Commissioning Policy

NHS Redditch and Bromsgrove Clinical Commissioning Group

NHS South Worcestershire Clinical Commissioning Group

NHS Wyre Forest Clinical Commissioning Group

Flash Glucose Monitoring in Adults

(managed within Adult 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 sensors for **Flash Glucose Monitoring (FlashGM)**, if clinically appropriate and within the recommendations of this policy, for patients* with insulin-dependent type 1 diabetes (unless otherwise stated) who have:

1. established insulin-dependent diabetes and
2. completed a structured education programme and
3. had their insulin regime optimised and
4. engaged with active self-management and
5. the ability to engage with and commit, via a patient/carer contract, to the requirements for use of FlashGM

and who meet one of the following national clinical criteria:

- 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

**and/or carer as appropriate for the requirement*

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Key individuals involved in developing the document:

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Circulated to the following individuals/groups for comments:

Name	Date	Version Reviewed
Area Prescribing Committee	15/03/19 distributed virtually for comment by 19/03/19	1.0
Clinical Commissioning Policy Collaborative, which includes: GPs, Commissioners, Medicines Commissioning, Public Health, Patient and Public Representatives		
Clinical Innovation Group		

Version Control:

Version No	Type of Change	Date	Description of change

Table of Contents

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 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 glucose (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 adults under the care of adult diabetes services with a diagnosis of diabetes mellitus and who require medical treatment involving use of insulin. People managed within the paediatric 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 CGM (including rtCGM and FlashGM) in people managed by paediatric 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 FlashGM is appropriate for use in adults under the care of adult diabetes services.

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. Type 2 diabetes most commonly occurs in adults and is usually managed by diet or oral medication; in some situations insulin is required to manage the disease.

3.4. NICE guidelines advise routine self-monitoring of blood glucose levels for all adults with type 1 diabetes, and recommend testing at least 4 times a day, including before each meal and before bed. NICE recommends testing up to 10 times a day if the following apply: to optimise HbA1c, increased frequency of hypoglycaemic episodes, as per DVLA requirements before driving, during periods of illness, before and after sport, when planning and during pregnancy, breastfeeding, impaired awareness of hypoglycaemia. Additional blood glucose testing (more than 10 times a day) is recommended for adults with type 1 diabetes if this is necessary because of the person's lifestyle (for example, driving for a long period of time, undertaking high-risk activity or occupation, travel) or if the person has impaired awareness of hypoglycaemia.

3.5. All newly diagnosed patients with type 1 disease or those with type 2 disease requiring insulin treatment require significant support and education to help manage their disease. This is currently managed by both primary and secondary care depending on the clinical circumstances and experience and skills of staff within primary care; there is an enhanced service arrangement "Ongoing Management for Type 1 and Type 2 Diabetes Patients Treated with Insulin" for primary care practitioners. Patients are either managed entirely by the general practice or jointly (shared care) with diabetes specialist nurses (DSN). Adults 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.

3.6. 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.

3.7. 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.

3.8. 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 diabetes mellitus in adults is 6% of the UK population or 1 in every 16 people having diabetes (diagnosed and undiagnosed). It is known that there are around 2,696 adults (aged 18 and over) with type 1 diabetes in Worcestershire.

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

Type 1 diabetes in adults: diagnosis and management
National Institute for Health and Care Excellence (NICE) guideline [NG17]. Published date: August 2015, last updated July 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 provides recommendations for use of CGM but 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 from 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:

