Birmingham and Solihull
Clinical Commissioning Group

CLINICAL COMMISSIONING POLICY

for

CONTINUOUS GLUCOSE MONITORING IN DIABETES

in relation to

- **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**

To note: This policy applies only to individuals who would be considered for continuous glucose monitoring. A further policy "Commissioning of flash glucose monitoring for patients with diabetes meeting the NHS England funding criteria" *is in place for patients who may be eligible for flash glucose monitoring.*

Version:	**V 2.0**
Ratified by:	**Quality and Safety Committee**
Name of originator/author:	**Kate Arnold – v1.0**
Name of revised update author:	**Hanadi Alkhder – v2.0**
Name of responsible committee/individual:	**Executive Management Team**
Name of executive lead:	**Richard Mendelsohn**
Date original ratified:	**23.10.18 – v1.0**
Updated and ratified:	**26.3.19 – v2.0**
Date issued:	**28.3.19**
Review date:	**Two years after ratification**
Target audience:	**Commissioners and providers of NHS services for patients with Type 1 or Type 2 diabetes**

Review and amendment log

Version no	Type of change	Date	Description of change
0.1		04.09.18	
0.2	Drafting Amends (HA) Clarification (HA)	05.09.18	Addition of sections on Application for funding and Mechanisms for supply Minor amends Explicit note that the policy applies to children and adults
0.3	Amends Addition	06.09.18	Final amends and addition of criterion relating to pre-school children FINAL DRAFT VERSION
0.4	Combination of CGM and flash for CGM draft policies Addition	25.09.18	 Addition of Appendix 1 Final draft version for CPSG
1.0		05.10.18	Final draft version for QSC ratification
2.0	Update	18.3.19	Removed flash glucose monitoring cohort from the policy with explanatory notes
		21.3.19	Changes approved by Chair of CPSG
2.0	Ratification	26.3.19	Final draft for QSC ratification
2.0	Publication	28.3.19	

Contents

Policy overview

Purpose

This policy sets out the criteria to be met for approval of funding for continuous glucose monitoring for patients with Type 1 or Type 2 diabetes.

Who this policy applies to

The policy applies to commissioners and providers of NHS services for adult and paediatric patients with Type 1 or Type 2 diabetes.

Key principles

The policy is based on the principle of providing high quality care for patients with Type 1 or Type 2 diabetes within the funds available to Birmingham and Solihull (BSol) Clinical Commissioning Group (CCG). Funding will be made available under this policy subject to the individual meeting the defined eligibility criteria.

It recognises that the CCG seeks to make decisions about which services to commission through a systematic approach. The intention of the CCG is to ensure access to NHS funding is equal and fair, whilst considering the needs of the overall population and evidence of clinical and cost effectiveness.

Given resource constraints, the CCG cannot meet every healthcare need of all patients within its area of responsibility. The fact that the CCG takes a decision not to commission a service to meet a specific healthcare need due to resource constraints is an inevitable fact of life in the NHS and does not indicate that the CCG is breaching its statutory obligations.

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. Both continuous glucose monitoring (CGM) and flash glucose monitoring have been considered via the CCG Clinical Priorities Advisory Group which has recommended that they be considered for commissioning, subject to the individual meeting the defined eligibility criteria.

Supporting principles

Guidance on the use of continuous glucose monitoring (CGM) is provided in three NICE guidelines:

- **NG 17 Type 1 diabetes in adults: diagnosis and management;**
- **NG 18 Diabetes (type 1 and type 2) in children: diagnosis and management; and**
- **NG 3 Diabetes in pregnancy: management from preconception to the post-natal period**

Since the publication of the NICE guidelines, a further technology for real-time management of glucose levels has been developed, notably flash glucose monitoring.

Both CGM and flash glucose monitoring measure interstitial glucose, and both enable patients to obtain frequent glucose levels without the need for finger-prick testing. Additionally, CGM has an audible alert function which triggers to advise patients and their carers when glucose levels become dangerously high or low. CGM costs approximately twice as much as flashGM.

The criteria set out in this policy were subject to an engagement process with clinicians at the major Trusts providing care for patients with Type 1 and Type 2 diabetes, via contracting leads. As a result of this engagement, the daily number of blood glucose test strips for all criteria other than hyperglycaemia was amended to 8 from 10. The figure of 10 was retained for hyperglycaemia in line with the NICE guidance. A criterion for neonates, infants and pre-school children was added.

Representation was also made in terms of the period of time for which CGM should be funded following childbirth for women who met the criteria for use of CGM during pregnancy, and the policy was amended accordingly.

