

Policy for Continuous Glucose Monitoring for Type 1 Diabetic Paediatric Patients (Under 18 years of age)

PRIOR APPROVAL REQUIRED

INTRODUCTION

Real-time continuous glucose monitoring (CGM) and flash glucose scanning (FGS) are new and evolving technologies in the management of type 1 diabetes. In addition CGM can be linked to insulin pump therapy providing sensor augmented pump technology (SAPT).

Continuous Glucose Monitoring (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 or diagnostic CGM) or as a continuous aid in glycaemic control (long term CGM). Diagnostic CGM is already funded as part of the specialist services that are currently commissioned.

CGM systems use a glucose sensor placed under the skin that continuously measures glucose levels. There are a number of different manufacturer devices available or under development. The simplest (eg Abbott Libre, £910 per year) measures glucose continually but needs to be actively scanned using a digital monitor and does not alert the patient if readings are low.

More complex devices transmit a continuous reading wirelessly to a display unit, worn like a pager, and alarm if low or high levels occur. Sensor-augmented devices can communicate directly with an integrated insulin pump to suspend delivery if hypoglycaemia is predicted. Cost of this is around £6000 a year.

With all new technologies like this, it is all the more important to ensure that the evidence base is robust so that patients are not exposed to the risks without good evidence of benefit. It is important for the NHS to optimise the safety and cost-effectiveness of procedures to ensure maximum benefit for the risks and costs involved.

It is thought that around 30% of people with type 1 diabetes have problematic hypoglycaemia which can affect many aspects of daily life and result in significant anxiety. This can have a substantial impact on quality of life by leading people to restrict their daily activities. It can also cause significant anxiety for carers, particularly parents who may have to wake several times a night to check on their child.

NICE GUIDANCE^{1,2}

NICE issued guidance in August 2015 about the diagnosis and management of type 1 and 2 diabetes in children and young people (NG18)¹. This covered a wide range of issues affecting clinical care, such as diet, exercise and insulin regimes. It also included mention of offering CGM in certain circumstances:

“Offer ongoing real-time continuous glucose monitoring with alarms to children and young people with type 1 diabetes who have:

- *Frequent severe hypoglycaemia OR*
- *Impaired awareness of hypoglycaemia associated with adverse consequences (for example, seizures or anxiety) OR*
- *inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities).”*

NG18 also included:

Consider ongoing real-time continuous glucose monitoring for:

- *neonates, infants and pre-school children,*
- *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 receiving treatments (for example corticosteroids) that can make blood glucose control difficult.*
- *Consider intermittent (real-time or retrospective) continuous glucose monitoring to help improve blood glucose control in children and young people who continue to have hyperglycaemia despite insulin adjustment and additional support.*

Reference:	Policy Name	Review Date	Version
BSW-CP053	Continuous Glucose Monitoring in Children	Aug 2021	2

NICE GUIDANCE continued:

The NICE guideline development group recommendation to only “consider” ongoing real-time continuous glucose monitoring systems (CGMS) for neonates, infants and pre-school children with type 1 diabetes reflected a lack of evidence of effectiveness of CGMs in such children (only a few studies having been conducted in this age group).

However, the group considered use of CGMs in this age group to be important because of the risk of adverse neurodevelopmental consequences of type 1 diabetes and parental anxiety (particularly in those with pre-school children). Further research in the form of a multi-centre RCT comparing CGMS with 5 or more capillary blood glucose tests per day is needed to achieve a large enough sample size. Important outcomes would include HbA1c levels, incidence of hypoglycaemia, satisfaction of the child and their family members or carers (as appropriate), and quality of life. Future research should ideally monitor neurodevelopmental consequences but this would require studies with long-term follow up.

