Commissioning Policy

NHS Redditch and Bromsgrove Clinical Commissioning Group

NHS South Worcestershire Clinical Commissioning Group

NHS Wyre Forest Clinical Commissioning Group

Continuous Glucose Monitoring in Children and Young People

(managed within Paediatric Diabetes Services)

April 2019

This policy applies to patients for whom the following Clinical Commissioning Groups are responsible:

- NHS South Worcestershire Clinical Commissioning Group (CCG)
- NHS Redditch & Bromsgrove Clinical Commissioning Group (CCG)
- NHS Wyre Forest Clinical Commissioning Group (CCG)

Collectively referred to as the Worcestershire CCGs

COMMISSIONING SUMMARY

Worcestershire CCGs (also termed "the Commissioner" in this document) **will fund** the provision of Continuous Glucose Monitors, if clinically appropriate and within the recommendations of this policy, for patients with insulin-dependent type 1 diabetes (unless otherwise stated) as follows:

Flash Glucose Monitoring (FlashGM)

- Monitoring > 8 times a day (also insulin-dependent type 2 on haemodialysis)
- Diabetes associated with cystic fibrosis
- During pregnancy (12 months total including post-delivery period)
- Unable to routinely self-monitor blood glucose due to disability requiring carer support for monitoring and insulin management
- Occupational or psychosocial circumstances warranting use
- Recurrent severe hypoglycaemia
- Impaired awareness of hypoglycaemia
- Avoidance of alternative specialist treatment e.g. insulin pump or rtCGM where appropriate

Real-time Continuous Glucose Monitoring (rtCGM)

- Frequent severe hypoglycaemia
- Hypoglycaemia unawareness with adverse consequences
- Inability to recognise or communicate hypoglycaemia symptoms
- Neonates/infants/<4yrs of age where persistent difficulties with blood glucose control

And where FlashGM has provided insufficient benefit:

- Impaired awareness of hypoglycaemia evidenced by FlashGM
- High levels of physical activity or recurrent severe hypoglycaemia following activity that cannot be resumed
- Comorbidities/other treatments causing persistent difficulties with blood glucose control
- Hyperglycaemia despite insulin adjustment and additional support

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Clinical Commissioning Policy Collaborative, which includes: GPs, Commissioners, Medicines Commissioning, Public Health, Patient and Public Representatives		
Area Prescribing Committee		

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1. Definitions

1.1 **Diabetes mellitus** (DM) is a chronic disease caused by inherited and/or acquired deficiency in production of insulin by the pancreas, or by the ineffectiveness of the insulin produced. Such a deficiency results in increased concentrations of glucose (sugar) in the blood, which in turn damages many of the body's systems, in particular the blood vessels and nerves. There are two principle forms of diabetes:

a. Type 1 diabetes (formerly known as insulin-dependent) in which the pancreas fails to produce the insulin which is essential for survival. This form develops most frequently in children and adolescents but is being increasingly noted later in life.
b. Type 2 diabetes (formerly named non-insulin-dependent) which results from the body's inability to respond properly to the action of insulin produced by the pancreas. Type 2 diabetes is much more common and accounts for around 90% of all diabetes cases worldwide. It occurs most frequently in adults but is being noted increasingly in adolescents as well.

1.2 **Continuous Glucose Monitoring** (CGM) is used in diabetic patients who rely on insulin to control their diabetes. It involves use of a small device worn just under the skin; this measures interstitial glucose (sugar) levels continuously throughout the day and night, identifying trends in glucose levels. Some devices provide alerts for highs and lows to facilitate disease control. There are different types of CGM available:

a. **Real-time CGM** (rtCGM) uniformly tracks glucose concentrations in the body's interstitial fluid, providing near real-time glucose data. There are different types of rtCGM, those that can be used independently (standalone) and those that are used with an insulin pump (insulin pump compatible).
b. **Intermittent CGM** (iCGM) uses similar methodology to show continuous glucose measurements retrospectively at the time of checking. This is also known as **Flash Glucose Monitoring** (FlashGM).

1.3 **Self-monitoring blood glucose** (SMBG) involves a skin prick to draw blood and the application of a chemically active test-strip to the blood. The test-strip is inserted into a meter which provides a reading for the concentration of glucose (sugar) in the blood at that time. This is the standard method of measuring and monitoring blood glucose in diabetic patients, particularly those who use insulin to manage their disease.

1.4 **Insulin pumps** are small electronic devices that deliver regular insulin to the body throughout the day and night. There are 2 types of insulin pump – a tethered pump and a patch pump. Both are attached to the body by a tiny tube called a cannula which sits just under the skin. Insulin pumps may be used with or without CGM.

1.5 **Hypoglycaemia** is where the level of glucose (sugar) in the blood drops to less that 4mmol/l; it mainly affects people with diabetes, especially those using insulin.

1.6 **Hyperglycaemia** is where the level of glucose (sugar) in the blood is excessively high; it mainly affects people with diabetes and if it persists can cause damage to the body's internal organs.

1.7 **Nocturnal hypoglycaemia** is an episode of abnormally low blood glucose (sugar) occurring at night-time during sleep.

