NHS
Shropshire, Telford and Wrekin
Clinical Commissioning Group

Commissioning Policy: Continuous Glucose Monitoring (CGM) for Type 1 Diabetes in Children and Young People aged up to 19 years.

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Document Control Sheet

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Document Amendment History

Version No.	Date	Brief Description
Version 4	11/11/21	Review of previous draft policy and updated 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**.

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 [NG18] in August 2015 [updated December 2020) concerning the diagnosis and management of type 1 and 2 diabetes in children and young people. This covered a wide range of issues affecting clinical care, such as diet, exercise and insulin regimes.[3]

Current advice is for children and young people with type 1 diabetes and their families or carers to routinely perform at least 5 capillary blood glucose tests per day and more frequent testing is often needed (for example with physical activity and during intercurrent illness).[3] NG18 also recommends offering a choice of equipment in order to optimise blood glucose control in response to adjustment of insulin, diet and exercise. It also mentions 'offering' and 'considering' CGM in certain circumstances where children and young people meet the defined clinical criteria.

A study of CGM system in 2012 reported that there is limited evidence for the effectiveness of real-time CGM system use in children, adults and patients with poorly controlled diabetes. 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. 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. There are indications that higher compliance with using the CGM device improves glycosylated haemoglobin A1c level (HbA1c) to a larger extent.[6]

There is ongoing research around CGM in children and young people (CITY and SENCE)[3] which may provide further evidence to the clinical and cost effectiveness of real-time CGM systems compared to capillary blood glucose tests, in the future. This policy will be updated to reflect any new recommendations which may result from the research.

2 Purpose

The purpose of this policy is to provide clear criteria for the commissioning of CGM for children and young people aged up to 19 years with Type 1 diabetes.

3 Eligibility criteria for CGM devices

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

The following basic eligibility criteria must be met before CGM (with an alarm) may be considered for children and young people with Type 1 diabetes:

- All patients and/or their families or carers (if appropriate) must have been informed of the advantages and disadvantages of continuous glucose monitoring and expressed a continued wish to initiate CGM.
- All patients and/or their families or carers (if appropriate) must be willing to commit to attendance of a structured education programme, 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 and/or their families or carers (if appropriate) must be willing to commit to use their CGM device at least 70% of the time and to calibrate it as needed.
- All patients and/or their families or carers (if appropriate) 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.

In addition to the above patients must meet ONE OR MORE of the following criteria despite optimised use of insulin therapy and conventional blood glucose monitoring eight or more times per day to check for hypoglycaemia before real-time CGM is offered:

1) Frequent severe hypoglycaemia[3] with no obvious preventable cause.
    - 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) and requires third party intervention (assistance from another person to treat).[4]

Or

2) Impaired awareness of hypoglycaemia (IAH) associated with adverse consequences (for example seizures).[3]
    - IAH defined as where an individual reaches a glucose concentration of <3.0 mmol/litre without symptoms of hypoglycaemia on more than two occasions in a single week. IAH without associated adverse consequences would not be considered sufficient grounds for eligibility.[4]

Or

3) Have an inability to recognise, or communicate about, symptoms of hypoglycaemia (for example because of cognitive or neurological disabilities).[3]
    - Exclusions: This would normally exclude neonates, infants and pre-school children.

Consider ongoing real-time continuous glucose monitoring for:

- Neonates, infants and pre-school children with inability to recognise, or communicate about, symptoms of hypoglycaemia.
- Children and young people who undertake high levels of physical activity (for example, sport at a regional, national or international level).
- Children and young people who have comorbidities (for example anorexia nervosa) or who are having treatments (for example corticosteroids) that can make blood glucose management difficult.[3]

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.[4]
- Patients using CGM will be assessed by their specialist at **one month** and must demonstrate the following or their CGM will be withdrawn;
    - Use of the CGM device for at least 70% of the time.[5]

  Or
    - Attendance of patient and/or their families or carers (if appropriate) at a structured education programme, unless extenuating circumstances.[5]

- Patients using CGM will be assessed by their specialist at **three months** and must demonstrate the following or their CGM will be withdrawn;
    - Use of the CGM device for at least 70% of the time.[5]

  Or
    - Improvement in glycaemic control – e.g. if HbA1c was > 7.5% (59mmol/mol) at start of CGM therapy, control improved by > 0.5% (6mmol/mol).[5]

  Or
    - Improvement in hypoglycaemia unawareness if introduced for hypoglycaemia unawareness (Clarke or Gold scales).[5]

Or

- Reduction in frequency of hypoglycaemia – particularly nocturnal hypoglycaemia (assessed from CGM download).[5]

- 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.[4] For example when a child reaches an age at which they are able to recognise and communicate symptoms of hypoglycaemia.

- For patients transitioning to adult diabetes services, it is the clinicians responsibility to ensure the continuation of CGM is clinically appropriate and meets the NHS Shropshire, Telford and Wrekin CCG adult CGM criteria.

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: Continuous subcutaneous insulin infusion (CSII) (without continuous glucose monitoring (CGM)) in adults and children with Type 1 diabetes.

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 guidance [NG18], Diabetes (type 1 and type 2) in children and young people: diagnosis and management, Updated December 2020, Available at: https://www.nice.org.uk/guidance/ng18/chapter/Recommendations#blood-glucose-and-plasma-glucose (Accessed: November 2021)

4. Birmingham and Solihull Clinical Commissioning Group (October 2018) Clinical Commissioning Policy for Continuous or Flash Glucose Monitoring, Available at: https://www.birminghamandsolihullccg.nhs.uk/publications/equality-analysis/2161-ea-commissioning-policy-for-continuous-or-flash-glucose-monitoring/file (Accessed: November 2021).

5. Association of Children's Diabetes Clinicians (April 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: http://www.a-c-d-c.org/wp-content/uploads/2012/08/CGM-FGS-Practical-Approach-ACDC-Guideline-April-2017.pdf (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)