More recent diagnostic guidance² (DG 21) discusses and compares two integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes. It recommends one system as an option for people with type 1 diabetes who experience frequent episodes of disabling low blood glucose (hypoglycaemia) despite optimal management with insulin pump therapy. However, it also states that the overall evidence base to support the best use of integrated sensor augmented pump therapy systems needs to be improved in order to demonstrate that using the system results in a sustained clinical impact on preventing or improving control of disabling hypoglycaemia.

It should be noted that as the NICE guidance was written in 2016, the devices discussed have already been superseded with new versions.

EVIDENCE 3

The evidence base for CGM is weak with many studies underpowered and not definitively conclusive. Evidence was most prevalent for impact on HbA1c and on incidence of hypoglycaemia. Few if any studies addressed the impact on quality of life, economic impact or on aspects of CGM use such as exercise.

CGM has been shown to lead to modest reduction in HbA1c both with insulin pump therapy (CSII) and in those on multiple daily injections (MDI). However this was not demonstrated universally in all studies. Improvement was approximately 0.3-0.5% HbA1c in the majority of studies. Individual RCT's demonstrated stronger evidence of benefit than systematic reviews and meta-analyses.

CGM reduces the incidence of hypoglycaemia, particularly nocturnal hypoglycaemia, both with CSII and MDI. But again this effect was not demonstrated in all studies. CGM seems to have the most positive effect on reducing (but not eliminating) hypoglycaemia in motivated patients with good metabolic control who are compliant with sensor wear. The efficacy of CGM improves with greater frequency of use. The highest efficacy is seen with usage >60% of the time.

Fear of hypoglycaemia is reduced with sensor augmented pump therapy (SAPT). Some studies suggested improvement in QOL but there has been no rigorous assessment of QOL.

Sensor augmented low glucose suspend pump therapy reduced the incidence of hypoglycaemic events particularly nocturnal hypoglycaemia.

Successful use of CGM and SAPT is likely to require intensive support and education. The degree to which support and the more advanced functions of CGM may optimise therapy is not well documented in the published studies.

RECOMMENDATION

Ongoing ‘Real-time’ CGM is recommended for the following paediatric patients with Type 1 diabetes mellitus (DM):

Neonates, infants & pre-school children:

- where there is impaired awareness of hypoglycaemia associated with adverse consequences (for example, seizures or anxiety) or inability to recognize, or communicate about, symptoms of hypoglycaemia (e.g. because of cognitive or neurological disabilities).

Children and young people with type 1 diabetes who have:

- frequent severe hypoglycaemia **OR**
- impaired awareness of hypoglycaemia associated with adverse consequences (for example, seizures or anxiety). GOLD score should be ≥ 4 or inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities).

Note that if CGM is to be commenced in addition to insulin pump therapy as a therapeutic tool to improve control the CGM should be commenced prior to the insulin pump therapy unless there is a clinical reason why sensor augmented pump therapy is indicated.

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Transition from paediatric care: For patients already using CGM and having demonstrated significant clinical benefit, funding will continue where this is maintained and where on-going provision is justified.

Note that if a patient does not need a hypoglycaemia alarm, then the Freestyle Libre system should be considered as a cheaper option. The STP policy on Freestyle Libre can be found here:

<https://prescribing.wiltshireccg.nhs.uk/prescribing-guidance-by-bnf-chapter/endocrine>

INITIATION AND CONTINUATION

The decision to start CGM will only be made by the diabetes consultant. The CGM device will be provided by the specialist team and initially on a 6 month trial basis only. It will only be continued if they have continued benefits such as a sustained decrease in the number of hypoglycaemia episodes, if that was the reason for initiation. Such targets for reductions in the number of episodes of hypoglycaemia should be set individually for each patient.

