

Commissioning Policy: The use of Flash Glucose Monitoring systems in eligible diabetic patients

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Document Amendment History

Version No.	Date	Brief Description
Version 4	22/11/21	Review, aligning of Shropshire CCG and Telford and Wrekin CCG processes and update to new CCG format.
Version 5	01/12/21	Update on structured education available locally and ketone testing strips.

The formally approved version of this document is that held on the NHS Shropshire, Telford and Wrekin CCG website: www.shropshiretelfordandwrekinccg.nhs.uk



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1 Introduction

Flash Glucose Monitoring systems monitor glucose levels using interstitial fluid levels rather than capillary blood glucose, which is used in finger prick testing. There are two elements to the products used to support Flash Glucose Monitoring - the monitoring device itself and the sensors. The sensors are worn on the person's arm and the monitor is applied to the sensor to take a glucose reading. Each sensor lasts up to 14 days and needs to be replaced after that time. Flash Glucose Monitoring is not the same as Continuous Glucose Monitoring (CGM).

Flash Glucose Monitoring systems are calibrated as part of the production process and do not require calibration using finger-prick testing. A finger-prick test using a blood glucose meter is still required in the following circumstances:

- During times of rapidly changing glucose levels, when interstitial fluid glucose levels may not accurately reflect blood glucose levels (e.g. acute illness such as influenza or diarrhoea and vomiting)
- If hypoglycaemia or impending hypoglycaemia is reported or the symptoms do not match the system readings.
- By Group 1 drivers (car and motorcycle) who use flash glucose monitoring systems at the times defined by DVLA requirements¹

The blood glucose level must be confirmed with a finger prick blood glucose reading in the following circumstances:

- o when the glucose level is 4.0 mmol/L or below
- o when symptoms of hypoglycaemia are being experienced
- when the glucose monitoring system gives a reading that is not consistent with the symptoms being experienced (eg symptoms of hypoglycaemia and the system reading does not indicate this)
- By Group 2 drivers (bus and lorry) who use this system must continue to monitor finger prick capillary blood glucose levels in line with the DVLA requirements¹. Flash Glucose Monitoring interstitial fluid glucose monitoring systems are not permitted for the purposes of Group 2 driving and licensing.

The NHS Long Term Plan announced that 'the NHS will ensure that, in line with clinical guidelines, patients with type 1 diabetes benefit from life changing flash glucose monitors from April 2019, ending the variation patients in some parts of the country are facing'².

On 7th March 2019 NHS England published a guidance document setting out the criteria for Flash Glucose Monitoring.³

The criteria was updated in November 2020 to include people with Type 1 diabetes or insulin treated Type 2 diabetes living with a learning disability

and recorded on their GP Learning Disability register.3

2 Purpose

The purpose of this policy is to provide clear, nationally defined criteria for the commissioning of Flash Glucose Monitoring in eligible diabetic patients.

3 Identification of patients appropriate for Flash Glucose Monitoring

Consideration of whether a person may be appropriate for Flash Glucose Monitoring and satisfies the criteria may form part of their annual diabetes review, or a review that takes place as a result of other changes in their diabetes needs.

The setting in which consideration of whether a person satisfies the criteria for Flash Glucose Monitoring takes place will be the setting within which the patient's wider diabetes care management responsibilities are carried out.

4 Criteria for Flash Glucose Monitoring

NHS Shropshire, Telford and Wrekin CCG recommend that Flash Glucose Monitoring is considered for patients who are aged 4 or above and meet one or more of the following:

1) People with Type 1 diabetes

OR with any form of diabetes who are on haemodialysis and on insulin treatment

who, in either of the above, are clinically indicated as requiring intensive monitoring i.e. ≥8 times per day, as demonstrated on a meter download/review over the past 3 months.

OR with diabetes associated with cystic fibrosis on insulin treatment.

