The East of England
Priorities Advisory Committee
A function of PrescQIPP

GUIDANCE STATEMENT

Continuous glucose monitoring (CGM) in children and young people up to the age of 19

PAC recommendations

Continuous glucose monitoring with alarms for children and young people with type 1 diabetes mellitus up to the age of 19.

Summary of criteria recommended for funding. All recommendations apply to patients with type 1 diabetes mellitus (T1DM).

1. Children diagnosed with T1DM aged <2 years old (see section 3 for further details).
2. Children who have had more than one episode of severe hypoglycaemia resulting in temporary cognitive impairment requiring external assistance for recovery, despite optimisation of diabetes care, defined as:
   - For younger children who normally require assistance to correct even mild hypoglycaemia: severe hypoglycaemia associated with severe neurological features usually resulting in coma or seizure and requiring parenteral therapy (glucagon or intravenous glucose).
   - For older children and young people with diabetes: Severe hypoglycaemia requiring the assistance of another person to administer carbohydrates, glucagon, or take other corrective actions.
3. Children with persistent hypoglycaemia unawareness (see a and b below) with disabling hypoglycaemia, despite optimised diabetes care or where the child is unable to communicate symptoms of hypoglycaemia with disabling hypoglycaemia (see c below).

   a) Score ≥4 on the Clarke hypoglycaemia unawareness questionnaire OR score ≥4 on the Gold hypoglycaemia unawareness Likert scale.

   b) Evidence of incidentally detected hypoglycaemia episodes from downloaded blood glucose monitoring data/significant hypoglycaemia lasting >15 minutes confirmed by diagnostic CGM or downloaded blood glucose monitoring data, that occurred during the waking day which the patients were unaware of.

   c) 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 (≥ 8 tests per day)
   - High frequency of blood glucose testing during the 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.
4. Routine funding for any other patients is considered a low priority and is not recommended.
5. Short term use of CGM for diagnostic purposes is included within the National Tariff and should not be separately funded.
6. The use of CGM will be audited and these recommendations will be reviewed after one year.

Background

The technology

Continuous glucose monitoring (CGM) with alarms

CGM devices consist of three key components:[1]

- A subcutaneous sensor that measures interstitial glucose levels
- A transmitter that sends readings to a display device
- A display device that shows interstitial glucose levels. This might be a separate hand held device (known as "standalone" CGM) or a pump (known as an "integrated system")

All CGM devices have an alarm function to alert the patient to episodes of hypoglycaemia. Integrated devices are capable of suspending insulin infusion when blood glucose (BG) falls below a pre-set level or suspend insulin infusion when hypoglycaemia is predicted from interstitial glucose readings. A summary of device features can be seen in appendix 2.

CGM devices continuously monitor interstitial glucose levels providing the patient and health care professionals with detailed information on glucose trends.

CGM systems require calibration using finger-prick blood glucose testing a minimum of twice a day. Finger-prick testing 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.[2]

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/parents/carer to use appropriately and therefore not all devices may be suitable for all patients.[2,3]

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.[4] The use of iGM/FGS, e.g. Freestyle Libre is not considered in this document.

NICE guidelines

The 2015 NICE guideline [NG18] for diagnosis and management of diabetes (type 1 and type 2) in children and young people recommends the use of CGM in certain patients.[5]

Offer ongoing real-time CGM 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).

Consider ongoing real-time CGM 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) CGM to help improve blood glucose control in children and young people who continue to have hyperglycaemia despite insulin adjustment and additional support.

The NICE guideline [NG3] for diabetes in pregnancy: management from preconception to the postnatal period, states:[6]

- Do not offer CGM routinely to pregnant women with diabetes.
- Consider CGM for pregnant women on insulin therapy:
  - Who have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia) or
  - Who have unstable blood glucose levels (to minimise variability) or
  - To gain information about variability in blood glucose levels.

In NG3, the term 'women' is used in the guideline to refer to all females of childbearing age, including young women who have not yet transferred from paediatric to adult services. [6]

NICE Diagnostic Guidance 21 (DG21) makes the following recommendations on the use of the MiniMed Paradigm Veo:[2]

The MiniMed Paradigm Veo system is recommended as an option for managing blood glucose levels in people with T1DM 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 CGM for managing T1DM 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.