Responsibilities of the family using CGM:

- Main carers and family to show commitment to the successful use of CGM and to engage fully with the medical advice and recommendations of the diabetes team
- To attend at least 4 clinic appointments/year, as per NICE guidance for review, HbA1C and blood checks.
- Commit to using CGM at least 70% of the time and to calibrate it as needed. Also to act on high and low readings appropriately.
- To download CGM at home monthly, to enable proactive management of the child's diabetes, and liaise with the team as agreed
- Take personal responsibility for care of the sensor i.e. Insurance and maintenance
- Take responsibility for ordering and receiving appropriate levels of consumables
- To attend all education sessions organised by the team
- To check blood glucose readings at least 6-8 times daily, depending on the device used and act on high and low readings appropriately
- Always perform a finger prick check for rapidly changing blood glucose levels or sensor readings <4mmol, for driving (if applicable) or if symptoms do not match the system reading.
- The CGM sensor and transmitters remain the property of the acute trust and should be returned promptly if no longer required or if assessed that CGM is no longer the best option for diabetes management.

Responsibilities of the Paediatric Diabetes Team:

- Assess the suitability of the patient for CGM against CCG policy
- Provide CGM education and assessment for child, family and nursery/school before CGM start, as per team CGM education and on an on-going basis
- Provide trouble-shooting support via nurse telephone helpline Monday to Friday 8:30-5pm and out of hours via on call paediatric registrar.
- Provide ongoing CGM education
- Arrange for a minimum of 4 follow up clinic visits in a year along with HbA1c measurements and ensuring family has 8 other contact with team/ year e.g. telephone contacts, school or education sessions
- If the CGM is found to meet the criteria for continuation at 6 months, review on-going suitability of CGM annually to ensure sustained improvement, safety of use to achieve goals and ongoing eligibility according to CCG policy criteria. Report back to the commissioner at 6 months and then annually for on-going funding.
- Ensure that the family know how to order supplies of sensors and consumables

Criteria to withdraw CGM:

Withdraw continuous CGM after 1 month if:

- CGM has not been used 70% of the time – every day.
- Family have not attended all recommended education sessions unless extenuating circumstances

Withdraw CGM at 3 months if:

CGM has not been used 70% of the time – every day.

No improvement in glycaemic control – e.g. HbA1c did not improve by >0.5% if it was >7.5% at start of CGM therapy

No improvement in scores on fear of hypoglycaemia scales where CGM was introduced for anxiety

No improvement in hypoglycaemia unawareness if introduced for hypoglycaemia unawareness (Gold score)

No reduction in frequency of hypoglycaemia – particularly nocturnal hypoglycaemia (assessed from CGM download)

Benefit from CGM should be clearly evidenced and documented in the notes. CGM does not need to be reviewed for withdrawal if it was introduced following hypoglycaemic seizures and provided it is being used 70% of the time each day or in younger children providing it is in regular use.

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PROVIDER REPORTING TO COMMISSIONERS

Specialist teams must audit and monitor outcomes in any patients started on the new system. Regular reviews will take place to ensure that continuing benefit is being achieved and also to ensure that patients and their families are regularly using the equipment.

Commissioners will require regular annual reports on outcomes to ensure continued funding.

Acute trust providers must use IT systems to support and allow implementation of the policy such as the ability to identify a list of patients currently using CGM to allow monitoring of outcomes of treatment and decision to allow continued funding in line with local CCG policy.

Commissioners will monitor the uptake of CGM as well as use of insulin pumps and will review this policy accordingly.

CLINICAL PRIORITIES FOR OUR CCGs

The CCG have a duty to prioritise spending of a finite resource locally and made a decision which it felt gave the most equitable and effective use of investment.

This policy will be reviewed in the light of any relevant national guidance that is published.

References:

- Diabetes (type 1 and type 2) in children and young people: diagnosis and management. NICE NG18, August 2015 (updated November 2016) <https://www.nice.org.uk/guidance/ng18>
- 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) NICE DG21 February 2016. <https://www.nice.org.uk/guidance/dg21>
- ACDC Executive Summary Clinical Guideline: 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 April 2017 <http://www.a-c-d-c.org/wp-content/uploads/2012/08/CGM-FGS-Executive-Summary-April-2017.pdf>

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