

# Continuous glucose monitoring (CGM) in adults aged 19 years and older

Based on the recommendations of the East of England Priorities Advisory Committee

## Summary of Criteria Recommended for Funding

All recommendations apply to patients with Type 1 Diabetes Mellitus (T1DM) only.

1. Adults who have more than one episode a year of severe hypoglycaemia resulting in cognitive impairment requiring external assistance for recovery, despite optimisation of diabetes care, defined as:

Severe hypoglycaemia requiring the assistance of another person to administer carbohydrates, glucagon, or take other corrective actions.
2. Adults with persistent hypoglycaemia unawareness<sup>a,b,c</sup> with disabling hypoglycaemia<sup>d</sup>, despite optimised diabetes care or where the person is unable to communicate symptoms of hypoglycaemia with disabling hypoglycaemia.<sup>d</sup>
  - a. Score  $\geq 4$  on the Clarke hypoglycaemia unawareness questionnaire OR
  - b. Score  $\geq 4$  on the Gold hypoglycaemia unawareness Likert scale
  - c. Evidence of incidentally detected hypoglycaemia episodes from downloaded blood glucose data/significant hypoglycaemia lasting  $>15$  minutes confirmed by diagnostic CGM or downloaded blood glucose data, that occurred during the waking day which the patients were unaware of or unable to communicate.
  - d. Disabling hypoglycaemia is defined as repeated and unpredictable episodes of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life. Disabling hypoglycaemia is associated with one or more of the following features:
    - High frequency of blood glucose testing ( $\geq 8$  tests per day).
    - High frequency of blood glucose testing during night that disturbs sleep.
    - Persistent efforts to maintain high blood glucose levels in excess of the recommended maximum target in order to avoid hypoglycaemic episodes, that adversely affect metabolic control.
3. Routine funding for any other patients is not recommended.
4. Short term use of CGM for diagnostic purposes is included within the National Tariff and should not be separately funded.
5. The use of CGM will be audited and these recommendations will be reviewed after 1 year.

## 1. Background:

### Continuous Glucose Monitoring with alarms (CGM)

#### 1.1 The technology:

1.1.1 CGM devices consist of a subcutaneous glucose-sensing electrode which sends interstitial glucose levels to a paired receiver and/or insulin pump via a transmitter. [1]

All systems provide 3 pieces of information:

- current interstitial fluid glucose
- expected future trend
- glucose history over the preceding hours, days and weeks

All devices give an updated result every 5 minutes (equivalent to 288 tests daily).

1.1.2 CGM systems require calibration using finger-prick blood glucose testing a minimum of twice a day. Finger-prick test using a blood glucose meter is still required during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels (i.e. acute illness such as influenza, diarrhoea and vomiting), or if hypoglycaemia or impending hypoglycaemia is reported, or the symptoms do not match the system readings.

1.1.3 All devices require a minimum level of expertise and understanding on how to use them, interpret readings and take appropriate action, and require a commitment from the patient/carer to use appropriately and therefore not all devices may be suitable for all patients.

1.1.4 CGM devices may be stand-alone e.g the Dexcom range, or may be integrated with insulin pumps. Integrated devices are capable of suspending insulin infusion when BG falls below a pre-set level or suspend insulin infusion when hypoglycaemia is predicted from interstitial glucose readings.

1.1.5 Intermittent interstitial glucose monitoring (iGM) or Flash Glucose Scanning systems (FGS) e.g. Freestyle Libre® currently does not alarm if glucose levels are high or low. [2] The use of iGM e.g. Freestyle Libre is not considered in this document.

#### 1.2 NICE guidance:

NICE guidelines [NG17]: Type 1 diabetes in adults: diagnosis and management, does not recommend routine use of Continuous Glucose Monitoring (CGM) in adults, but states that CGM may be considered in certain patients [3].

Summary of NG17 Type 1 diabetes in adults: diagnosis and management recommendations on CGM [3]:

Do not offer real time continuous glucose monitoring routinely to adults with type 1 diabetes. [new 2015]

- 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 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.
  - Complete loss of awareness of hypoglycaemia.
  - Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.
  - 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. [new 2015]

- For adults with type 1 diabetes who are having real time continuous glucose monitoring, use the principles of flexible insulin therapy with either a multiple daily injection insulin regimen or continuous subcutaneous insulin infusion (CSII or insulin pump) therapy. [new 2015]
- Real-time continuous glucose monitoring should be provided by a centre with expertise in its use, as part of strategies to optimise a person's HbA1c levels and reduce the frequency of hypoglycaemic episodes. [new 2015]

The NICE Guidance Development Group concluded that current data do not support the routine use of CGM and that while there is some evidence of clinical benefit, this is not compelling and it is not currently a cost-effective intervention. [3]

The high cost of CGM devices and consumables prohibits the routine commissioning of CGM for all groups of patients for which NICE guidance state that CGM should be considered.