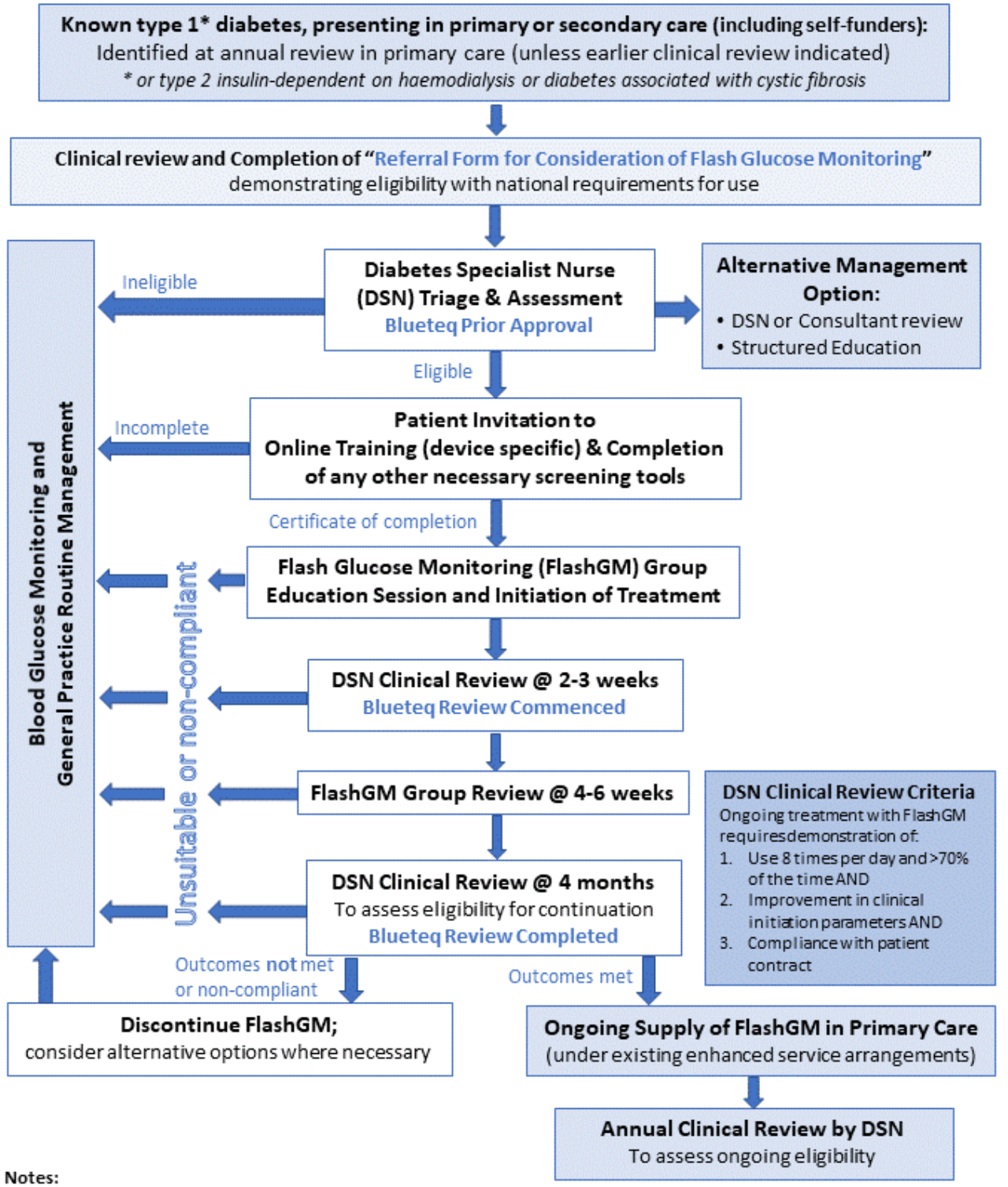
- Education on FlashGM has been provided (online or in person)
- Agree to scan glucose levels no less than 8 times per day and use the sensor >70% of the time
- Agree to regular reviews with the local clinical team
- Previous attendance, or due consideration given to future attendance, at a type 1 diabetes 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 pathway below summarises the management arrangements for patients being considered for FlashGM.



