Policy for Continuous Glucose Monitoring for Type 1 Diabetic Patients

PRIOR APPROVAL REQUIRED

This policy sets out the criteria to be met for approval of funding for continuous glucose monitoring for patients with Type 1 diabetes.
The policy applies to commissioners and providers of NHS services for adult and paediatric patients with Type 1 diabetes.

Legal considerations

The policy is based on NICE guidelines. These have the status of guidance, and there is no legal obligation to make funding available.
Guidance on the use of continuous glucose monitoring (CGM) is provided in three NICE guidelines:
NICE NG 17 Type 1 diabetes in adults: diagnosis and management;
NICE NG 18 Diabetes (type 1 and type 2) in children: diagnosis and management; *and*
NICE NG 3 Diabetes in pregnancy: management from preconception to the post-natal period
Continuous Glucose Monitoring (CGM) NOT Flash Glucose Monitoring is now the preferred option for pregnant women with type 1 diabetes. See NHSE information for further advice:
https://www.england.nhs.uk/ltphimenu/diabetes-prevention/improved-access-to-technologies-flash-glucose-monitors-for-people-with-type-1-diabetes-and-continuous-glucose-monitoring-for-pregnant-women/

Eligibility for CGM devices

CGM devices should not be *routinely* offered to people with type 1 or type 2 diabetes.
The following **basic eligibility criteria** for CGM must be met before CGM may be considered for any patient:

- 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.
- 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 or Freestyle Libre, dietetic care, structured education and, where necessary, specialist psychological support to manage their diabetes prior to being considered for a CGM device.
- 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.
- Patients must be willing to commit to use their CGM device at least 70% of the time. All patients must be willing to commit to training in the use of their device and to on-going regular follow-up and monitoring.

Patients will be considered for CGM if despite optimised use of insulin and conventional blood glucose monitoring eight or more times per day, they meet one or more of the following criteria:

1. Frequent severe hypoglycaemia: patients with Type 1 diabetes mellitus with more than 1 episode in the previous year of severe hypoglycaemia with no obviously preventable precipitating cause
    - o *For this policy, severe hypoglycaemia is defined as having low blood glucose levels (<4.0 mmol/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)*

Or

2. Patients with Type 1 diabetes mellitus with impaired awareness of hypoglycaemia (IAH)
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. Complete loss of awareness should be measured using the Gold or Clarke questionnaire and assessed in combination with clinical presentation
Or

3. Patients with Type 1 diabetes mellitus with inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities).

Or
4. Neonates, infants and pre-school children with inability to recognise, or communicate about, symptoms of hypoglycaemia.

- *Note: The child should be reviewed regularly (at least every six months) and the need for CGM re-evaluated once s/he is able to communicate effectively. It is anticipated that the child will have transferred to an alternative method of glucose monitoring before s/he starts school. If not, a further application for funding, demonstrating how the child meets one of the other criteria in this policy will need to be made, as funding under this criterion will normally be discontinued when the child reaches school age.*

Transition from paediatric care: For patients already using CGM and having demonstrated significant clinical benefit justifying on-going provision, commissioners will require regular update reports for continuing funding as adults.
Note that Freestyle Libre system should have been considered as a cheaper option and ruled out if it would not be appropriate for the patient.
The NHS BSW CCG policy on Freestyle Libre can be found HERE

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 patient/family/carer using CGM:

- Patient/carers/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 clinic appointments, 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, to enable proactive management of the patient'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 sensor readings regularly 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 Diabetes Team:

- Assess the suitability of the patient for CGM against CCG policy
- Provide CGM education and assessment for patient/carer/family/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 for paediatrics only, out of hours via on call system.
- Provide ongoing CGM education
- Arrange for follow up clinic visits along with HbA1c measurements. For paediatric patients, also ensuring family has 8 other contacts with team per 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 patient/carer/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.
- Patient/carer/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 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.

Dual technology (Insulin pump plus CGM):

A prior approval form with information as to why the patient needs to add CGM to a pump is required.

A flow chart of how a patient should progress through various diabetes technologies should be used with this policy and can be found HERE (ADD LINK).

Application for funding for CGM

Clinicians wishing to apply for funding for CGM for a patient meeting the criteria in this policy should do so via the prior approval form on https://bswccg.nhs.uk/your-health/what-we-do-and-don-t-fund

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 (link above).

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 December 2020) 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 DG21February 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
- Type 1 diabetes in adults: diagnosis and management. NICE NG17 August 2015, updated Dec 2020. https://www.nice.org.uk/guidance/ng17
- Diabetes in pregnancy: management from preconception to the postnatal period. NICE NG3 February 2015, updated December 2020. https://www.nice.org.uk/guidance/ng3