### 1.3 NICE Diagnostic guideline 21 makes the following recommendations on the use of the MiniMed Paradigm Veo. [4]

The MiniMed Paradigm Veo system 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 and
- the company arranges to collect, analyse and publish data on the use of the MiniMed Paradigm Veo system

The MiniMed Paradigm Veo system should be used under the supervision of a trained multidisciplinary team who are experienced in continuous subcutaneous insulin infusion and continuous glucose monitoring for managing type 1 diabetes only if the person or their carer:

- agrees to use the sensors for at least 70% of the time
- understands how to use it and is physically able to use the system and
- agrees to use the system while having a structured education programme on diet and lifestyle, and counselling.

People who start to use the MiniMed Paradigm Veo system should only continue to use it if they have a decrease in the number of hypoglycaemic episodes that is sustained. Appropriate targets for such improvements should be set.

- 1.3.1 NICE DG21 does not support the routine use of The Animas Vibe and Dexcom G4 Platinum CGM systems. [4] NICE Medtech innovation briefing MIB51 reviews the MiniMed 640G system (Medtronic) system but makes no specific recommendations on its use. [5] However, experience of using the technologies is developing and feedback from East of England Clinicians is that in practice, all these systems are in use with good outcomes for patients. CGM technologies are developing quickly with more devices coming on to the market. This document does not seek to recommend a particular device.
- 1.3.2 The high cost of CGM devices and consumables prohibits the routine commissioning of CGM for all groups of patients for who NICE recommend CGM should be considered. PAC have worked with clinicians in the East of England to identify patient groups to which the provision of this treatment should be targeted. PAC supports use in patients in the priority patient groups specified in this document. Use in other patient groups is considered a low priority for funding.

## 2. General funding recommendations:

2.1 CGM must be initiated and managed by a consultant-led Specialist Diabetes Team.

2.2 Funding approval including treatment aims, continuation and stopping criteria must be agreed with the commissioner before commencement of treatment – see individual criteria below.

2.3 Funding should be provided for an initial period of 6 months and reviewed every 12 months.

2.4 Funding should be continued where there is evidence of:

- Achievement of treatment goals specified for each criteria below.
- Evidence for need for continuation of treatment e.g. evidence of continued hypo unawareness as agreed with commissioner prior to commencement of treatment.

2.5 Funding for treatment should be discontinued where:

- Patient/carers are unable to cope with sensor/ managing technology despite intensive support by the diabetic team.
- Failure to wear the sensor >70% of the time. [4]
- Failure to achieve treatment goals specified for each criteria.

2.6 Diabetes teams must ensure that:

- The motivation of patient and their ability to manage the technology appropriately has been assessed.
- Patients are given education and training in the use of the CGM.

2.7 Before commencing treatment, clinicians must agree with the patient / carer the treatment aims and terms of use e.g. agree to use the sensors for at least 70% of the time, and confirming that they understand that:

- Funding for treatment will be withdrawn if treatment aims are not met or the technology is not used as per the agreed treatment plan.
- The need for ongoing CGM will be reviewed and that it will be discontinued at an appropriate time.

2.8 Teams must submit data on use of CGM annually to commissioners for the purposes of audit of the use of CGM technology.

## 3. PAC recommendations and rationale:

### Recommendation 1:

Adults who have more than one episode a year of severe hypoglycaemia resulting in cognitive impairment requiring external assistance for recovery, despite optimisation of diabetes care, defined as: [6]

- Severe hypoglycaemia requiring the assistance of another person to actively administer carbohydrates, glucagon, or take other corrective actions.

### Rationale:

Severe hypoglycaemic episodes often cause significant adverse events, such as seizures, and can result in permanent structural changes in the brain.

Additionally, anxiety about the recurrence following a severe hypoglycaemic event leads to high frequency of blood glucose testing ( $\geq 8$  tests per day) including testing during the night that disturbs sleep which is associated with a significant adverse effect on quality of life, and persistent efforts to maintain high blood glucose levels in excess of the recommended maximum target in order to avoid hypoglycaemic episodes, that adversely affect metabolic control.

#### **Treatment aims:**

- Reduction in the number of hypoglycaemic events
- Achievement and maintenance of target HbA1c agreed by the MDT
- Reduce blood glucose variability
- Improve quality of life

#### **Entry criteria**

- More than one episode a year of severe hypoglycaemia requiring the assistance of another person to actively administer carbohydrates, glucagon, or take other corrective actions despite optimised diabetes care.