1.8 **HbA1c** is a measurement in the blood that represents the average blood glucose (sugar) levels for the last two to three months. A high HbA1c means there is too much sugar in the blood indicating that diabetes complications are more likely to occur.

1.9 **Exceptional clinical circumstances** are clinical circumstances pertaining to a particular patient, which can properly be described as exceptional, when compared to the clinical circumstances of other patients with the same clinical condition and at the same stage of development of that condition (i.e. similar patients). A patient with **exceptional clinical circumstances** will have clinical features or characteristics which differentiate that patient from other patients in that cohort and result in that patient being likely to obtain significantly greater clinical benefit (than those other patients) from the intervention for which funding is sought.

1.10 A **Similar Patient** is a patient who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. The existence of more than one similar patients indicates that a decision regarding the commissioning of a **service development** or commissioning policy is required of the Commissioner.

1.11 An **individual funding request (IFR)** is a request received from a provider or a patient with explicit support from a clinician, which seeks exceptional funding for a single identified patient for a specific treatment.

1.12 An **in-year service development** is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Commissioner agrees to fund outside of the annual commissioning round. Such unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.

2. Scope of policy

2.1 This policy is part of a suite of locally endorsed commissioning policies. Copies of these commissioning policies are available on the following website address: http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/

2.2 This policy applies to all patients for whom the Worcestershire Clinical Commissioning Groups (CCGs) have responsibility including:

- People provided with primary medical services by GP practices which are members of any one of the CCGs and
- People usually resident in any of the areas covered by the CCG's and not provided with primary medical services by any CCG.

2.3 Where a patient's clinical presentation does not clearly meet the requirements for secondary care referral within the context of this policy, and where a GP is uncertain or concerned about the appropriate treatment/management pathway, referral for advice & guidance should be considered as an alternative to a referral for clinical assessment.

2.4 There may be occasions when a primary care referral is made for specialist assessment which appears to meet the policy requirements, but which on specialist clinical examination either does not meet the clinical criteria for the intervention or is not considered clinically suitable for the intervention. Such patients should be discharged without the intervention.

2.5 For patients who do not fall within the eligibility criteria set out in the policy but where there is demonstrable evidence that the patient has exceptional clinical circumstances, an Individual Funding Request may be submitted for consideration. The referring clinician should consult the Commissioner's "Operational Policy for Individual Funding Requests" document for further guidance on this process.

For a definition of the term "exceptional clinical circumstances", please refer to the definitions section of this document.

2.6 This policy applies to children and young people under the care of paediatric diabetes services with a diagnosis of diabetes mellitus and who require medical treatment involving use of insulin. People managed within an adult diabetes service or those with a diagnosis of DM who do not require insulin to manage their disease are not within the scope of this policy.

Notes:

i. There is a separate policy for use of FlashGM in people managed by adult diabetes services with a diagnosis of diabetes and who use insulin to manage their disease.
ii. A separate policy is being developed for use of rtCGM in people managed by adult diabetes services with a diagnosis of diabetes and who use insulin to manage their disease;' this should be available during 2019.

2.7 The purpose of this policy is to define when CGM is appropriate for use in children and young people under the care of paediatric diabetes services. The policy will also determine eligibility for the different types of CGM depending on presenting circumstances.

3. Background

3.1. The National Health Service (NHS) Constitution, which details the principles and values that guide the NHS, has been applied in the agreement of this policy.

3.2. NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group consider all lives of all patients whom they serve to be of equal value and, in making decisions about funding treatment for patients, will seek not to discriminate on the grounds of sex, age, sexual orientation, ethnicity, educational level, employment, marital status, religion or disability except where a difference in the treatment options made available to patients is directly related to a particular patient's clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.

3.3. Type 1 diabetes most commonly occurs in childhood, the disease can also develop in adults, and always requires insulin therapy for treatment. NICE guidelines advise routine self-monitoring of blood glucose levels for all children at least 5 times daily. However, some insulin regimes rely on additional testing to inform dosage calculations.

3.4. All children and young people require significant support and education to help manage their disease; under the best practice tariff for diabetes in children and young people, a clinical review is recommended at least four times a year by specialist diabetes multidisciplinary teams. Children and young people whose diabetes is not well controlled or who are experiencing problems (for example, hypoglycaemia requiring third party assistance) will require additional support for management of the disease. When problems persist consideration may be given to use of either insulin pump therapy or CGM.

3.5. Insulin pump therapy has been routinely available on the NHS since 2008, with a variety of different rtCGM becoming available some years later, most recently those that are insulin pump compatible.

3.6. FlashGM became available in 2016 but was not routinely available on the NHS. NHS reimbursement of sensors for FlashGM was permitted from October 2017, however, this was dependant on the local commissioning arrangement. Worcestershire commissioners, through the Area Prescribing Committee (APC) did not support use in Worcestershire due to concerns with the evidence base to inform appropriate and beneficial use.

3.7. There is currently only one type of FlashGM readily available on the NHS; this product is licensed for people age 4 years and over. Other products are in development.

