NHS Shropshire Clinical Commissioning Group

NHS Telford and Wrekin Clinical Commissioning Group

NHS Shropshire Clinical Commissioning Group and NHS Telford & Wrekin Clinical Commissioning Group Joint Commissioning Policy:

The use of Flash Glucose Monitoring systems in eligible diabetic patients

Commissioning Policy

From 1st April 2019, Telford and Wrekin CCG and Shropshire CCG will commission Flash Glucose Monitoring for patients who meet the nationally defined criteria outlined below.

Flash Glucose Monitoring should be initiated by a clinician that has received appropriate training on the initiation and use of the product.

In Shropshire CCG, initiation of Flash Glucose Monitoring for new patients should be by a diabetes specialist team.

In Telford and Wrekin CCG, initiation of Flash Glucose Monitoring for new patients should be by a diabetes specialist team or primary care clinician (where appropriate).

Requests to initiate Flash Glucose Monitoring should be submitted via Blueteq (secondary care and community diabetes team) or the CCGs' prior approval template (community diabetes team/primary care where Blueteq access is not available) which should be completed and forwarded to the relevant CCG.

The use of flash glucose monitoring systems is not routinely commissioned outside these criteria and funding requests will only be considered through the Individual Funding Request process if there are clear grounds for clinical exceptionality.

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 requirements[1] i.e
    - The blood glucose level must be confirmed with a finger prick blood glucose reading in the following circumstances:
        - when the glucose level is 4.0 mmol/L or below

  - 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)
- 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 requirements[1]. **Flash Glucose Monitoring interstitial fluid glucose monitoring systems are not permitted for the purposes of Group 2 driving and licensing**

Background

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]

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 type 1 diabetes care management responsibilities are carried out. For many people this consideration will take place in secondary care.

Any clinician initiating Flash Glucose Monitoring must have received appropriate training on the initiation and use of the product e.g. online training can be accessed via https://progress.freestylediabetes.co.uk/sign-up

Criteria for Flash Glucose Monitoring

NHS Shropshire and NHS Telford & Wrekin CCGs 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.

2) 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.

3) 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. Confirmation of patients meeting criteria should be done via the relevant Blueteq form or CCG prior approval template which should be forwarded to the relevant CCG.

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. *If, however, 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.*[3]

   In addition, all patients (or carers) **MUST**:

   - Receive education on Flash Glucose Monitoring (either online or in person) before initiation of treatment
   - Agree to scan glucose levels no less than 8 times per day and use the sensor >70% of the time
   - Be able to accurately interpret and act appropriately on the feedback from the Flash Glucose Monitor
   - Commit to ongoing regular follow-up and monitoring from the diabetes specialist team at intervals as deemed clinically appropriate
   - Have completed, or due consideration given to completing, a relevant diabetes structured education programme (e.g. for Type 1 diabetics - Shropshire Titration of Insulin and Lifestyle Education (STILE) programme, Dose Adjustment for Normal Eating (DAFNE)). *NB: Telford and Wrekin CCG requires patients who are initiated on Flash Glucose Monitoring to have either previously completed, or commit to completing a relevant diabetes structured education programme within the initial 6 month trial period.*

- Agree the expected outcomes of usage and to the withdrawal of Flash Glucose Monitoring if the continuation criteria are not met

Supply of a Flash Glucose Monitoring System should only be made following relevant CCG approval either by completion of the agreed Blueteq form (secondary care and community diabetes team) or the CCG's prior approval template (community diabetes team/primary care where Blueteq access is not available). Initial approval will be on a 6 month trial basis only.

Where Flash Glusose Monitoring is initiated by a specialist diabetes team, a copy of the Blueteq approval letter/CCG approval template 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 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.

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.

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] Continued funding requests for Flash Glucose Monitoring following the 6 month trial period should be submitted via Blueteq (secondary care and community diabetes team) or the CCG's continued funding template (community diabetes team/primary care where Blueteq access is not available) which should be completed and forwarded to the relevant CCG.

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 completed a relevant diabetes structured education programme either prior to commencing Flash Glucose Monitoring or during the 6 month trial period (this requirement only applies to patients registered with a Telford and Wrekin GP practice).

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 or Telford and Wrekin CCGs. This includes patients who are currently self-funding flash glucose monitoring. Where the criteria are not met but the clinician believes that there are grounds for clinical exceptionality – an Individual Funding Request should be submitted to the responsible commissioner.

Use of Flash Glucose Monitoring is NOT recommended in patients with Type 2 Diabetes with the exception of patients on haemodialysis or with cystic fibrosis and on insulin therapy as outlined in the above criteria.

This policy is based on the best available information at the time of writing.

References

1 https://www.gov.uk/guidance/diabetes-mellitus-assessing-fitness-to-drive <accessed 08/03/2019>
2 https://www.longtermplan.nhs.uk/wp-content/uploads/2019/01/nhs-long-term-plan.pdf Published January 2019 <accessed 08/03/2019>
3 https://www.england.nhs.uk/wp-content/uploads/2019/03/flash-glucose-monitoring-national-arrangements-funding.pdf Published March 2019 <accessed 11/03/2019>
4 https://www.nice.org.uk/guidance/ta151 Published July 2018 <accessed 08/03/2019>
5 https://www.nice.org.uk/guidance/ng17 Published August 2015, updated July 2016 <accessed 08/03/2019>.