucose monitoring.

Following initiation, ongoing supply of sensors will be via primary care prescribing on an FP10 prescription.

1.2.2 Type 1 Diabetes

Intermittently scanned CGM (isCGM – also known as Flash) will be commissioned in accordance with NICE NG 17 and NG 18.

isCGM will be offered to all children and young people aged 4 years and over who are unable to use rtCGM or who express a clear preference for isCGM.

isCGM (along with rtCGM) will be offered to all adults with type 1 diabetes based on individual preferences, needs characteristics and the functionality of the devices available.

If multiple devices meet their needs and preferences, offer the device with the lowest cost.

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

isCGM will be commissioned in accordance with NICE NG 28 for adults with type 2 diabetes.

Patients with non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production, or with any form of diabetes on haemodialysis will be commissioned under the same arrangements as for patients with type 2 diabetes.

isCGM will be offered to adults 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 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 isCGM
- They would otherwise be advised to self-measure 8 times a day

Pregnant patients

isCGM may be offered as an alternative to rtCGM for pregnant patients who are eligible for rtCGM as outlined in 1.1.2 of this policy but are unable to use rtCGM or express a clear preference for isCGM

1.2.3 Monitor and review the person's use of isCGM as part of reviewing their diabetes care plan.

If there are concerns about the way a person is using the isCGM 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.

1.3 For insulin pump patients unable to achieve targets for glycaemic control measures as defined by the current local insulin pump policy, 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); or trial a combination of insulin pump and flash glucose monitoring device (isCGM); should be made by the responsible specialist clinician in conjunction with the patient.

Combination continuous glucose monitoring (rtCGM) and flash glucose monitoring (isCGM) will not be routinely commissioned by the CCG.

Continuous glucose monitoring (rtCGM) or flash glucose monitoring (isCGM) should only be continued in patients if they demonstrate the additional benefits defined in policy sections 1.1.3 and 1.2.3 respectively.

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 leads to an absolute lack of the 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 many

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-blood glucose monitoring in type 2 patients, except in patients using medicines which may cause hypoglycaemia (e.g. sulphonylureas and insulins).

Currently most patients self-monitor blood glucose by applying a drop of blood to a testing strip. This strip is then inserted into a meter to display a blood glucose level. For those patients who are not satisfactorily managed with self-monitored finger prick blood-glucose testing, continuous glucose monitoring and flash glucose monitoring are alternative glucose monitoring methods.

Continuous glucose monitoring systems (rtCGM) use a sensor to continuously measure interstitial fluid glucose levels and automatically transmit readings to a receiver every 5 minutes. 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.

Flash glucose monitoring systems (referred to by NICE as intermittently scanned continuous glucose monitoring – isCGM) use a sensor to measure interstitial fluid glucose levels every minute and stores glucose levels at 15-minute intervals for 8 hours. Glucose levels can be seen at any time by scanning a reader over the sensor. The sensor must be scanned at least every 8 hours to provide a full 24 hours of data. The sensor must be scanned to detect when the glucose level is too high or too low.

2.3 The scope of this policy includes requests for continuous glucose monitoring and flash 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.

2.4 The scope of this policy does not include the provision of continuous glucose monitoring and flash glucose monitoring devices 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.

2.5 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 or flash glucose monitoring device; and
- being distressed by having type 1 or 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.

2.6 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.

3. Appropriate Healthcare

3.1 The purpose of continuous glucose monitoring and flash glucose monitoring devices are 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).

3.2 The ICB regards the achievement of this purpose of continuous glucose monitoring and flash glucose monitoring as according with the Principle of Appropriateness. Therefore, this policy does not rely on the principle of appropriateness. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the ICB may consider the Principle of Appropriateness in the particular circumstances of the patient in question before confirming a decision to provide funding.

4. Effective Healthcare

4.1 The ICB does not call into question the effectiveness of continuous glucose monitoring or flash 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 and flash 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 or flash 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 or flash 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 non-mandatory 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.

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10. References

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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.

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).

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 testing outlined by NICE clinical guidance (i.e. 12 or more tests daily).

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