4. Relevant National Guidance and Facts

4.1 Type 1 diabetes accounts for 8% of all people with diabetes mellitus but almost 100% of children and young people with diabetes. The prevalence of type 1 diabetes mellitus in England and Wales in 2017 in those less than 16 years old is 187 per 100,000; this equates to around 192 under 16-year olds in Worcestershire. It is known that there are in excess of 270 children and young people (aged 0 to 18) with diabetes in Worcestershire all of whom are managed by local secondary care specialist diabetes services. The incidence of newly diagnosed type 1 diabetes in children and young people aged less than 16 years old (from an audit conducted across England and Wales in 2016/17) was 25.4 per 100,000 general population.

4.2 The following guideline has been used to inform development of this policy:

Diabetes (type 1 and type 2) in children and young people: diagnosis and management. National Institute for Health and Care Excellence (NICE) guideline [NG18]. Published date: August 2015, last updated: November 2016.

A variety of other NICE guidance has been published but these primarily relate to insulin pump therapy and are not directly relevant to this policy.

4.3 The NICE guideline recommends:

Offer ongoing real-time continuous glucose monitoring 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)

NICE recommends that real-time continuous glucose monitoring may be considered for the following groups:

- 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
- children and young people who continue to have hyperglycaemia despite insulin adjustment and additional support (real-time or retrospective)

The NICE guideline was written before intermittent CGM (FlashGM) became available and so does not provide any recommendations for this.

4.5 In November 2018, NHS England announced that FlashGM would be available for patients with insulin-dependent diabetes who meet agreed national clinical criteria. On 7th March 2019 the clinical criteria were published for reimbursement of FlashGM on the NHS on 1st April 2019; these allow consideration for use in the following patient cohorts:

1. **Type 1 diabetes requiring intensive monitoring >8 times daily**, as demonstrated on a meter download/review over the past 3 months

2. **Type 1 or 2 diabetes on haemodialysis requiring intensive monitoring >8 times daily**, as demonstrated on a meter download/review over the past 3 months
3. **Diabetes associated with cystic fibrosis**
4. **Type 1 diabetes during pregnancy** (12 months total including post-delivery period)
5. **Type 1 diabetes with disability and carer support** who are unable to routinely self-monitor blood glucose
6. **Type 1 diabetes with occupational or psychosocial circumstances** (e.g. working in insufficiently hygienic conditions to safely facilitate finger-prick testing) that warrant a 6-month trial with appropriate adjunct support.
7. **Type 1 diabetes experiencing recurrent severe hypoglycaemia**
8. **Type 1 diabetes with impaired awareness of hypoglycaemia**

4.6 The national guidance also sets other requirements for use of FlashGM, notably:

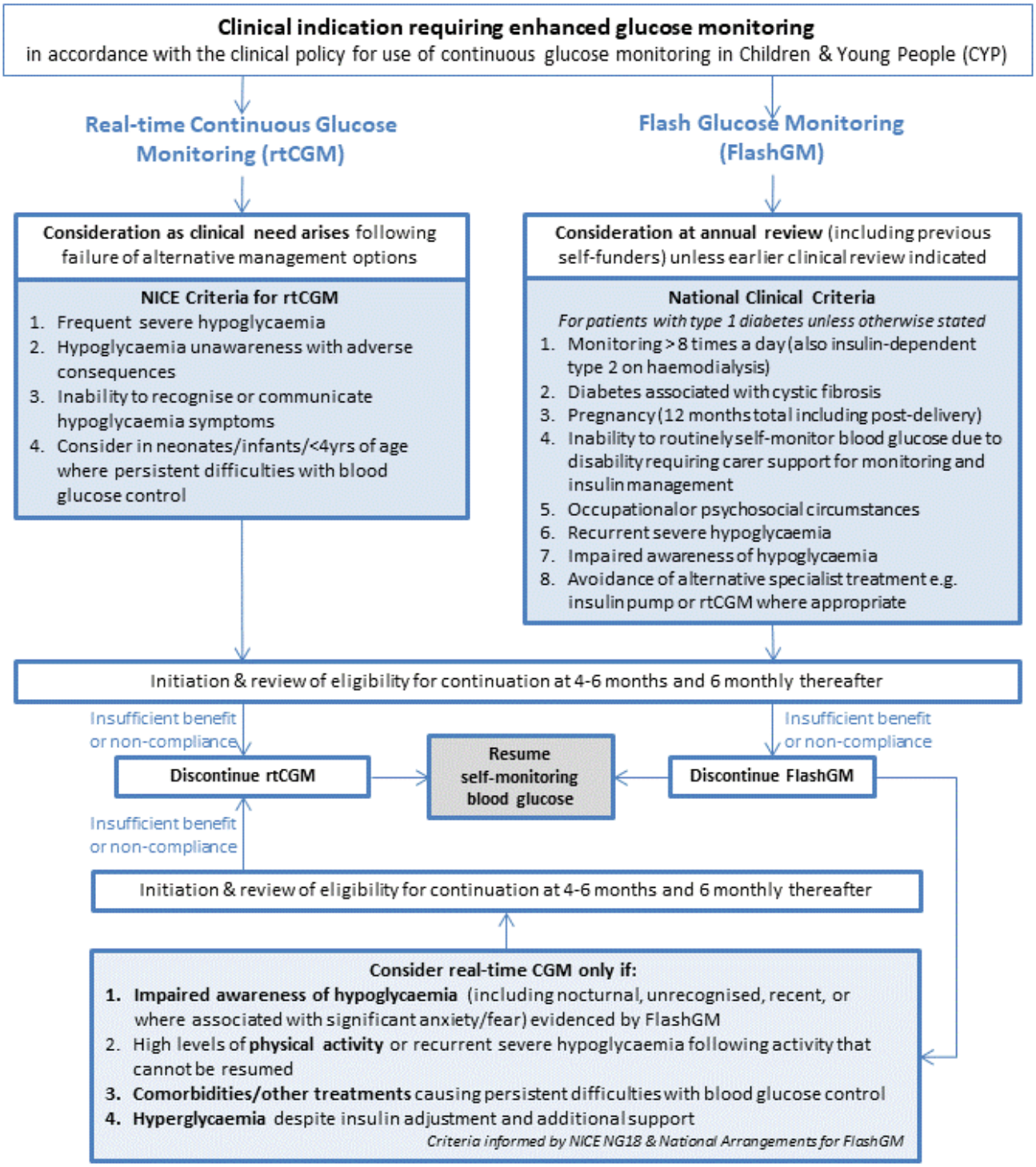
- Education on FlashGM has been provided (online or in person)
- Agree to scan glucose levels no less than 8 times per day and use the sensor >70% of the time
- Agree to regular reviews with the local clinical team
- Previous attendance, or due consideration given to future attendance, at a type 1 diabetes structured education programme (DAFNE or equivalent if available locally)
- Continuing prescription for long-term use of FlashGM post initial 6 months is contingent upon evidence of agreeing with the above conditions and that on-going use of FlashGM is demonstrably improving an individual's diabetes self-management- for example improvement of HbA1c or Time In Range; improvement in symptoms such as diabetic ketoacidosis (DKA) or hypoglycaemia; or improvement in psycho-social wellbeing