#### **Review and stopping criteria**

- Review at 6 months and subsequently every 12 months against treatment aims and compliance criteria.
- 3 month trial without CGM after 3 years' treatment. Need for continued treatment assessed against criteria for funding CGM and Flash Glucose Scanning systems.

#### **Recommendation 2:**

Adults with persistent hypoglycaemia unawareness <sup>a,b,c</sup> with disabling hypoglycaemia <sup>d</sup>, despite optimised diabetes care, or where the adult is unable to communicate symptoms of hypoglycaemia with disabling hypoglycaemia. <sup>d</sup>

- a. Score  $\geq 4$  on the Clarke hypoglycaemia unawareness questionnaire OR
- b. Score  $\geq 4$  on the Gold hypoglycaemia unawareness Likert scale
- c. Evidence of incidentally detected hypoglycaemia episodes from downloaded blood glucose data/ significant hypoglycaemia lasting  $>15$  minutes confirmed by diagnostic CGM or downloaded blood glucose data, that occurred during the waking day which the patients were unaware of or unable to communicate. [7]
- d. Disabling hypoglycaemia is defined as repeated and unpredictable hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life [8]. Disabling hypoglycaemia is associated with one or more of the following features:
  - High frequency of blood glucose testing ( $\geq 8$  tests per day)
  - High frequency of blood glucose testing during night that disturbs sleep
  - Persistent efforts to maintain high blood glucose levels in excess of the recommended maximum target in order to avoid hypoglycaemic episodes, that adversely affect metabolic control.

#### **Rationale:**

The occurrence of frequent and unpredictable hypoglycaemia in people who are hypo unaware or unable to communicate symptoms of hypoglycaemia has significant consequences on the care of the person, and for their quality of life and that of their family/carers. Patients are also anxious about occurrence of severe hypoglycaemia.

The unpredictable nature of hypoglycaemia results in the need for frequent blood glucose testing ( $\geq 8$  times a day) and often testing during the night or while the person would otherwise be asleep. This has a significant negative impact on the quality of life of the person and the family/carers. The fear of severe hypos leads patients to maintain glucose levels at higher than recommended in order to reduce the risk of hypos, which results in poor control of HbA1c levels and increase of risk of long-term complications.

People with persistent hypoglycaemia awareness or where the person is unable to communicate symptoms of hypoglycaemia require a glucose monitoring system with alarms to alert them or their family/carers to a hypoglycaemic event. Flash glucose monitoring does not currently have an alarm and is not a suitable technology for this group of patients.

**Treatment aims:**

- Reduction in the number of hypoglycaemic events
- Achievement and maintenance of target HbA1c agreed by the MDT
- Reduce blood glucose variability
- Improve quality of life

**Entry criteria**

- Evidence of incidentally detected hypoglycaemia episodes from downloaded blood glucose data/ significant hypoglycaemia lasting  $>15$  minutes confirmed by diagnostic CGM or downloaded blood glucose data, that occurred during the waking day which the patients were unaware of or unable to communicate.  
AND
- Score  $\geq 4$  on the Clarke hypoglycaemia unawareness questionnaire OR score  $\geq 4$  on the Gold hypoglycaemia unawareness Likert scale  
AND
- Frequent blood glucose testing ( $\geq 8$  times per day) that is clinically appropriate on the recommendation of the diabetes specialist team, confirmed by data download from blood glucose testing meter.

**Review and stopping criteria:**

- Review at 6 months and subsequently every 12 months against treatment aims and compliance criteria.
- 3 month trial without CGM after 3 years' treatment. Need for continued treatment assessed against criteria for funding CGM and Flash Glucose Scanning systems.

All adults with Type 1 diabetes are advised to perform blood glucose testing a minimum of 4 times per day; pre meals to calculate bolus doses of insulin, and before bed time.

Additional tests are required to confirm a result indicating hypoglycaemia, where the result does not match symptoms and during times of illness.

It is estimated that most adults who are managed using insulin pumps blood glucose test on average 5 times per day. The use of CGM would see a drop in number of blood glucose tests to approximately 4 tests per day, representing a modest cost saving.

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7. Standardizing Clinically Meaningful Outcome Measures Beyond HbA1c for Type 1 Diabetes: A Consensus Report of the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the American Diabetes Association, the Endocrine Society, JDRF International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange Diabetes Care 2017;40:1622–1630 <https://doi.org/10.2337/dc17-1624>
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