NHS
Shropshire, Telford and Wrekin
Clinical Commissioning Group

Commissioning Policy: Continuous Glucose Monitoring (CGM) for Type 1 Diabetes in Adults and Pregnant women with Type 1 or Type 2 Diabetes on insulin therapy

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Document Control Sheet

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Document Amendment History

Version No.	Date	Brief Description
Version 4	15/11/21	Review and updated to reflect NICE guidance [NG3] (updated 2020), transferred to new CCG format.

The formally approved version of this document is that held on the NHS Shropshire, Telford and Wrekin CCG website: www.shropshiretelfordandwrekinccg.nhs.uk

Printed copies or those saved electronically must be checked to ensure they match the current online version.

Contents

This policy applies only to individuals who would be considered for **continuous glucose monitoring (CGM)**.

A further policy **"Commissioning Policy: The use of Flash Glucose Monitoring systems in eligible diabetic patients"** is in place for patients who may be eligible for flash glucose monitoring.

1 Introduction

CGM systems are available for use in Type 1 diabetes, as a **'temporary diagnostic tool'** to help patients better manage their blood glucose levels (short term CGM) or as a **'continuous aid in glycaemic control'** (long term CGM).

CGM systems use a sensor placed under the skin, which continuously measures glucose levels. It measures the amount of glucose in the interstitial fluid[1], which lags behind the glucose level in the blood by up to 15 minutes and this lag time is increased if blood glucose levels are changing rapidly e.g. after eating or if exercising.[2] For this reason, a finger prick blood glucose check is recommended if changing treatment (e.g. taking more insulin or treating a hypo).[1]

NICE issued clinical guidance [NG17] in August 2015 concerning the diagnosis and management of Type 1 diabetes in adults. This covered a wide range of issues affecting clinical care, such as diet, exercise and insulin regimes. It states that real-time continuous glucose monitoring should NOT be routinely offered to adults with Type 1 diabetes, only that it should be "considered" in certain circumstances.[4]

NICE guidance [NG3] states all pregnant women with type 1 diabetes should be offered continuous glucose monitoring (CGM) to help them meet their pregnancy blood glucose targets and improve neonatal outcomes.[5] CGM may also be considered in certain circumstances for pregnant women using insulin therapy that do not have type 1 diabetes.[5]

A study of CGMs in 2012 reported that there is limited evidence for the effectiveness of real-time CGM use in children, adults and patients with poorly controlled diabetes.[6] The largest improvements in glycaemic control were seen for sensor-augmented insulin pump therapy in patients with poorly controlled diabetes who had not used an insulin pump before.[6] The risk of severe hypoglycaemia or ketoacidosis was not significantly increased for CGM users but as these events occurred infrequently these results have to be interpreted cautiously.[6] There are indications that higher compliance with using the CGM device improves glycosylated haemoglobin A1c level (HbA1c) to a larger extent.[6]

NICE recommendations on continuous glucose monitoring are due to be updated and NICE diagnostics guidance on integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes is currently being updated. This policy will be updated as necessary to reflect any changes to recommendations.

2 Purpose

The purpose of this policy is to provide clear criteria for the commissioning of Continuous Glucose Monitoring (CGM) for adults with Type 1 diabetes and pregnant women with Type 1 or Type 2 diabetes on insulin therapy.

3 Eligibility criteria for CGM devices

Shropshire, Telford and Wrekin CCG do NOT routinely commission Continuous Glucose Monitoring (CGM).

CGM should only be offered where there is a clear expectation of clinical benefit, and it is the clinician's judgement that no other technology will meet the need of the patient. It is recognised that patients and parents/carers may have strong opinions regarding the use of CGM, but the final decision must rest with the clinician and be on clinical grounds.[7]

The following basic eligibility criteria must be met before CGM may be considered for adult patients with Type 1 diabetes and pregnant women with Type 1 or Type 2 diabetes on insulin therapy:

- All patients must have followed the clinical pathway of usual interventions including regular and appropriate monitoring of blood glucose using a glucose meter and testing strips, dietetic care and structured education.[7]
- All patients must have been informed of the advantages and disadvantages of continuous glucose monitoring and expressed a continued wish to initiate CGM.
- All patients must be willing to commit to training in the use of their device and to on-going regular follow-up and monitoring (including remote follow-up where this is offered).
- All patients must be willing to commit to use their CGM device at least 70% of the time and to calibrate it as needed.
- All patients must have demonstrated appropriate levels of competence to perform carbohydrate counting (e.g. DAFNE regimen), blood glucose monitoring and to interpret this data in order to competently adjust insulin doses.
- The use of a CGM device must be supported by a multidisciplinary specialist diabetic team, and the device must be provided by a centre with expertise in its use, as part of a strategy to optimise a person's HbA1c levels and reduce the frequency of hypoglycaemic episodes.[4]

In addition to all of the above, patients must meet ONE OR MORE of the following criteria despite optimised use of insulin therapy and conventional blood glucose monitoring 10 or more times per day to check for hypoglycaemia:

1) More than one episode a year of severe hypoglycaemia with no obvious preventable cause[4] and requires third party intervention (assistance from another person) to treat.