4.7 Finally the national guidance recognises that there is a cohort of patients who have self-funded FlashGM in advance of the device being available on the NHS. For these patients:

- those with clinical responsibility for their diabetes care must be satisfied that the patient's clinical history suggests that they would have satisfied one or more of these criteria (as above) prior to commencing use of FlashGM had these criteria been in place prior to April 2019 AND
- they have shown improvement in HbA1c since self-funding commenced

5. Patient Eligibility

5.1 The summary below demonstrates the clinical indications for use of CGM (including FlashGM) in Children and Young People (CYP) with diabetes in Worcestershire for which the following eligibility criteria apply, split by real-time CGM and FlashGM:



Notes:

i. rtCGM should not be used to reduce HbA1c or hypoglycaemia in CYP with a HbA1c >10%
ii. CYP services are responsible for provision of readers and sensors for FlashGM until patients meet continuation criteria; at this time general practitioners will be asked to continue ongoing supply with other repeat medication requirements
iii. CYP services are responsible for supply of device and consumables associated with rtCGM throughout the period of use
iv. Patients who have self-funded FlashGM are required to follow this pathway to assess NHS funding eligibility
v. The clinical policy for use of continuous glucose monitoring in CYP provides definitions as appropriate

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5.2 All CYP with insulin dependent diabetes being considered for any type of CGM will need to demonstrate that they (or their carer as appropriate) has:

1. established insulin-dependent diabetes
2. had their insulin regime optimised
3. attended an educational session for diabetes management
4. committed to self-management with attendance at clinical review 3 times a year or more
5. committed, via a patient/carer contract, to the requirements for use of CGM including:
   i. engagement with recommended education (prior to commencement and ongoing)
   ii. baseline assessment
   iii. understanding of the continuation criteria
   iv. regular review

Flash Glucose Monitoring

5.3 Consideration of eligibility for a 4-6 month trial of FlashGM will be undertaken at the next scheduled clinical review with the paediatric diabetes team unless clinical circumstances indicate an earlier review.

5.4 A trial of FlashGM may be an option for children aged 4 years and older and young people with insulin dependent diabetes where the patient, in addition to the above, meets one of the following clinical criteria:

1. **Type 1 diabetes requiring intensive monitoring >8 times daily**, as demonstrated on a meter download/review over the past 3 months

2. **Type 1 or 2 diabetes on haemodialysis requiring intensive monitoring >8 times daily**, as demonstrated on a meter download/review over the past 3 months

3. **Diabetes associated with cystic fibrosis**

4. **Type 1 diabetes during pregnancy** (12 months total including post-delivery period)

5. **Type 1 diabetes with disability and carer support** who are unable to routinely self-monitor blood glucose

6. **Type 1 diabetes with occupational or psychosocial* circumstances** (e.g. working in insufficiently hygienic conditions to safely facilitate finger-prick testing) that warrant a 6-month trial with appropriate adjunct support.
   * Psychosocial circumstances will be assessed using the Paediatric Quality of Life Inventory (PedsQL)

