



West Yorkshire and Harrogate Commissioning Policy

Treatment	Flash Glucose Monitoring
For the treatment of	Monitoring glucose levels in adults and children over 4 years of age with type 1 diabetes mellitus. Also type 2 diabetes in certain cases (see 8.)
Commissioning position	<p>West Yorkshire and Harrogate Health and Care Partnership commissions the use of Flash Glucose Monitoring Systems (FGS) for:</p> <ol style="list-style-type: none"> 1. People with type 1 diabetes <ul style="list-style-type: none"> OR with any form of diabetes on hemodialysis and on insulin treatment Who in either of the above, are clinically indicated as requiring intensive monitoring >8 times daily, 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 -12 months in total inclusive of post-delivery period 3. People with type 1 diabetes 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 (eg. working in insufficiently hygienic conditions to safely facilitate finger-prick testing) or psychosocial circumstances that warrant a 6-month trial of flash glucose monitoring with appropriate adjunct support 5. Previous self-funders of flash glucose monitors with type 1 diabetes where those with responsibility for their diabetes care are satisfied that their clinical history suggests that they would have satisfied one or more of these criteria prior to them commencing use of flash glucose monitoring had these criteria been in place prior to April 2019 AND shown improvement in HbA1c since self-funding. 6. For those 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 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 who would not otherwise meet the criteria, but for whom provision of a Flash Glucose Monitoring System might prevent the need for an insulin pump.
8. 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.

Added January 2021

Other requirements:

1. Education on Flash Glucose Monitoring has been provided by a suitably trained member of the diabetes team.
2. Agree to scan glucose levels no less than 8 times per day NB this should be spread over the day, and use the sensor >70% of the time.
3. Agree to regular reviews with the local clinical team
4. Previous attendance, or due consideration given to future attendance, at a type 1 diabetes structured education programme (DAFNE or equivalent) if available locally.

Diabetes Specialist Teams Responsibilities*

1. Assess type 1 diabetic patients for suitability for flash glucose monitoring and ensure any appropriate patients meet the criteria within the NHSE guidance before considering initiation. Record the criteria for initiation in patients' medical records.
2. Discuss use of flash glucose monitoring with patient and complete a patient contract form (appendices 1 &2) to ensure they are aware that continuation of supply beyond 6 months is contingent on achieving a demonstrable improvement and engagement with other diabetes care processes. The expected improvement or benefit from treatment should be recorded and agreed with the patient.
3. Patients need to sign up to share their scan data with the diabetes team on Libreview.com or other suitable platform.
4. Arrange training on the use of flash glucose monitoring products with a suitable trained member of the team or group training.
5. Supply a starter pack to patient (monitor and 1 sensor lasting 2 weeks)
6. Inform patient of safe disposal of sensors as clinical waste, supply clinical waste bags or large sharps bins as per local arrangement.
7. Inform GP practice in timely manner that patient has been initiated on flash glucose monitoring. For Cystic Fibrosis and Haemodialysis patients inform all relevant clinicians involved in their care.

Communications should include the following information:

- a) Which criteria the patient meets for initiation of flash glucose

	<p>monitoring</p> <ul style="list-style-type: none"> b) What is expected improvement or benefit at 6 months from flash glucose monitoring c) What is frequency of ongoing need for patient to continue BGTS as well as flash glucose monitoring - State expected reduction in BGTS usage. d) A copy of the patient contract form e) Next review appointment <p>8. Arrange to review the patient at an appropriate interval but no later than 6 months after initiation.</p> <p>9. Review the patient at 6 months to determine whether they have achieved the expected improvement or benefit to continue flash glucose monitoring (see under 'Review') and record outcome on agreed audit tool as appropriate.</p> <p>10. Inform GP practice in a timely manner whether the patient should continue on flash glucose monitoring following 6 month review. Communications should include the following information:</p> <ul style="list-style-type: none"> a) What improvement or benefit has been achieved from flash glucose monitoring in line with patient contract. b) Whether patient is continuing on flash glucose monitoring or agreed to stop due to lack of benefit or patient choice. c) What is frequency of ongoing need for patient to continue BGTS as well as flash glucose monitoring. Expected reduction in BGTS usage. d) Next review appointment <p>* The definition of 'diabetes specialist' will be subject to local interpretation. This will be defined by each of the nine CCGs of WY&H. This may include Consultant Diabetologists and Endocrinologists, GPs with a specialist interest in Diabetes and Advanced Nurse Practitioners or Practice Nurses with skills in the management of diabetes. This will reflect current local service models and the knowledge and skills of local primary and community care clinicians.</p> <p>Primary Care Prescribers Responsibilities</p> <ul style="list-style-type: none"> 1. Do not initiate diabetic patients on flash glucose monitoring in primary care. Refer patients to discuss their eligibility with the diabetes team at their next planned review. 2. Patients who do not meet the NHSE criteria may purchase privately. Continue to prescribe sensors for patients who have been initiated by diabetes specialist team on flash glucose monitoring. 3. Following receipt of communication (letter/task) from the diabetes specialist team add Freestyle Libre sensors to the patients repeat prescription authorised for 6 months. Add a note so that all prescribers can see when the review date is due. NB. 2 sensors last for 28 days If the sensors fall off within 14 days the patient should contact Abbott Customer Care to obtain a replacement they should not be issued again on prescription. 4. Reduce the quantity of BGTS from the patient's prescription record
--	--

in line with the diabetes team instructions regarding need for ongoing monitoring.

5. At the end of the initial 6 months' supply ensure the patient has been reviewed by the specialist team and has achieved the planned improvements or benefits before re-authorising further supply of sensors. NB the practice should receive communication following this specialist review to confirm success or failure of flash glucose monitoring
6. Ensure the patient receives an ongoing review of flash glucose monitoring as part of their regular diabetes reviews.

Review at 6 months by Specialist Diabetes Team

The following should take place 6 months after initiation

- Check patients are scanning glucose levels at least 8 times a day. NB this should be spread over the day. Libreview.com can be used for this purpose.
- Check patients have reduced the use of BGTS taking into account any defined need for continued use in some patients.
- Check patients have achieved the improvements or benefits stated in the patient contract and agreed at initiation of flash glucose monitoring. Where this was an improvement in HbA1c a reduction in HbA1c of 5mmol/mol should be seen or a 10% improvement in 'time in range' i.e. the amount of time an individual is able to maintain their blood sugar level within the target range.
- Check patients continue to engage with diabetes care processes including attendance at planned appointments, engagement with training and education, attendance for foot and eye care appointments and annual vaccination (where indicated).
- Record the outcome of the review in patients' medical records and update the agreed audit tool if appropriate. Communicate outcome of the review to the GP practice (see section 9 under specialist responsibilities)

Ongoing reviews by Specialist Diabetes Team or GP Practice (if patient no longer under specialist care) as part of regular planned diabetes review

- Check patients are scanning glucose levels at least 8 times a day. NB this should be spread over the day.
- Check patients have maintained a reduction in use of BGTS taking into account any defined need for continued use in some patients.
- Check patients have maintained the improvements or benefits stated in the patient contract and agreed at initiation of flash glucose monitoring.
- Check patients continue to engage with diabetes care processes including attendance at planned appointments, engagement with training and education, attendance for foot and eye care appointments and annual vaccination (where indicated).
- Record the outcome of the review in patients' medical records.
- Stop prescribing if the patient is no longer benefitting from flash glucose monitoring.