- Pregnant women with Type 1 diabetes Flash Glucose Monitoring will be provided for a total of 12 months inclusive of antenatal and post-delivery period.
- People with Type 1 diabetes who are unable to routinely self-monitor blood glucose due to disability who require carers to support glucose monitoring and insulin management.
- 4) People with Type 1 diabetes for whom the specialist diabetes MDT determines have occupational (e.g. working in insufficiently hygienic conditions to safely facilitate finger-prick testing) or psychosocial circumstances, which warrant a 6-month trial of Flash Glucose Monitoring with appropriate support.
- 5) Previous self-funders of Flash Glucose Monitoring who have Type 1 diabetes and where those with clinical responsibility for their diabetes care are satisfied, that their clinical history suggests that they would have met

one or more of the initiation criteria in this policy, prior to them commencing use of Flash Glucose Monitoring, had these criteria been in place prior to April 2019 AND have shown an improvement in HbA1c since commencing self-funding. Consideration of whether a patient meets criteria for NHS funding can be undertaken by the patient's diabetes specialist (at the time of their next routine review) or primary care clinician.

- 6) For patients with Type 1 diabetes and recurrent severe hypoglycaemia or impaired awareness of hypoglycaemia, NICE suggests that Continuous Glucose Monitoring with an alarm is the standard. Other evidence-based alternatives with NICE guidance or NICE TA support are 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.
- 7) People with Type 1 diabetes or insulin treated Type 2 diabetes who are living with a learning disability and recorded on their GP Learning Disability register.

In addition the following basic criteria must also be met:

- All patients and/or their families or carers (if appropriate) must receive education on Flash Glucose Monitoring (either online or in person) before initiation of treatment.
- All patients and/or their families or carers (if appropriate) must agree to scan glucose levels no less than 8 times per day and use the sensor >70% of the time.
- All patients and/or their families or carers (if appropriate) must be able to accurately interpret and act appropriately on the feedback from the Flash Glucose Monitor.
- All patients and/or their families or carers (if appropriate) must commit to ongoing regular follow-up and monitoring from the diabetes specialist team at intervals as deemed clinically appropriate (including remote follow-up where this is offered).
- All patients and/or their families or carers (if appropriate) must have completed, or due consideration given to completing a relevant diabetes structured education programme if appropriate e.g. for Type 1 diabetics -Dose Adjustment for Normal Eating (DAFNE).
- All patients and/or their families or carers (if appropriate) must agree the expected outcomes of usage and to the withdrawal of Flash Glucose Monitoring if the continuation criteria are not met.

5 Criteria for Continuation

Long term prescribing responsibility will generally be accepted by primary care. This does not preclude, where appropriate, clinical oversight of a person's use of Flash Glucose Monitoring remaining within secondary care alongside wider management of their diabetes.³

Continuing prescriptions for the long term use of Flash Glucose Monitoring following the initial 6 month trial period will be contingent upon evidence demonstrating that the criteria below have been met.³

- 1) Patient must have used the scanner no less than 8 times per day and for at least 70% of the time during the trial period i.e. at least 5 days per week as demonstrated by a meter download at treatment review.
- 2) Patient must have attended regular reviews with the local clinical team and agreed to continue to do so.
- 3) Patient must have agreed to complete, or due consideration given to completing a relevant diabetes structured education programme if appropriate.

In addition to the above, there must be a demonstrable improvement in the individual's diabetes self-management for example:

- a) An improvement of Hb1Ac or time in range
- b) An improvement in symptoms such as diabetic ketoacidosis or hypoglycaemia
- c) An improvement in psycho-social wellbeing, quality of Life could be assessed using a validated rating scale

NOTE: NHS funding for Flash Glucose Monitoring will be withdrawn if the patient fails to meet the above criteria and patients should be made aware of this at the time of initiation.

It is the responsibility of the specialist diabetes team to inform the patient's primary care clinician and the CCG if Flash Glucose Monitoring is to be withdrawn at any time.

Patients who do NOT meet the above criteria for initiation OR continuation will NOT routinely be entitled to NHS funding by Shropshire, Telford and Wrekin CCG. This includes patients who are currently self-funding Flash Glucose Monitoring.

Use of Flash Glucose Monitoring is NOT recommended in patients with Type 2 Diabetes with the exception of patients on haemodialysis, with cystic fibrosis and on insulin therapy and patients with insulin treated Type 2 diabetes who are living with a learning disability and recorded on their GP Learning Disability register as outlined in the above criteria.