7. **Type 1 diabetes experiencing recurrent severe hypoglycaemia****
   ** Recurrent severe hypoglycaemia - defined as more than 1 episode of hypoglycaemia, within a 6 month period, that:
   i. has required third party assistance due to a reduced conscious level needing treatment with oral glucose gel or intra-muscular (IM) glucagon and
   ii. is a diabetic emergency and
   iii. is a very infrequent event

8. **Type 1 diabetes with impaired awareness*** of hypoglycaemia**
   *** Impaired awareness of hypoglycaemia associated with adverse consequences (for example seizures or anxiety) – assessed using:
   i. the Clarke Hypoglycaemic Index and Gold Score necessitating a score of >4 and ≥ 4 respectively and
   ii. the Hypoglycaemia Fear Questionnaire necessitating a mean score of 2 or over on the worry subscale of the Children's Hypoglycaemia Fear Survey (CHFS) and Hypoglycaemia Fear Survey – Parent (HFS-P) and/or a mean score of 3 or over on the Parents of Young Children HFS-PYC.

9. **Type 1 diabetes where FlashGM may enable avoidance of alternative specialist treatment** e.g. insulin pump or rtCGM where appropriate

5.5 Following initiation of FlashGM in eligible people and agreement of the patient contract, baseline parameters will be recorded in relation to the monitoring parameters necessary to determine eligibility for ongoing use. These parameters will be taken from information prior to commencement of FlashGM and information gathered during use of the first FlashGM sensor.

5.6 Eligibility for ongoing use of FlashGM will be assessed initially at 4-6 months and 6 monthly thereafter and will require demonstration of compliance with the patient contract and:

a. wearing the sensor for more than 70% of the time and scanning at least 8 times a day

b. clinic attendance at least twice in the first 6 months and then at least 3 times a year thereafter

c. attendance at annual education event (the initiation session counts for year 1)

d. improved self-management evidenced by one or more of the following parameters and depending on the reason for commencement:

i. Reduced number of SMBG tests
ii. Improved HbA1c (>5 mmol/mol if ≥ 58 mmol/mol pre-FlashGM)
iii. Improved time in defined patient range
iv. Reduced number of hypoglycaemic events or time in hypoglycaemia (< 4mmol/l)
v. Reduced time in hyperglycaemia (>14mmol/l)
vi. Improved hypoglycaemic awareness - necessitating an improvement from baseline (pre-FlashGM) in one or more of the following assessment tools: Clarke Hypoglycaemic Index, Gold Score or Hypoglycaemia Fear Questionnaire
vii. Improvement in psycho-social well-being – necessitating an improvement from baseline in the PedsQL

5.7 Specialist diabetes teams at provider trusts are responsible for determining eligibility for FlashGM, initiating use of the device (including education) and arranging supply of sensors during the initiation period (4-6 months). When ongoing eligibility is demonstrated (beyond 4-6 months), general practitioners will be asked to maintain ongoing supply of sensors together with any other established diabetes medication requirements.

5.8 Specialist diabetes teams are required to complete a Blueteq proforma (appendix 1) to demonstrate eligibility for use of FlashGM, with annual review to ensure eligibility for continuation.

5.9 People who self-funded FlashGM prior to availability on the NHS will be assessed for NHS eligibility in accordance with the above arrangements, including:

1. demonstrating that they met one of the clinical criteria (section 5.4 above) prior to commencing use of FlashGM AND
2. demonstrating:
    a. completion of the requirements in section 5.2
    b. completion of any necessary assessment tools
    c. evidence of benefit from FlashGM since commencement in accordance with section 5.6

Where CYP diabetes specialists are assured that eligible patients meet the parameters below, ongoing eligibility may be determined at an earlier stage, this will need to be individualised to the patient's circumstances:

a. FlashGM use has been optimised and patient is both competent and confident with use
b. the sensor is worn for more than 70% of the time with scanning at least 8 times a day
c. attendance at annual education event (the initiation session counts for year 1)
d. improvement in HbA1c since self-funding commenced

Where a patient is not able to immediately demonstrate the above parameters further support and education will be offered with re-assessment at 4-6 months in accordance with the arrangements outlined above.

Real-time Continuous Glucose Monitoring

5.10 Consideration for real-time CGM will be undertaken as clinical need arises following failure of alternative management options.