NICE DG21 does not support the routine use of the Animas Vibe and Dexcom G4 Platinum CGM systems.[2] The NICE Medtech Innovation Briefing (MIB51) reviews the MiniMed 640G system (Medtronic) system but makes no specific recommendations on its use.[7] However, experience of using the technologies is developing and feedback from East of England (EoE) 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. Since writing this document, Medtronic have launched the MiniMed 670G closed loop integrated insulin pump/CGM system. This document does not look at the place of this new technology in therapy.

The high cost of CGM devices and consumables prohibits the routine commissioning of CGM for all groups of patients identified in the NICE guidance. PAC have worked with clinicians in the EoE to define the patient groups which NICE recommend should be offered CGM. Where NICE have recommended that CGM should be considered, PAC support the use of CGM in very young children who are diagnosed with T1DM under the age of two in line with advice from EoE

paediatric specialists. Use in children who undertake high levels of physical activity or who have co-morbidities that make blood glucose control difficult, or in pregnancy is currently considered a low priority for funding.

The NHS Long Term Plan published in January 2019 states that by 2020/21, all pregnant women with T1DM will be offered CGM, helping to improve neonatal outcomes. At the time of writing, no details were available on funding arrangements to support this initiative. These recommendations will be reviewed when more information is available.[8]

General funding recommendations

CGM must be initiated and managed by a consultant-led specialist diabetes team.

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

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

Funding should be continued where there is evidence of:

- Achievement of treatment goals specified for each criteria below.
- The need for continuation of treatment, e.g. evidence of continued hypoglycemia unawareness as agreed with the Commissioner prior to commencement of treatment.

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.[2]
- Failure to achieve treatment goals specified for each criteria.

Diabetes teams must ensure that:

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

Before commencing treatment, clinicians must agree a contract with the child/parent/carer agreeing 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.

Teams must submit data on use of CGM annually to the Eastern Paediatric Diabetes Network and Commissioners for the purposes of audit of the use of CGM technology.

PAC recommendations and rationale

NB. Cost impact estimates have been based on a range of devices that are currently used in practice in the EoE using current known EoE contract prices or list prices. Cost impact estimates are indicative only – see accompanying spreadsheet for details. This document does not seek to recommend a particular device.

Recommendation 1

Children diagnosed with T1DM aged <2 years old

Rationale

This group of children are extremely challenging to manage as they are unable to recognise or communicate symptoms of hypoglycaemia and have unpredictable dietary intake leading to marked variability of blood glucose levels. Therefore, these patients need a high number of blood glucose tests and often testing during the night to manage the diabetes. All of these factors result in considerable parental anxiety and poor quality of life for the patient and the parents. Furthermore, in order to avoid hypos, the high blood glucose levels are accepted resulting in poor metabolic control. Early intensive control of hyperglycaemia is critically important as it is associated with reduced risk of diabetes-related complications in later life.[9]

Treatment aims

- Reduce frequency of hypoglycaemic events
- Achievement and maintenance of target HbA1c agreed by the Diabetes Team
- Reduce blood glucose variability
- Improve quality of life

Entry criteria

- Diagnosed with T1DM age <2 years

Review and stopping criteria

- Review ability to recognise and communicate symptoms of hypoglycaemia and continued need for CGM at each scheduled review.
- Three month trial without CGM at age five years. Need for continued treatment assessed against criteria for funding CGM and Flash Glucose Scanning systems.

Patient numbers

The number of children under two years of age diagnosed with T1DM are low, and the time of preparing this document there were only three children <2 years age being treated in the EoE.

Estimate no more than one patient per CCG however, treatment would be continued until age five.

Cost impact estimate per CCG

System	Cost per CCG per year
Medtronic Guardian2 Link transmitter and Enlite sensor	£3,794
Medtronic Minilink system	£3,594
Dexcom G6 stand-alone system	£2,445

Recommendation 2

Children who have had more than one episode of severe hypoglycaemia resulting in temporary cognitive impairment requiring external assistance for recovery, despite optimisation of diabetes care, defined as:[10]

- For younger children who normally require assistance to correct even mild hypoglycaemia: severe hypoglycaemia associated with severe neurological features usually resulting in coma or seizure and requiring parenteral therapy (glucagon or intravenous glucose).
- For older children and young people with diabetes: 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 (≥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 Diabetes Team
- Reduce blood glucose variability
- Improve quality of life.