Notes:

- DSNs are responsible for provision of sensors for eligible patients until review @ 4 months; at this time general practitioners will be asked to continue ongoing supply for appropriate patients alongside other repeat medications
- Patients referred for consideration of FlashGM will be managed jointly via the enhanced service arrangement
- Patients who have self-funded FlashGM are required to follow this pathway to assess NHS funding eligibility; subsequent review requirements will be individualised to the patient's circumstances (see section 5.15 of the policy)
- DSNs will be available for additional support during the initiation stage and as the need arises; appointments will involve either face-to-face or non-face-to-face depending on the patient's requirements
- **General practitioners should only prescribe FlashGM when they have been advised to do so by DSNs**

April 2019

5.2 Consideration of whether a person may be appropriate for FlashGM will be undertaken at the patient's next annual clinical review or at an earlier review that takes place as a result of changes in diabetic needs; this review could be either in general practice or secondary care depending on how the patient is managed. An earlier review might only be indicated for patients who become pregnant, are experiencing recurrent severe hypoglycaemia or those with hypoglycaemia unawareness.

5.3 At the annual clinical review (or earlier as above), appropriateness of clinical referral for consideration of FlashGM will be determined by the health professional. The review should include an assessment of blood glucose monitoring (from a meter download) over the last few months to inform eligibility for referral and completion of the referral form (see section 5.6).

5.4 Patients being considered for FlashGM will need to demonstrate that they (or their carer as appropriate) meet all the following requirements:

1. established insulin-dependent diabetes

2. completed a structured education programme (unless considered inappropriate eg. pregnancy, housebound, residential/nursing home, carer administration). This would involve one of the following:
   - Expert Insulin - Attendance at 4 or more of the 6 planned sessions OR
   - DAFNE (Dose Adjustment For Normal Eating) – Attendance at 4 or more of the 5 planned sessions OR
   - Completion of a refresher course within the last 2 years (where expert insulin or DAFNE > 2yrs ago)

3. optimised insulin regime

4. engaged with active self-management, evidenced by regular attendance at review appointments by patient or carer

5. ability to engage with and willing to commit, via a patient/carer contract, to the requirements for use of FlashGM (including use > 70% of the time and scanning ≥ 8 times a day

5.5 Patients being considered for FlashGM will also need to demonstrate that they meet one of the national clinical indications for use of FlashGM:

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 by DSN using a validated scoring tool

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

8. **Type 1 diabetes with impaired awareness*** of hypoglycaemia**

*** Impaired awareness of hypoglycaemia will be assessed by DSN using a validated scoring tool eg. the Clarke Hypoglycaemic Index or Gold Score necessitating a score of >4 and ≥ 4 respectively

5.6 A "Referral form for consideration of Flash Glucose Monitoring in Adults" (appendix 1) will need to be completed for patients who meet the above requirements and submitted to the DSN team for consideration of eligibility.

5.7 DSN are responsible for triaging referral forms and determining eligibility for a 4-6 month trial of FlashGM. It may be determined that some patients require alternative management or clinical review prior to commencing a trial of FlashGM; it may also be determined that a patient referred does not meet the requirements of this policy. Some patients will be returned to general practice management.

5.8 Where a patient meets the requirements for a trial of FlashGM they will be invited to complete device specific online training. The patient may also be asked to complete other assessment tools to help guide DSN triage and agree a baseline value for monitoring purposes eg. psychosocial circumstances or impaired awareness of hypoglycaemia.

5.9 Upon completion of online training (evidence submitted by patient) and any other screening tools, patients who remain eligible for a trial of FlashGM will be invited to attend a Group Education Session. At this session patients will receive training regarding use of the device, provision of a reader and at least 1 sensor and will need to agree the patient contract.

5.10 Further support for use of Flash GM will be provided at regular defined intervals:

i. Clinical review at 2-3 weeks
ii. Group review at 4-6 weeks
iii. Clinical review to assess eligibility for continuation at 4 months.

Additional DSN support will be provided during the initiation stage and as the need arises; appointments will involve either face-to-face or non-face-to-face depending on the patient's requirements

5.11 Following initiation of FlashGM in eligible people, 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 (2-3 week review).

