NHS Shropshire Clinical Commissioning Group and NHS Telford & Wrekin Clinical Commissioning Group Joint Commissioning Policy: Continuous Glucose Monitoring (CGM) for Type 1 diabetes in Children and Young People aged up to 19 years.

(This policy does not apply to Flash Glucose Monitoring.)

Policy statement: NHS Shropshire CCG and NHS Telford & Wrekin CCG do NOT routinely commission Continuous Glucose Monitoring (CGM). Both CCGs recommend the use of a CGM system, with a built in alarm, for Children and Young People aged up to 19 years with Type 1 diabetes, who meet the clinical criteria specified in this policy.

In line with NICE guidance it would be expected that CGM will only be required for a limited number of patients per year. CGM will require prior approval via Blueteq at the time of initiation. If the number of requests is higher than expected then this policy will be reviewed.

Background
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, 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. For this reason, a finger prick blood glucose check is recommended if changing treatment (e.g. taking more insulin or treating a hypo). The cost of commissioning a CGM is £3,000 to £3,500 per patient per year.

NICE issued clinical guidance (CG18) in August 2015 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. It also included mention of ‘offering’ and ‘considering’ CGM in certain circumstances.

Summary of the evidence

Cost-effectiveness depends on many factors, including comparison with standard monitoring with finger prick blood glucose tests – the frequency of which can vary greatly. NICE guidance NG18 points out that “Excessive testing can be more expensive than continuous glucose monitoring and clinicians can use excessive testing as a rationale for requesting funding for continuous monitoring system.”

The NICE guideline development group considered the clinical and cost effectiveness of real-time CGM systems compared to 5 or more capillary blood glucose tests per day in children aged 5 years or younger with type 1 diabetes who use insulin pump therapy. Their recommendation was to “consider” ongoing real-time CGM systems for neonates, infants and pre-school children with Type 1 diabetes. This weak recommendation reflected a lack of evidence of effectiveness of CGM in such children (only a few studies having been conducted in this age group).
The group considered use of CGM in this age group to be important because of the risk of the 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 randomized controlled trial (RCT) comparing CGM system with 5 or more capillary blood glucose tests per day would be needed to achieve a large enough sample size.

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.

### Funding criteria for CGM in Children and Young People aged up to 19 years

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.

Offer ongoing real-time continuous glucose monitoring (with an alarm) to children and young people with Type 1 diabetes who:

- Have been informed of the advantages and disadvantages of continuous glucose monitoring and expressed a continued wish to initiate CGM.
- 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.
- Demonstrate a willingness to engage in all necessary training regarding the optimal use of CGM and commit to ongoing regular follow-up and monitoring (including remote follow-up where this is offered)
- Are willing to commit to using CGM at least 70% of the time OR for a minimum of 5 days per week and to calibrate it as needed

AND

Who meet **ONE OR MORE** of the following criteria despite optimal use of insulin therapy and undertaking of conventional blood glucose monitoring eight or more times per day:

- Frequent severe hypoglycaemia with no obvious preventable cause 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)

- Impaired awareness of hypoglycaemia (IAH) associated with adverse consequences
  
  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.\(^6\)

OR

- Have an inability to recognise, or communicate about, symptoms of hypoglycaemia (for example because of cognitive or neurological disabilities).\(^2\)
  
Exclusions: This would normally exclude neonates, infants and pre-school children
  
Consider ongoing real-time continuous glucose monitoring for\(^6\):

- 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) that can make blood glucose control difficult.

---

**Withdrawal criteria for CGM in Children and Young People aged up to 19 years**

**CGM should be withdrawn after one month who:**\(^4\)

- Have not attended all education unless extenuating circumstances
  
  or
  
- Have not used the device for at least 70% of the time (5 days a week)

**CGM should be withdrawn after three months who:**\(^4\)

- Have not used the device for at least 70% of the time (5 days a week)
  
  OR
  
- Have no improvement in glycaemic control – HbA1c did not improve by >0.5% if it was >7.5% at start of CGM therapy
  
  OR
  
- Have no improvement in hypoglycaemia unawareness if introduced for hypoglycaemia unawareness (Clarke score)
  
  OR
  
- Have no reduction in frequency of hypoglycaemia – particularly nocturnal hypoglycaemia (assessed from CGM download)

---

**Continuation review of CGM**

- To ensure CGM is clinically appropriate, objective measures of improvement should be agreed and documented for each patient individually prior to application for funding.\(^6\)
- Patients using CGM will be assessed by their specialist at one month and three months to ensure that the benefits of CGM are demonstrated (see above).
- 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\(^5\). 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 CCG and NHS Telford & Wrekin CCG adult CGM criteria.

- Blueteq approval for continuation will be required

This policy is based on the best available information at the time of writing.

References

Adopted from Vale of York, Gloucestershire, Greater Preston and Birmingham and Solihull CCG