6 Application for funding Flash Glucose Monitoring

Requests to initiate and continue Flash Glucose Monitoring should come from Diabetes Specialist Teams only (Community Diabetes Team or Secondary Care).

Requests to transfer from self-funding to NHS funding can be undertaken by the patient's diabetes specialist or primary care clinician.

Community Diabetes Team and Secondary Care Diabetes Team (STW) Initiation (6 month trial)

Requests to initiate Flash Glucose Monitoring should be submitted via Blueteq. Initial approval will be on a 6 month trial basis only.

A copy of the Blueteq approval letter should be sent to the patient's GP together with a request for the primary care clinician to accept prescribing responsibility for the flash glucose monitoring sensors.

 Adjunct blood glucose and ketone testing strips should continue to be prescribed according to the Local Health Economy Net Formulary, with the expectation that demand/frequency of supply will be reduced.

Out of Area Diabetes Specialist Team Initiation (6 month trial)

Requests to initiate Flash Glucose Monitoring should be submitted via Blueteq. Where Blueteq access is not available, the CCG Flash Glucose Monitoring Prior Approval Initiation Form should be completed and submitted via email to the CCG. Initial approval will be on a 6 month trial basis only.

Once approved, a copy of the Blueteq approval letter or the CCG approval letter (if no Blueteq access) should be sent to the patient's GP together with a request for the primary care clinician to accept prescribing responsibility for the flash glucose monitoring sensors.

 Adjunct blood glucose and ketone testing strips should continue to be prescribed according to the Local Health Economy Net Formulary, with the expectation that demand/frequency of supply will be reduced.

Continuation of Flash Glucose Monitoring Funding

Continued funding requests for Flash Glucose Monitoring for patients meeting the criteria following the 6 month trial period should be submitted via Blueteq continuation form for automatic approval. If Blueteq access is unavailable the CCG's Flash Glucose Monitoring Continuation Form should be completed and emailed to the relevant CCG.

Patients previously Self-Funding Flash Glucose Monitoring

Requests for previous self-funders to transfer to NHS funding should be submitted via Blueteq (Community Diabetes Team and Secondary Care Diabetes Team). Where Blueteq access is unavailable (Primary Care Clinician/GP), the CCG Flash Glucose Monitoring Previously Self-Funding Form should be completed and submitted via email to the CCG.

Once approved, if submitted via Blueteq a copy of the Blueteq approval letter should be sent to the patient's GP together with a request for the primary care clinician to accept prescribing responsibility for the flash glucose monitoring sensors. Where Blueteq access is unavailable, a CCG approval letter will be sent to the Primary Care Clinician/GP.

 Adjunct blood glucose and ketone testing strips should continue to be prescribed according to the Local Health Economy Net Formulary, with the expectation that demand/frequency of supply will be reduced.

7 Exceptional circumstances

The CCG recognises that there may be exceptional circumstances where the clinician believes 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.

8 Related documents

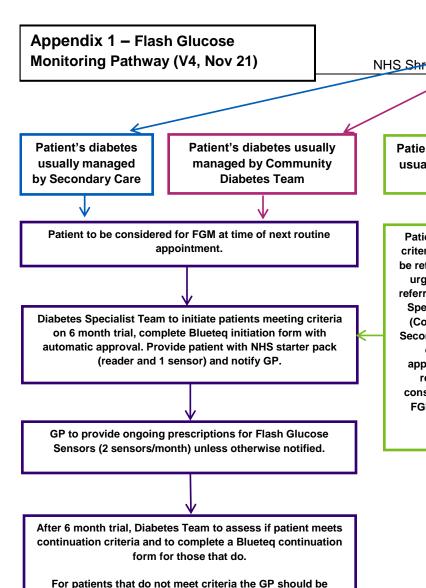
The following documents contain information that relates to this policy:

- Flash Glucose Monitoring Prior Approval Initiation form
- Flash Glucose Monitoring Continuation Form
- Flash Glucose Monitoring Previously Self-Funding Form
- Commissioning Policy: Continuous Glucose Monitoring (CGM) for Type 1 Diabetes in Children and Young People aged up to 19 years.
- Commissioning Policy: Continuous Glucose Monitoring (CGM) for Type 1 Diabetes in Adults and Pregnant women with Type 1 or Type 2 Diabetes on insulin therapy

9 References

 Driver and Vehicle Licensing Agency, Diabetes mellitus: assessing fitness to drive, Published March 2016, Updated March 2021, Available at: https://www.gov.uk/guidance/diabetes-mellitus-assessing-fitness-to-drive (Accessed: November 2021)

- 2. The NHS Long Term Plan, Version1.2, August 2019, Available at: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf (Accessed: November 2021)
- NHS England, Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients, Published March 2019, Updated November 2020, Available at: https://www.england.nhs.uk/wp-content/uploads/2019/03/National-arrangements-for-funding-of-relevant-diabetes-patients-June-2020-Updated-final.pdf (Accessed: November 2021)
- 4. NICE guideline [NG17] Type 1 diabetes in adults: diagnosis and management, Published August 2015, Updated July 2021, Available at: https://www.nice.org.uk/guidance/ng17 (Accessed: November 2021)
- NICE guideline [NG18], Diabetes (type 1 and type 2) in children and young people: diagnosis and management, Published August 2015, Updated December 2020, Available at: https://www.nice.org.uk/guidance/ng18 (Accessed: November 2021)
- NICE guideline [NG3], Diabetes in pregnancy: management from preconception to the postnatal period, Published February 2015, Updated December 2020, Available at: https://www.nice.org.uk/guidance/ng3 (Accessed: November 2021)
- 7. Dudley Clinical Commissioning Group, Commissioning Statement Flash Glucose Monitoring Systems, May 2019, Available at: https://www.dudleyformulary.nhs.uk/download/519/blood-glucose-testing-commissioning-statement-on-flash-glucose-monitoring-systems (Accessed: April 2019)



notified to discontinue prescribing the sensors.

Monitoring from GP or Diabetes Specialist Team

Patient requests Flash Glucose

Shropshire, Telford and Wrekin

Clinical Commissioning Group

Patient's diabetes usually managed by GP

Patients meeting criteria for FGM to be referred as nonurgent. routine referral to Diabetes Specialist Team (Community or **Secondary Care as** clinically appropriate) for review and consideration for FGM initiation.

Patient's self-funding Flash Glucose Monitoring

GP assessment

Patient to be assessed by GP against criteria.

CCG FGM Previously Self-Funding Form to be completed and forwarded to the CCG.

CCG grant approval for patient's that meet the NHSE funding criteria for FGM.

6 month trial will not be applicable in these patients as they should already demonstrate a reduction in HbA1c.

> CCG to inform GP of approval and upload patient's details onto Blueteq.

Following approval GP to prescribe Flash Glucose Sensors (2 sensors/month). DS Team assessment

Patient to be assessed by Diabetes Specialist Team at the time of their next routine review, against criteria.

Blueteg confirmation of eligibility form to be completed to obtain automatic approval.

6 month trial will not be applicable in these patients as they should already demonstrate a reduction in HbA1c.

Diabetes Specialist Team to inform GP of approval.

Following approval GP to prescribe Flash Glucose Sensors (2 sensors/month).

Patient seen by out of area **Diabetes Specialist Team**

Patient to be assessed by out of area team against commissioning policy criteria, Blueteq initiation or CCG Prior Approval Initiation Form to be completed and forwarded to the CCG.

CCG to grant 6 month funding approval for patient's that meet the NHSE funding criteria for FGM.

Diabetes Team to initiate patient on 6 month trial, provide patient with NHS starter pack (reader and 1 sensor) and notify GP.

GP to provide ongoing prescriptions for Flash Glucose Sensors (2 sensors/month) unless otherwise notified.

After 6 month trial, Diabetes Team to assess if patient meets continuation criteria and to complete a Blueteg continuation form for those that do. If Blueteq not available, a CCG FGM Continuation Form to be completed and forwarded to the CCG for approval for those that meet criteria.

For patients that do not meet criteria the GP should be notified to discontinue prescribing the sensors.