5.11 Real-time CGM with alarms may be offered to children and young people with type 1 diabetes who meet the requirements in section 5.2 and who have one of the following indications:

a. Recurrent severe hypoglycaemia - defined as more than 1 episode of hypoglycaemia, within a 6 month period, that:
    i. has required third party assistance due to a reduced conscious level needing treatment with oral glucose gel or intra-muscular (IM) glucagon and
    ii. is a diabetic emergency and
    iii. is a very infrequent event

b. Impaired awareness of hypoglycaemia associated with adverse consequences (for example seizures or anxiety) – assessed using:
    i. the Clarke Hypoglycaemic Index and Gold Score necessitating a score of >4 and ≥ 4 respectively and
    ii. the Hypoglycaemia Fear Questionnaire necessitating a mean score of 2 or over on the worry subscale of the Children's Hypoglycaemia Fear Survey (CHFS) and Hypoglycaemia Fear Survey – Parent (HFS-P) and/or a mean score of 3 or over on the Parents of Young Children HFS-PYC.

c. Inability to recognise, or communicate about, symptoms of hypoglycaemia (for example because of cognitive or neurological disabilities)

5.12 Real-time CGM may be considered for neonates, infants and children under 4 years of age where there are persistent difficulties with blood glucose control and who meet the requirements in section 5.2.

5.13 Real-time CGM may be considered for children and young people with type 1 diabetes who have demonstrated insufficient benefit from FlashGM and who meet one of the following indications:

a. Impaired awareness of hypoglycaemia (including nocturnal, unrecognised, recent, or where associated with significant anxiety/fear) evidenced by FlashGM

b. High levels of physical activity (eg. sport at a regional, national or international level) or recurrent severe hypoglycaemia following activity that cannot be resumed

c. Comorbidities/other treatments causing persistent difficulties with blood glucose control

d. Hyperglycaemia despite insulin adjustment and additional support

5.14 Eligibility for ongoing use of rtCGM will be assessed at **1 month** and **3 months** and will require demonstration of:

1 month assessment:

a. wearing CGM for more than 5 days per week and

b. family attendance at education session and 1 week follow-up session

3 month assessment:

a. wearing CGM for more than 5 days per week and

b. clinic attendance at least twice in the first 6 months and then at least 3 times a year thereafter

c. reduced number of SMBG tests

d. improved self-management evidenced by one or more of the following parameters and depending on the reason for commencement:

   i. Improved HbA1c (>5 mmol/mol if ≥ 58 mmol/mol pre-rtCGM)
   ii. Improved time in defined patient range
   iii. Reduced number of hypoglycaemic events or time in hypoglycaemia (< 4mmol/l)
   iv. Reduced time in hyperglycaemia (>14mmol/l)
   v. Improved hypoglycaemic awareness - necessitating an improvement from baseline (pre-rtCGM) in one or more of the following assessment tools: Clarke Hypoglycaemic Index, Gold Score or Hypoglycaemia Fear Questionnaire
   vi. Improvement in psycho-social well-being – necessitating an improvement from baseline in the PedsQL

5.15 Notes regarding rtCGM:

a. All eligible CYP will have a months trial with a loan system before being provided with their own personal CGM system
b. The multidisciplinary specialist team will determine the appropriate choice of CGM in consideration of age, ability to link to insulin pump, potential benefit from predictive low glucose suspend technology and cost-effectiveness
c. If CGM is to be commenced in addition to insulin pump therapy, CGM should be commenced prior to the insulin pump
d. Some patients, within the identified cohorts, may require diagnostic CGM over a short period of time to inform better management; such patients may not be offered CGM for long-term use

5.16 Specialist diabetes teams at provider trusts are responsible for determining eligibility for rtCGM, initiating use (including education) and device and consumable supply throughout the period of use by the child.

5.17 Specialist diabetes teams are required to complete a Blueteq proforma (appendix 2) to demonstrate eligibility for use of rtCGM, with annual review to ensure eligibility for continuation.

6. Supporting Documents

- NICE Guideline NG18: Diabetes (type 1 and type 2) in children and young people: diagnosis and management. Updated November 2016.
- NHS England - Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients. March 2019
- Worcestershire CCGs: Operational Policy for Individual Funding Requests
- Worcestershire CCGs: Prioritisation Framework for the Commissioning of Healthcare Services
- NHS England: Ethical Framework for Priority Setting Resource Allocation
- NHS England: Individual Funding Requests
- NHS Constitution, updated 27th July 2015

APPENDIX 1: Blueteq Initiation Form – Flash Glucose Monitoring in CYP

Links to:
http://www.redditchandbromsgroveccg.nhs.uk/strategies-policies-and-procedures/commissioning-ifr-policies-a-z/

PATIENT DETAILS

As per agreement

POLICY REQUIREMENTS

1. **PATIENT ELIGIBILITY** Please confirm that the patient meets the requirements for initiation of Flash Glucose Monitoring (FlashGM) within the current Worcestershire CCGs Commissioning Policy "**Continuous Glucose Monitoring in Children and Young People**"	Yes (required)/No

2. **DIABETIC STATUS**

Please confirm that the patient (or carer as appropriate) has:

- established insulin-dependent diabetes
- had their insulin regime optimised
- attended an educational session for diabetes management
- committed to self-management with attendance at clinical review 3 times a year or more
- committed, via a patient/carer contract, to the requirements for use of CGM

Required to tick 5/5

3. **CLINICAL INDICATION**

Please confirm the indication for FlashGM:

1. Type 1 diabetes requiring intensive monitoring >8 times daily
2. Type 1 or 2 diabetes on haemodialysis requiring intensive monitoring >8 times daily
3. Diabetes associated with cystic fibrosis
4. Type 1 diabetes during pregnancy (12 months total including post-delivery period)
5. Type 1 diabetes with disability and carer support
6. Type 1 diabetes with occupational or psychosocial* circumstances (please provide detail below)
7. Type 1 diabetes experiencing recurrent severe** hypoglycaemia
8. Type 1 diabetes with impaired awareness*** of hypoglycaemia
9. Type 1 diabetes where FlashGM may enable avoidance of alternative specialist treatment

Choose one of above indications

* Psychosocial circumstances will be assessed using the PedsQL scoring tool

** Recurrent severe hypoglycaemia is defined as more than 1 episode within a 6 month period, that:

i. has required third party assistance due to a reduced conscious level needing treatment with oral glucose gel or IM glucagon and
ii. is a diabetic emergency and
iii. is an infrequent event

*** impaired awareness of hypoglycaemia must be assessed by use of:

i. the Clarke Hypoglycaemic Index or Gold Score necessitating a score of >4 and ≥ 4 respectively and
ii. the Hypoglycaemia Fear Questionnaire necessitating a mean score of 2 or over on the worry subscale of the Children's Hypoglycaemia Fear Survey (CHFS) and Hypoglycaemia Fear Survey – Parent (HFS-P) and/or a mean score of 3 or over on the Parents of Young Children HFS-PYC

4. **BASELINE MONITORING PARAMETERS**

HbA1c

Current HbA1c (mmol/mol): …… Test Date: …… *baseline*

Pre-FlashGM HbA1c (mmol/mol): …… Test Date: ……

(prior users only)

Average number of **SMBG tests/day:** ☐ *Box to enter value* *baseline*

Hypoglycaemic (<4mmol/l) episodes in 2 weeks prior to commencement? *Box to enter value or drop down of:*

None ☐ 1 to 2 ☐ 3 to 5 ☐ > 5 ☐

Hypoglycaemic awareness: **Clarke Score**: ☐ *Box to enter value* *baseline*

Gold Score: ☐ *Box to enter value* *baseline*

Hypoglycaemic Fear: **CHFS:** ☐ *Box to enter value* *baseline*

HFS-P: ☐ *Box to enter value* *baseline*

HFS-PYC: ☐ *Box to enter value* *baseline*

Psychosocial distress score: **PedsQL**: ☐ *Box to enter value* *baseline*

5. **CHOICE OF DEVICE**

Please confirm the device being initiated: *drop-down box with FSL (others to be added as appropriate)*

6. **OTHER CLINICAL INFORMATION**

Textbox for free typing

APPENDIX 2: Blueteq Initiation Form – Continuous Glucose Monitoring in CYP

Links to:
http://www.redditchandbromsgroveccg.nhs.uk/strategies-policies-and-procedures/commissioning-ifr-policies-a-z/

PATIENT DETAILS

As per agreement

POLICY REQUIREMENTS

1. **PATIENT ELIGIBILITY** Please confirm that the patient meets the requirements for initiation of Continuous Glucose Monitoring (CGM) within the current Worcestershire CCGs Commissioning Policy "**Continuous Glucose Monitoring in Children and Young People**"	Yes (required)/No

2. **DIABETIC STATUS**

Please confirm that the patient (or carer as appropriate) has:

- established insulin-dependent diabetes
- had their insulin regime optimised
- attended an educational session for diabetes management
- committed to self-management with attendance at clinical review 3 times a year or more
- committed, via a patient/carer contract, to the requirements for use of CGM

Required to tick 5/5

3. **CLINICAL INDICATION**

Please confirm the indication for CGM:

1. Frequent severe hypoglycaemia
2. Hypoglycaemia unawareness with adverse consequences
3. Inability to recognise or communicate hypoglycaemia symptoms
4. Neonates/infants/<4yrs of age where persistent difficulties with blood glucose control
5. Impaired awareness of hypoglycaemia evidenced by FlashGM – Please specify: including nocturnal, unrecognised, recent, anxiety/fear *drop down box*
6. High levels of physical activity or recurrent severe hypoglycaemia following activity that cannot be resumed (please provide details below)
7. Comorbidities/other treatments causing persistent difficulties with blood glucose control (please provide details below)
8. Hyperglycaemia despite insulin adjustment and additional support

Choose one of above indications

* Psychosocial circumstances will be assessed using the PedsQL scoring tool

** Recurrent severe hypoglycaemia is defined as more than 1 episode within a 6 month period, that:

i. has required third party assistance due to a reduced conscious level needing treatment with oral glucose gel or IM glucagon and
ii. is a diabetic emergency and
iii. is an infrequent event

*** impaired awareness of hypoglycaemia must be assessed by use of:

i. the Clarke Hypoglycaemic Index or Gold Score necessitating a score of >4 and ≥ 4 respectively and
ii. the Hypoglycaemia Fear Questionnaire necessitating a mean score of 2 or over on the worry subscale of the Children's Hypoglycaemia Fear Survey (CHFS) and Hypoglycaemia Fear Survey – Parent (HFS-P) and/or a mean score of 3 or over on the Parents of Young Children HFS-PYC