Date effective from	July 2019
Policy to be reviewed by	July 2021
Background information	<p>NHSE issued guidance in March 2019 on the national arrangements for the funding of flash glucose monitoring for relevant patients with type 1 diabetes. (https://www.england.nhs.uk/publication/flash-glucose-monitoring-national-arrangements-for-funding-of-relevant-diabetes-patients/)</p> <p>Prior to this guidance three commissioning policies have been in place since 2018 from the three Area Prescribing Committees in West Yorkshire which were similar but not identical in their criteria for accessing this technology.</p> <p>The FGS consists of a sensor worn on the upper arm that measures interstitial glucose every minute and a reader device that is scanned over the sensor to get a result. It can produce a near continuous record of measurements which can be accessed on demand. It can also indicate glucose level trends over time.</p> <p>The FGS is indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with diabetes mellitus. The product is classified as a device and received European CE mark certification in August 2014.</p> <p>The sensors may also be read with an appropriate application on a Smart phone which has near-field communication.</p> <p>This new technology helps to reduce the burden of finger prick blood tests but there is not any evidence available as yet as to whether it reduces complications and long-term outcomes for diabetic patients. There is no NICE directive for CCGs to fund this new technology but NICE has undertaken a Medtech innovation briefing [1].</p>
Summary of evidence/rationale	<p>The main points from the evidence are from 5 studies involving 700 people [1]. This includes 2 randomised controlled trials; one that includes people with type 1 diabetes (n=241; the IMPACT study) and the other including people with type 2 diabetes (n=224; the REPLACE study) [1].</p> <p>Three of the studies reported device accuracy compared with self-monitored blood glucose, with results ranging from 84% to 88% accuracy and from 99% to 100% clinical acceptability, using an error grid. One study reported device accuracy and acceptability of 97% to 99% compared with venous blood sampling [1].</p> <p>Patients using FreeStyle Libre® experienced less time in hypoglycaemia than patients using SMBG, averaging 1.24 hours per day (SE 0.24) or 38% less time (p<0.0001) in hypoglycaemia and 1 hour more per day in euglycaemia (p=0.0006). The number of hypoglycaemic events per day reduced by mean of 0.45 (by over 25%; p<0.0001) [1].</p> <p>The limited data available suggests that using FreeStyle Libre® for up to 12 months reduces time spent in hypoglycaemia compared with self-monitoring of blood glucose using finger-prick tests, and reduces the</p>

	<p>average number of finger-prick blood glucose tests needed [1].</p> <p>There is limited safety data available on the use of the FGS. The only published study carried out by Bailey et al reported there were no unexpected adverse device effects reported during the clinical study. Finger prick capillary blood glucose monitoring is still advised during periods of rapidly changing levels of interstitial glucose when interstitial glucose levels may not accurately reflect blood glucose levels, if hypoglycaemia or impending hypoglycaemia is reported, or the patient's symptoms do not match the system readings. Three of the studies reported device accuracy compared with self-monitored blood glucose. The investigators concluded that interstitial glucose measurements via the FreeStyle Libre® system were accurate compared with capillary blood glucose reference values, and this accuracy was maintained over 14 days lifespan of the Freestyle Libre® sensor.</p> <p>Cost effectiveness / resource impact:</p> <p>There is currently no UK cost-effectiveness data available for FGS to be able to determine whether this new technology is cost-effective for the NHS.</p> <p>The resource impact depends upon the extent to which improved glucose control through the adoption of FGS translates into fewer complications (hypoglycaemia and the longer term microvascular and macrovascular complications of hyperglycaemia), reduced admissions and reduced use of blood glucose test strips.</p> <p>NHSE have agreed time limited national funding arrangements for 2019/20 and 2020/21. CCGs will be refunded at each quarter end on the basis of primary care prescribing data from NHSBSA.</p> <p>In 2019/20 CCGs will be reimbursed £26.03 for each sensor prescribed, less than the actual cost of £35 taking into account the expected savings from reduced requirement to fund blood glucose testing strips. Annual reimbursement of £676.78 per patient. A year's cost of sensors is £910 per patient. The FGS reader is not available on prescription and will be provided free of charge by the manufacturer.</p> <p>CCGs will be reimbursed up to a maximum of 20% of their type 1 diabetes population (as set out in 2017/18 National Diabetes Audit)</p>
Contact for this policy	West Yorkshire and Harrogate Health and Care Partnership Pharmacy Leadership Group

References

1.) FreeStyle Libre for glucose monitoring; Medtech innovation briefing [MIB110] Published date: July 2017. Accessed: 13.06.2018 <https://www.nice.org.uk/advice/mib110>