The policy

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, 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
    - *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) 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. Complete loss of awareness in adults 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 frequent (more than 2 episodes a week) asymptomatic nocturnal hypoglycaemia
    - *Precipitating causes must be excluded*
    - *This assessment must be made using a blinded diagnostic CGM*
    - *Hypoglycaemia is defined as <4mmol/L*

Or

4. Patients with Type 1 diabetes mellitus with inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities).
    - *Exclusions: This would normally exclude neonates, infants and pre-school children*

Or

5. 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.*

Or

6. Pregnant women with Type 1 or Type 2 diabetes on insulin therapy who have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia) as defined above
    - *Note: The mother should resume their routine (non-pregnant) glucose monitoring regime within six months of delivery if breast-feeding, or three months of delivery if not breast-feeding.*
    - *Note: flash glucose monitoring may be a suitable alternative for patients in this cohort*

Or

7. Patients with Type 1 diabetes with frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.
    - *Precipitating causes must be excluded*
    - *Hypoglycaemia is defined as <4mmol/L*
    - *Note: flash glucose monitoring may be a suitable alternative for patients in this cohort*

Or

8. Patients with Type 1 diabetes with extreme fear of hypoglycaemia, which remains despite optimized medical therapy and intervention by a psychologist.
    - *Measured using the 'Hypoglycaemia Fear Survey'*
    - *Note: flash glucose monitoring may be a suitable alternative for patients in this cohort*

Or

9. Patients with Type 1 diabetes who continue to have hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher in adults; HbA_{1c} level of 69mmol/mol [8.5%] or higher in children) that persists despite testing at least **10 times** a day, despite insulin adjustment and additional support.
    - *Note: flash glucose monitoring may be a suitable alternative for patients in this cohort*

For those patients with Type 1 diabetes and recurrent severe hypoglycemia or impaired awareness of hypoglycemia, NICE suggests that Continuous Glucose Monitoring (CGM) with an alarm is the standard. Other evidence-based alternatives with NICE guidance or NICE TA support are insulin pump therapy, psychological support, structured education, islet transplantation and whole pancreas transplantation. However, if the person with diabetes and their clinician consider that a **flash glucose monitoring** system would be more appropriate for the individual's specific situation, then this can be considered.

For further information, relating to the commissioning of Flash Glucose Monitoring please refer to the CCG policy "Commissioning of Flash Glucose monitoring for patients with diabetes meeting the NHS England funding criteria"

Continuation criteria for CGM

Clinically appropriate, objective measures of improvement should be agreed and documented for each patient individually prior to application for funding.

Patients using CGM will be assessed by their specialist at one month and six months to ensure that the benefits of CGM are being realized.

The CGM Device will be withdrawn in patients where the device has not been used for at least 70% of the time and/or the agreed measures for improvement have not been achieved.

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.

Please see special conditions relating to neo-nates, infants and pre-school children incorporated in eligibility criteria above.

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 BlueTeq system.

Supply mechanisms for CGM

CGM, including provision of the most cost-effective monitor and organisation of consumables, will be managed through the specialist centres. Payment mechanisms currently in place for insulin pumps will be utilized for CGM.

General practitioners will remain responsible for prescribing of blood glucose testing strips, with guidance from the specialist centre on appropriate monthly quantities.

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, here.

IFR contact information follows, however please refer to the CCG IFR policy for more information.

Individual Funding Request Case Manager

Floor Two, Kingston House, 438 High Street, West Bromwich, West Midlands, B70 9LD

Telephone: 0121 612 1660

Email address for Individual Funding Request team

ifr.bsol1@nhs.net

Equality Statement

The general equality duty requires public authorities (such as the CCG) to have due regard to the aims of the general equality duty when making decisions and setting policies. To do this, it is necessary for the organisation to understand the potential impact of its decision-making on different people. This can help to identify practical steps to tackle any negative impacts or discrimination, and to advance equality.

The CCG endeavours to challenge discrimination, promote equality and respect human rights and aims to design and implement policies, services and measures that meet the diverse needs of our population, workforce and patients, ensuring that none are placed at a disadvantage.

Equality Analysis

The CCG undertakes an Equality Analysis of policies, decisions, service design etc. to assess the impact of decision making against:

- the nine protected characteristics (age, disability, ethnic origin, sex, sexual orientation, gender reassignment, religion and belief, marriage or civil partnership, pregnancy or maternity status),
- other groups or communities known to suffer disadvantage, such as the homeless, carers, sex workers
- Human Rights
- Known health inequalities

The analysis also includes explores the potential to support the Social Value Act.

An Equality Analysis of this policy was undertaken on 02.10.18. This has been published on the CCG webpages under Equality, Diversity and Inclusion.