4. **BASELINE MONITORING PARAMETERS**

HbA1c

Current HbA1c (mmol/mol): …….…….. Test Date: ……..…… *baseline*

Pre-FlashGM HbA1c (mmol/mol): ……. Test Date: ……..……

(prior users only)

Average number of **SMBG tests/day:** ☐ *Box to enter value* *baseline*

Hypoglycaemic (<4mmol/l) episodes in 2 weeks prior to commencement? *Box to enter value or drop down of:*

None ☐ 1 to 2 ☐ 3 to 5 ☐ > 5 ☐

Hypoglycaemic awareness: **Clarke Score**: ☐ *Box to enter value* *baseline*

Gold Score: ☐ *Box to enter value* *baseline*

Hypoglycaemic Fear: **CHFS:** ☐ *Box to enter value* *baseline*

HFS-P: ☐ *Box to enter value* *baseline*

HFS-PYC: ☐ *Box to enter value* *baseline*

Psychosocial distress score: **PedsQL**: ☐ *Box to enter value* *baseline*

5. **CHOICE OF DEVICE**

Please confirm the device being initiated: *drop-down box with device options (others to be added as appropriate)*

Does the patient use an Insulin Pump: Yes/No *drop down box*

6. **OTHER CLINICAL INFORMATION**

Textbox for free typing

7. Equality Impact Assessment

Organisation	NHS Redditch & Bromsgrove CCG, NHS South Worcestershire CCG, NHS Wyre Forest CCG		
Department	Medicines Commissioning	Name of lead person	Fiona Bates
Piece of work being assessed	Continuous Glucose Monitoring in Children and Young People		
Aims of this piece of work	To define the arrangements for accessing the different types of CGM in Worcestershire including eligibility criteria, choice of CGM, and continuation criteria		
Date of EIA	14/03/19	Other partners/stakeholders involved	Area Prescribing Committee, Clinical Commissioning Policy Collaborative
Who will be affected by this piece of work?	Children and Young People with Diabetes		

Single Equality Scheme Strand	**Baseline data and research on the population that this piece of work will affect.** What is available? E.g. population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. **Include consultation with service users wherever possible**	**Is there likely to be a differential impact?** Yes, no, unknown
Gender	There are about 35,000 children and young people with diabetes, under the age of 19, in the UK. Figures from 2009 suggested that there were about 29,000 children under the age of 18. About 96% have type 1 diabetes; about 2% have type 2 diabetes and 2% have other rare forms of diabetes or their diagnosis is not defined. Slightly more boys seem to have diabetes than girls: 52% boys and 48% girls, though girls are twice as likely to have type 2 diabetes. Incidence is similar amongst males (25.9 per 100,000) compared to females (24.4 per 100,000).	No
Race	There is limited information in relation to children or those with type 1 disease; the national paediatric diabetes audit in 2016/17 suggests that children in the "mixed", "black" and "other" ethnicity groups have higher rates of diabetes than would be expected for their population. Type 2 diabetes (predominantly adults) is: - up to six times more common in people of South Asian descent - up to three times more common among people of African and African-Caribbean origin. - almost four times as prevalent in Bangladeshi men, and almost three times as prevalent in Pakistani and Indian men compared with men in the general population. - more than five times as likely among Pakistani women, at least three times as likely in Bangladeshi and Black Caribbean women, and two-and-a-half times as likely in Indian women,	No

	compared with women in the general population.	
Disability	There is no available evidence regarding the breakdown of the UK population with diabetes who have a disability and whether this creates a differential impact.	No
Religion/ belief	There is limited evidence regarding the direct impact of religion on the likely development of diabetes however this is strongly linked to ethnicity.	No
Sexual orientation	There is no published information that indicates that sexual orientation affects the development of diabetes.	No
Age	There is a significant difference regarding the type of diabetes developed depending on age: - adults are more likely to develop type 2 disease - children are more likely to develop type 1 disease The criteria within this policy are primarily focussed on type 1 disease and this will have a differential impact.	Yes
Social deprivation	Deprivation is strongly associated with higher levels of obesity, physical inactivity, unhealthy diet, smoking and poor blood pressure control. All these factors are inextricably linked to the risk of diabetes or the risk of serious complications for those already diagnosed. This is more likely to be associated with type 2 disease and there may therefore be a differential impact in adults but this is limited for children. The national paediatric diabetes audit in 2016/17 suggests similar prevalence of children with type 1 diabetes across all deprivation quintiles.	No
Carers	This is unlikely to impact on children and young people.	No
Human rights	The local commissioning policy would not seek to affect a patient's human rights.	No

Equality Impact Assessment Action Plan

Strand	Issue	Action required	How will you measure the outcome/impact	Timescale	Lead
Age	There is a significant difference regarding the type of diabetes developed depending on age: - adults are more likely to develop type 2 disease - children are more likely to develop type 1 disease The criteria within this policy are primarily focussed on type 1 disease and this will have a differential impact.	The guidance informing this policy has been agreed nationally and is therefore outside of the control of local commissioners.	NA		