Entry criteria

- Younger children who normally require assistance to correct even mild hypoglycaemia: One or more episode of severe hypoglycaemia associated with severe neurological features usually resulting in coma or seizure and requiring parenteral therapy (glucagon or intravenous glucose), despite optimised diabetes care.

OR

- Older children and young people: One or more episode 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 six months and subsequently every 12 months against treatment aims and compliance criteria.
- Three month trial without CGM after three years treatment. Need for continued treatment assessed against criteria for funding CGM and Flash Glucose Scanning systems.

Patient numbers

Estimate: 3% of caseload

Estimate: 1.57 patients per 100,000 total CCG population

Cost impact estimate per 100,000 population

System	Cost per CCG per year
Medtronic Guardian2 Link transmitter and Enlite sensor	£5,955
Medtronic Minilink system	£5,642
Dexcom G6 stand-alone system	£3,838

Recommendation 3

Children with persistent hypoglycaemia unawareness (see a and b below) with disabling hypoglycaemia (see c below), despite optimised diabetes care or where the child is unable to communicate symptoms of hypoglycaemia with disabling hypoglycaemia (see c below).

a) Score ≥4 on the Clarke hypoglycaemia unawareness questionnaire OR score ≥4 on the Gold hypoglycaemia unawareness Likert scale

b) Evidence of incidentally detected hypoglycaemia episodes from downloaded blood glucose monitoring data/ significant hypoglycaemia lasting >15 minutes confirmed by diagnostic CGM or downloaded blood glucose monitoring data, that occurred during the waking day which the patients were unaware of or unable to communicate.[11]

c) 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.[12] Disabling hypoglycaemia is associated with one or more of the following features:

- High frequency of blood glucose testing (≥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 children who are hypoglycaemia unaware or unable to communicate symptoms of hypoglycaemia has significant consequences on the care of the child, and for their quality of life and that of their family/carers. Patients and parents are also anxious about occurrence of severe hypoglycaemia; those with hypoglycaemia unawareness have six-fold greater incidence of severe hypoglycaemic episodes.[13]

The unpredictable nature of hypoglycaemia results in the need for frequent blood glucose testing (≥8 times a day) and often testing during the night or while the child would otherwise be asleep. This has a significant negative impact on the quality of life of the child and the family/carers. The fear of severe hypos lead parents/carers to maintain higher glucose levels 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.

Children with persistent hypoglycaemia awareness or where the child is unable to communicate symptoms of hypoglycaemia require a glucose monitoring system with alarms to alert 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.

Children with recently developed hypoglycaemia unawareness should be considered for management using FGS.

Treatment aims

- Reduction in the number of hypoglycaemic events
- Achievement and maintenance of target HbA1c agreed by the Diabetes Team
- 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

AND

- Score ≥4 on the Clarke hypoglycaemia unawareness questionnaire OR score ≥4 or the Gold hypoglycaemia unawareness Likert scale

AND

- Frequent blood glucose testing (≥8 times per day) that is clinically appropriate on the recommendation of the diabetes specialist team, confirmed by data download from the blood glucose testing meter

AND

- For patients with recently developed hypoglycaemia awareness (<3 months), management with Flash Glucose Scanning System (FGS) has failed to restore hypoglycaemia awareness.

Review and stopping criteria

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

Patient numbers

- Estimate: 4% of caseload
- Estimate 3.18 patients per 100,000 total CCG population

Cost impact estimate per 100,000 population

System	Cost per CCG per year
Medtronic Guardian2 Link transmitter and Enlite sensor	£12,075
Medtronic Minilink system	£11,440
Dexcom G6 stand-alone system	£7,782

Cost impact assessment

Estimated cost impacts are indicative only.

In 2015/16 the prevalence of T1DM in children and young people aged 0 to 15 years old in England and Wales was 195.4 per 100,000 of the general population*; slightly higher among males (197.9 per 100,000) compared to females (191.7 per 100,000).[14]

Extrapolating to cover all children under the age of 19, approximate prevalence is 244 per 100,000 of the general population*.