5.12 Eligibility for ongoing use of FlashGM will be assessed initially at 4-6 months and annually 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. reduced number of SMBG tests

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. Improved HbA1c (as per target agreed at initiation)
   ii. Improved time in defined patient range
   iii. Reduced time in hypoglycaemia (< 4mmol/l)
   iv. Reduced time in hyperglycaemia (>14mmol/l)
   v. Reduced diabetes related admissions/A&E attendance for DKA/hyperglycaemia in last 12 months
   vi. Reduced diabetes related admissions/A&E attendance for hypoglycaemia in last 12 months
   vii. Improved hypoglycaemic awareness - necessitating an improvement from baseline (pre-FlashGM) in one or more of the following assessment tools: Clarke Hypoglycaemic Index or Gold Score
   viii. Improvement in psycho-social well-being – necessitating an improvement from baseline in the validated tool

5.13 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.

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

5.15 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 5.5 above) prior to commencing use of FlashGM AND
2. demonstrating:
   a. completion of the requirements in section 5.4
   b. completion of online training for FlashGM and any other necessary assessment tools
   c. evidence of benefit from FlashGM since commencement in accordance with section 5.12

Where DSN are assured that eligible patients meet the parameters below, the patient may not need to complete all elements of the pathway, 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. evidence of reduced number of SMBG tests since self-funding commenced
   d. attendance at annual education event (the initiation session counts for year 1)
   e. 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 pathway arrangements outlined above.

6. Supporting Documents

- NICE Guideline NG17: Type 1 diabetes in adults: diagnosis and management. National Institute for Health and Care Excellence (NICE) guideline [NG17]. Published date: August 2015, last updated July 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: Referral form for Consideration of Flash Glucose Monitoring in Adults

Notes:

i. Only for completion at primary care annual review (including previous self-funders) unless clinical circumstances indicate earlier review eg. pregnancy, impaired awareness of hypoglycaemia* or recurrent severe hypoglycaemia** (see over)

ii. Patients should be advised to bring blood glucose meters to the annual review to enable a meter download assessment

PATIENT DETAILS					
Date of Referral:		Date Referral Received:			
GP Practice:		Referring GP/PN/DSN:			
Patient Name:		Patient Date of Birth:			
Patient Address:		Patient's Ethnicity:			
		Is an interpreter required? If yes please indicate language	**YES / NO** ……		
		Patient's Current Contact Number:			
NHS Number:		Hospital Number (if known):			
Current Weight:		Height:		Current BMI:	

POLICY CRITERIA – extract from full policy, which is accessible via this link
http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/?assetdet1029359=39308

Please confirm that the patient (and/or carer as appropriate) has:	**Tick as Required**
1. **Established type 1* insulin-dependent diabetes** (recommended > 6 months) ** or type 2 on haemodialysis or diabetes associated with cystic fibrosis*	☐ *(required)*
2. **Completed a structured education programme**** (unless inappropriate – pregnancy, housebound, residential/nursing home, carer administration):	*One of the following options required:*
Expert Insulin - Attendance at 4 or more of the 6 planned sessions	☐ *or*
or	
DAFNE (Dose Adjustment For Normal Eating) – Attendance at 4 or more of the 5 planned sessions	☐ *or*
or	
Completion of a refresher course within the last 2 years *(where expert insulin or DAFNE > 2yrs ago)*	☐ *or*
or	
Inappropriate: please indicate why: ……	☐
*** this will be validated by diabetes specialist teams who hold records of attendance & completion*	
3. **Optimised insulin regimen**	☐ *(required)*
4. **Engaged with active self-management** *(evidenced by regular attendance at review appointments by patient or carer)*	☐ *(required)*
5. **Ability to engage with and willing to commit, via a patient contract, to the**	☐ *(required)*

requirements of FlashGM *(including use >70% of the time and scanning ≥ 8 times a day)*

Clinical Indication (as per national criteria)

Please confirm the indication for consideration of FlashGM in patients on insulin treatment:	**Tick indication**
1. **Type 1 diabetes requiring intensive monitoring >8 times daily**, as demonstrated on a meter download/review over the past 3 months Daily monitoring frequency: ……	☐
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 Daily monitoring frequency: ……	☐
3. **Diabetes associated with cystic fibrosis**	☐
4. **Type 1 diabetes during pregnancy**	☐
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. Please describe: …… ……	☐
7. **Type 1 diabetes experiencing recurrent severe** hypoglycaemia**	☐
8. **Type 1 diabetes with impaired awareness* of hypoglycemia**	☐

* Psychosocial circumstances and impaired awareness of hypoglycaemia will be assessed by Diabetes Specialist Nurses involving the use of validated scoring tools

** 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

Other Relevant Information

Please review the patient's blood glucose meter download and provide the following additional information to facilitate diabetes specialist nurse triage:

- Is the patient under **Consultant or Diabetes Specialist Nurse** care? YES / NO
- How many **hypoglycaemic (<4mmol) episodes** has the patient experienced over the last 2 weeks?