- For this policy, severe hypoglycaemia is defined as having low blood glucose levels (<4.0mmol/litre) that precipitates recognised signs of severe hypoglycaemia (confusion and disorientation, convulsions/fitting/seizures, intense nightmares, loss of consciousness, coma [7]

Or

2) A complete loss of awareness of hypoglycaemia[4]

Or

3) Frequent episodes of asymptomatic hypoglycaemia (more than two episodes a week) which is causing problems with daily living or performance impairment.[4]
   - Precipitating causes must be excluded.
   - This assessment must be made using a blinded diagnostic CGM (Navigator system).
   - Hypoglycaemia is defined as <4mmol/L.

Or

4) Hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day over a three month period.[8]

Or

5) All pregnant women with type 1 diabetes.[5]
   - Offer flash glucose monitoring to pregnant women with type 1 diabetes who are unable to use continuous glucose monitoring or express a clear preference for it.

Or

6) **Consider** continuous glucose monitoring for 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.

NOTE: For pregnant women who are using continuous glucose monitoring, a member of the joint diabetes and antenatal care team with expertise in these systems should provide education and support (including advising women about sources of out-of-hours support).[5]

4 Continuation criteria for CGM devices

- Clinically appropriate, objective measures of improvement should be agreed and documented for each patient individually prior to application for funding.[7]
- Patients using CGM will be assessed by their specialist at **one month** and **three months** to ensure that the benefits of CGM are demonstrated;
    - reduction in frequency of hypoglycaemia (assessed by CGM downloads).
    - Where CGM commenced for persistent hyperglycaemia, continuation should only occur in patients with HbA1c sustained at or below 53mmol/mol **AND/OR** a fall in HbA1c of 27mmol/mol or more.[4]
- The CGM device will be withdrawn in patients where the device has not been used for at least 70% of the time and/or the agreed measures for improvement have not been achieved.[4]
- Patients should be kept under regular review (at least annually), and consideration given to stepping down to less intensive forms of glucose monitoring wherever clinically appropriate.[7]
- Pregnant woman with Type 1 or Type 2 diabetes using insulin should re-assume their routine (non-pregnant) glucose monitoring regime within; **six months** of delivery if breast-feeding or **three months** of delivery if not breastfeeding.[7]

5 Application for funding CGM

Clinicians wishing to apply for funding for CGM for a patient meeting the criteria in this policy should do so via the Blueteq system.

6 Exceptional circumstances

The CCG recognises that there may be exceptional circumstances where it is clinically appropriate to fund CGM outside the terms of this policy. Funding for such cases will be considered by the CCG following application to the CCG's Individual Funding Request Panel, whereby the IFR process will be applied.

Guidance regarding IFRs, and an application form, can be found on the CCG website, here.

7 Related documents

The following documents contain information that relates to this policy:

- NHS Shropshire Clinical Commissioning Group and NHS Telford & Wrekin Clinical Commissioning Group Joint Commissioning Policy: The use of Flash Glucose Monitoring systems in eligible diabetic patients, Published Jan 2018, Updated Nov 2020.

8 References

1. Diabetes UK, Continuous Glucose Monitoring (CGM), Available at: https://www.diabetes.org.uk/guide-to-diabetes/managing-your-diabetes/testing/continuous-glucose-monitoring-cgm (Accessed: November 2021)
2. NICE guidance [DG21], 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), Published February 2016, Available at : https://www.nice.org.uk/guidance/dg21/chapter/4-The-diagnostic-tests (Accessed: November 2021)
3. NICE Medtech innovation briefing [MIB233], Dexcom G6 for real-time continuous glucose monitoring, Published November 2020, Available at: https://www.nice.org.uk/advice/mib233/chapter/Summary (Accessed: November 2021)
4. NICE guideline [NG17], Type 1 diabetes in adults: diagnosis and management. Published August 2015, Updated July 2021, Available at: https://www.nice.org.uk/guidance/ng17 (Accessed: November 2021)
5. NICE guidance [NG3], Diabetes in pregnancy: management from preconception to the postnatal period, Published February 2015, Available at: https://www.nice.org.uk/guidance/ng3 (Accessed: November 2021)
6. Continuous glucose monitoring systems for type 1 diabetes mellitus Miranda Langendam, et al, Published, January 2012, Available at: https://pubmed.ncbi.nlm.nih.gov/22258980/ (Accessed: November 2021)
7. Clinical Commissioning Policy for Continuous Glucose Monitoring in diabetes, Birmingham and Solihull Clinical Commissioning Group, Available at: https://www.birminghamandsolihullccg.nhs.uk/about-us/publications/policies/2490-policy-for-continuous-glucose-monitoring-in-diabetes/file (Accessed: November 2021)
8. NHS Shropshire Clinical Commissioning Group and NHS Telford & Wrekin Clinical Commissioning Group Joint Commissioning Policy: Continuous Glucose Monitoring (CGM) for Type 1 diabetes in Adults, Published December 2018, Available at: https://www.shropshiretelfordandwrekinccg.nhs.uk/wp-content/uploads/CGM-for-adults-with-Type-1-joint-policy.pdf (Accessed: November 2021)