*National Paediatric Diabetes Audit report quotes prevalence in terms of the general paediatric population of children age 0-15.

All children with T1DM are advised to perform blood glucose testing a minimum of five times per day; pre meals to calculate bolus doses of insulin, before bed time and one random test.

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

Most children who are managed using insulin pumps blood glucose test on average 8 times per day. The use of CGM would see a drop in number of blood glucose tests to approximately 5 tests per day, representing a modest cost saving.

PAC approval date	14th January 2019
Version	1
Consultation process	PAC members, East of England Paediatric Diabetes Network
QA process	Katie Smith, Senior Clinical Pharmacist PrescQIPP, 27 February 2019

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Appendix 1: Assessment against Ethical and Commissioning Principles

Treatment assessed

Continuous Glucose Monitoring (CGM) for children.

East of England Priorities Advisory Committee Recommendation

- CGM is recommended for children with Type 1 diabetes mellitus (T1DM) who fulfil one or more of the following criteria:
  - Children diagnosed with T1DM aged < 2 years old.
  - Children who have had more than 1 episode of severe hypoglycaemia resulting in temporary cognitive impairment requiring external assistance for recovery, despite optimisation of diabetes care.
  - Children with persistent hypoglycaemia unawareness with disabling hypoglycaemia, despite optimised diabetes care or where the child is unable to communicate symptoms of hypoglycaemia with disabling hypoglycaemia.
- Routine funding for any other patients is considered a low priority and is not recommended.

Clinical effectiveness

There is limited data on the long term outcomes of using CGM in terms of fewer complications and reduced emergency admissions.

Cost effectiveness

Cost effectiveness of the use of CGM has yet to be established. More data on the cost-effectiveness of CGM is required.

Equity

No issues identified.

Needs of the community

The needs of the community are considered to be low as well established and accurate methods of monitoring glucose exist.

Need for healthcare (incorporates patient choice and exceptional need)

CGM is an emerging technology. It may address issues for those patients who are unable to recognise or communicate the symptoms of hypoglycaemia.

Policy drivers

NICE recommends the use of CGM as an option in certain circumstances, but it is not recommended for routine use.

Disinvestment

CGM is currently a high cost technology and routine funding would require disinvestment in other areas of healthcare provision.

Appendix 2: Summary of available CGM devices[15,16,17]

	CGM component	Insulin pump capable of integration	Key features	Average annual cost[1]	Evidence/NICE review
Integrated pumps with CGM	Medtronic MiniLink transmitter and Enlite sensor	Paradigm Veo (Medtronic)	• Alarm • Suspends insulin infusion if BG < lower limit	**£3,594	NICE DG21:[2] Recommended as option with conditions
	Medtronic Guardian 2 Link transmitter and Enlite sensor	MiniMed 640G*	• Alarm • Suspends insulin infusion if BG predicted to go < lower limit • Allows dose of insulin to be very small	**£3,794	No NICE guidance issued. NICE Medtech innovation briefing (MIB51)[7] No NICE guidance issued.
	A6 TouchCare CGM System	A6 TouchCare® (Medtrum)	• Alarm • Fully integrated system with low glucose suspend (LGS) and predictive LGS mechanism • CGM can be used as a standalone system	Not yet known	No NICE guidance issued.
Stand-alone CGM devices	Dexcom G4 Platinum	N/A	• Alarm	***£3,185 (+ receiver £350)	NICE DG21:[2] Insufficient evidence to support routine use as an integrated system for use with insulin pumps.Not considered by NICE as a stand-alone devices.
	Dexcom G5 mobile	N/A	• Alarm	***£3,065 (+ receiver £275)	
	Dexcom G6	N/A	• Alarm	***£2,445 (+ receiver £275)	Not considered by NICE
	Eversense XL CGM system (Roche	N/A	• Alarm	Not yet known	Not considered by NICE

*Since writing this document, Medtronic have launched the MiniMed 670G closed loop integrated insulin pump/CGM system. This document does not look at the place of this new technology in therapy.
**Based on East of England contract prices June 2018
***List prices provided by Dexcom June 2018 (NB may be eligible for up to 24% bulk purchase discount)