  None ☐ 1 to 2 ☐ 3 to 5 ☐ > 5 ☐

- Has the patient experienced **severe hypoglycaemia** over the last 12 months? YES / NO
  (please provide detail below)
- How many hospital admissions has the patient had for **diabetic ketoacidosis** over the last 2 years? ……
- Has the patient got any history of **mental health issues/learning difficulties**? YES / NO
  (please provide detail below)
- Has the patient **previously self-funded FlashGM** where: YES / NO
  i. the clinical history prior to commencing FlashGM satisfies one of the indications above (please indicate) AND
  ii. the policy criteria outlined on page 1 are met

  Pre-FlashGM HbA1c: …… Test Date: ……

  Date FlashGM started: ……

Patient's previous medical history *to populate*

Patient's current medication list *to populate*

EXAMINATION/PMH/DH/ALLERGIES

Please provide all recorded values for **HbA1c** over the last 12 months *results to populate*

Please confirm whether there is any other relevant information:

PATIENTS NOT MEETING THE POLICY

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 clinically exceptional circumstances, an Individual Funding Request may be considered. The referring clinician should consult the Commissioner's "Operational Policy for Individual Funding Requests" document for further guidance on this process.
http://www.redditchandbromsgroveccg.nhs.uk/strategies-policies-and-procedures/commissioning-ifr-policies-a-z/

Completed referral forms should be emailed to one of the following:

Redditch and Bromsgrove Practices: wah-tr.redditchbromsgrovediabetes@nhs.net
South Worcestershire Practices: wah-tr.southworcsdiabetes@nhs.net
Wyre Forest Practices: wah-tr.wyreforestdiabetes@nhs.net

APPENDIX 2: Blueteq Initiation Form – Flash Glucose Monitoring in Adults

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 "**Flash Glucose Monitoring in Adults**"	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

Choose one of above indications

* Psychosocial circumstances must be assessed by use of a validated 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

*** impaired awareness of hypoglycaemia must be assessed by use of the Clarke Hypoglycaemic Index or Gold Score necessitating a score of >4 and ≥ 4 respectively

4. **BASELINE MONITORING PARAMETERS**

HbA1c

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

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

(prior users only)

Target Improvement in HbA1c (mmol/mol): ……. *baseline*

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 ☐

Hospital admissions for **diabetic ketoacidosis** over the last 2 years? YES / NO

Episodes of **severe hypoglycaemia*** over the last 12 months? YES / NO

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

Psychosocial distress score: **Score**: ☐ *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

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	Flash Glucose Monitoring (FlashGM) in Adults		
Aims of this piece of work	To define the arrangements for accessing FlashGM in Worcestershire including eligibility criteria, continuation criteria and management responsibilities		
Date of EIA	15/03/19	Other partners/stakeholders involved	Area Prescribing Committee, Clinical Commissioning Policy Collaborative
Who will be affected by this piece of work?	Adults		

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	Currently, the number of people diagnosed with diabetes in the UK is estimated to be 3.5 million Slightly more men than women have been diagnosed with diabetes. Audits suggest that about 56% of all adults with diabetes in the UK are men and 44% are women	No
Race	There is limited information in relation to those with type 1 disease. 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, compared with women in the general population.	No
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 therefore there is a differential impact in adults.	Yes
Carers	There is no published information that indicates that being a carer affects the development of diabetes.	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		
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 therefore there is a differential impact in adults as the criteria within this policy are primarily focussed on type 1 disease.	The guidance informing this policy has been agreed nationally and is therefore outside of the control of local commissioners.	NA		