

Policy for Continuous Glucose Monitoring for Type 1 Diabetic Adult Patients (>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 (see separate policy here: <https://prescribing.wiltshireccg.nhs.uk/prescribing-guidance-by-bnf-chapter/endocrine>).

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 or partners.

NICE GUIDANCE^{1,2}

NICE issued guidance in August 2015 about the diagnosis and management of type 1 diabetes in adults (NG17)¹. This covered a wide range of issues affecting clinical care, such as diet, exercise and insulin regimes. In this guidance, NICE stated "Do not offer real-time continuous glucose monitoring **routinely** to adults with type 1 diabetes."

NICE said that we should **consider** real-time continuous glucose monitoring for adults with type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed, and who have any of the following despite optimised use of insulin therapy and conventional blood glucose monitoring:

- More than one episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.
- Complete loss of awareness of hypoglycaemia.
- Frequent (more than two episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.

NICE GUIDANCE continued:

- Extreme fear of hypoglycaemia.
- Hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day (see recommendations 1.6.11 and 1.6.12). Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more.

In the research recommendations section of NICE NG17 it states: *Current continuous glucose monitoring systems were found not to be cost-effective in the de novo analysis carried out for this guideline, even in people who had impaired awareness of hypoglycaemia. In adults with type 1 diabetes who have high HbA1c values, there still may be some value in using continuous glucose monitoring systems, and further research is needed to determine whether newer technologies would prove to be cost-effective, particularly in this group.*

More recent NICE diagnostic guidance² (DG 21, February 2016) discusses and compares two integrated sensor-augmented pump therapy systems (the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system) for managing blood glucose levels in type 1 diabetes.

MiniMed Paradigm Veo is recommended as an option for managing blood glucose levels in people with type 1 diabetes only if:

- they have episodes of disabling hypoglycaemia despite optimal management with continuous subcutaneous insulin infusion

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.

NICE also state that, in general, the cost-effectiveness analyses undertaken in DG21 could not be considered robust because the insufficient evidence base for clinical effectiveness leads to a large amount of uncertainty in the incremental clinical-effect estimates.

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

EVIDENCE

A Cochrane systematic review from 2012³ and NICE systematic review (NICE DG21) form the basis of the evidence for CGM. These, and subsequent small, low quality studies show that real-time CGM is associated with only a modest improvement in HbA1c (0.30% reduction).

- No clinical difference between real-time or retrospective CGM and SMBG has been shown for:
 - hypoglycaemia (episodes/day)
 - severe hypoglycaemia (per 100 patient years)
 - severe hypoglycaemia (annualised rate)
 - adverse events
 - QoL measures of physical health, mental health, Hypoglycemia Fear Survey (HFS) Problem Areas In Diabetes (PAID) and total score
 - HbA1c (retrospective CGM)
 - number of people experiencing episodes of severe hypoglycaemia.
- One RCT found that real-time-CGM with an alarm compared to SMBG was associated with:
 - Reduced time spent outside target (h/day): 9.6 vs 11.0 (95% CI -2.52 to -0.28, p=0.0149)
 - Reduced time in hypoglycaemia (h/day): 1.0 vs 1.6 (95% CI -1.2 to -0.1, p=0.030).
- It is not clear to what extent the reduced time outside target (1.4h/day) or reduced time in hypoglycaemia (0.6h/day) is clinically significant nor whether over time, the cumulative reduction in these events prevents the incidence of complications and comorbidities.
- There were no studies that included adherence and patient satisfaction.

More recently, the HypoDE study⁴ has shown that a significant reduction in hypoglycaemia events in patients using CGM versus standard monitoring methods (incidence rate ratio 0.28, 95% CI 0.2-0.39, p<0.0001).

COST EFFECTIVENESS

Estimates of cost-effectiveness of CGM compared to SMBG are unreliable. None of the studies included found CGM to be cost-effective at the £20,000 per QALY threshold.

RECOMMENDATION

CGM is recommended for the following adult patients with Type 1 diabetes mellitus (DM) as long as they have previously attended structured education (e.g. Freedom for Life), are NOT using an insulin pump and who have any of the following despite optimised use of insulin therapy and conventional blood glucose monitoring:

- **More than one episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.**
- **Frequent (more than two episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.**
- **Inability to recognise hypoglycaemia** due to an inability to recognise, or communicate about symptoms of hypoglycaemia (e.g. due to cognitive or neurological disabilities), especially in people who live on their own or are single parents to young children. GOLD score should be ≥ 4 .

Note that if CGM is to be commenced in addition to insulin pump therapy as a therapeutic tool to improve control this will require an IFR.

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 if a patient does not need a hypoglycaemia alarm, then the Freestyle Libre system should be considered as a cheaper option.

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 **six month trial basis only**. It will only be continued if the patient has a decrease in the number of hypoglycaemia episodes that is sustained. Targets for reductions in the number of episodes of hypoglycaemia should be set individually for each patient.

Responsibilities of the patient using CGM:

- 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 four clinic appointments per 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 data at home monthly, to enable proactive management of 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 $< 4\text{mmol}$, 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.

INITIATION AND CONTINUATION contd

Responsibilities of the Diabetes Team:

- Assess the suitability of the patient for CGM against CCG policy
- Provide CGM education and assessment for the patient before CGM starts, as per team CGM education and on an on-going basis
- Provide trouble-shooting support via nurse telephone helpline
- Provide ongoing CGM education
- Arrange for a minimum of 4 follow up clinic visits in a year along with HbA1c measurements
- 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 NICE 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 ONE month if:

- CGM has not been used 70% of the time – every day.
- Non-attendance at education sessions unless extenuating circumstances

Withdraw CGM at THREE 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.

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.

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 are regularly using the equipment.

Commissioners may require regular reports on outcomes to ensure continued funding.

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 has a duty to prioritise spending of a finite resource locally and made a decision which it feels 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:

1. Type 1 diabetes in adults: diagnosis and management. NICE NG17 August 2015, updated July 2016.
<https://www.nice.org.uk/guidance/ng17>
2. 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>
3. Continuous glucose monitoring systems for type 1 diabetes mellitus. Cochrane Review January 2012; Langendam M, Luijf YM, Hooft L, DeVries JH, Mudde AH, Scholten RJPM.
http://www.cochrane.org/CD008101/ENDOC_continuous-glucose-monitoring-systems-for-type-1-diabetes-mellitus
4. Real-time continuous glucose monitoring in adults with type 1 diabetes and impaired hypoglycaemia awareness or severe hypoglycaemia treated with multiple daily insulin injections (HypoDE): a multicentre, randomised controlled trial. The Lancet April 7th 2018; 391:1367-1377.
<https://www.ncbi.nlm.nih.gov/pubmed/29459019>