NHS
North Yorkshire
Clinical Commissioning Group

Commissioning Statement:

Condition or Treatment:	Flash Glucose Monitoring System for use in adults, young people and children for ,onitoring glucose levels in adults and children over 4 years of age with type 1 diabetes mellitus
Commissioning position:	Flash Glucose Monitoring System (FGS) is only commissioned for: 1. People with Type 1 Diabetes OR with any form of diabetes on haemodialysis and on insulin treatment who, in either of the above, are clinically indicated as requiring intensive monitoring of over 8 times daily by their diabetes specialist, 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, eligible for 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 (e.g. working in insufficiently hygienic conditions to safely facilitate finger-prick testing) or psychosocial circumstances that warrant a 6 month trial of FGS with appropriate adjunct support. 5. Previous self-funders of FGS with Type 1 diabetes where those with clinical responsibility for their diabetes care are satisfied that their clinical history suggests that they would have satisfied one or more of the above criteria, prior to them commencing use of FGS, had these criteria been in place prior to April 2019 AND have 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
- 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 who have had 2 or more admissions due to diabetic ketoacidosis in the previous 12 months.

8. Patients with type 1 diabetes who meet the NICE criteria for insulin pump therapy where a trial of FGS may avoid the need to initiate an insulin pump.

9. 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

Other requirements:

- Education on Flash Glucose Monitoring has been provided (online or in person)
- Agreement to scan glucose levels at least 8 times per day and use the sensor over 70% of the time
- Agreement 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, such as BITES or DAFNE

The initiation of patients on to FGS will be the responsibility of the diabetes specialist team in secondary care, continued supplies will be the responsibility of primary care prescribers.

Continued prescription for long-term use of FGS, following 6 month review, would be contingent upon evidence of agreeing with the above conditions and that on-going use of FGS is demonstrably improving diabetes self-management. The decision to continue will be made by the diabetes specialist team in secondary care only if one or more of the following are demonstrated:

	• Reduction in usage of blood glucose test strips (approximate target to be agreed, however it is acknowledged that more frequent testing may be required in certain circumstances e.g. during periods of illness or to fulfil DVLA requirements). • Reduction in hypoglycaemia frequency • Reversal of impaired awareness of hypoglycaemia • Reduction in episodes of diabetic ketoacidosis • Improvement of HbA1c or time in range. • Reduction in hospital admissions • Improvement in psycho-social wellbeing
Secondary Care Specialist Team Responsibilities:	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 patient's medical record. 2. Discuss use of flash glucose monitoring with patient and 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 minimum of one sensor lasting two 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) The criteria the patient meets for initiation of flash glucose monitoring b) The expected improvement or benefit at 6 months from flash glucose monitoring c) The frequency of ongoing need for patient to continue BGTS as well as flash glucose monitoring - State expected reduction in BGTS usage. d) Next review appointment 8. Arrange to review the patient at an appropriate interval but no later than 7 months after initiation. 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. 10. At 6 month review: Inform GP practice as soon as practical and within seven days whether the patient should continue on flash glucose monitoring. Communications should include the following information: a) The improvement or benefit achieved from flash glucose monitoring. b) Whether patient is continuing on flash glucose monitoring or agreed to stop due to lack or benefit or patient choice. c) The frequency of ongoing need for patient to continue BGTS as well as flash glucose monitoring. Expected reduction in BGTS usage. d) Next review appointment
Primary Care GP Responsibilities	Primary Care Prescribers Responsibilities 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 NHS commissioned 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.
Further information	Secondary care specialist teams are responsible for completing audit data when FGS is first started and after six months. If audit data is not collected within four weeks of the end of the six month trial, the patient will not be eligible for FGS. Patients will need to be made aware of this and sign a contract agreeing to the terms of use of FGS. Treatment outcomes must be audited in all patients started on FGS by

	specialist teams. The specialist teams will be responsible for ensuring FGS is being appropriately used by ensuring patients satisfy the above criteria. The specialist team will provide audit data to the CCG if requested who will periodically review the data. All patients (or carers) must be willing to undertake training in the use of FGS. They must commit to regular scans of the device demonstrating evidence of FGS use in self-management, and commit to ongoing regular follow-up and monitoring. They must also agree the expected outcomes with usage and that NHS provision of FreeStyle Libre® will be withdrawn if one or more of the above criteria are not met. Prescribing instructions: • The specialist team will provide the patient with a 2 week sensor supply and the FGS device. • The specialist team will notify the GP their patient has been initiated on FGS • GPs will need to then issue a prescription for 2 FGS sensors per month. • After 6 months, the specialist team will advise if the patient is eligible for continued supplies of FGS sensors on prescription. Adjunct blood testing strips should be prescribed according to locally agreed best value guidelines with an expectation that demand/frequency of supply will be reduced. Patients with Type 2 Diabetes who do not meet the above criteria are NOT eligible for FGS on the NHS. Reluctance to carry out finger prick testing (e.g. due to distress or inconvenience) alone is not considered to be criteria qualifying the use of FGS. Patients already purchasing FGS who do not meet the above criteria will not be entitled to NHS prescriptions. A clinician can make an Individual Funding Request (IFR) for treatment when a patient does not meet the stated criteria for funding. Funding can only be approved if a case of “exceptional clinical need” has been demonstrated.
Summary of clinical evidence:	FGS measures interstitial glucose levels from a sensor applied to the skin as an alternative to routine finger-prick blood glucose testing, and can produce a near-continuous record of measurements which can be accessed on demand. It can also indicate glucose level trends over time. Glucose readings can be seen anytime by scanning the sensor with a FGS reader or an android mobile device with ‘Near-field Communication’ (NFC) capabilities via the LibreLink companion app. FreeStyle Libre® is indicated in people aged 4 or over with diabetes mellitus, who have multiple daily injections of insulin or who use insulin pumps and are self-managing their diabetes. FreeStyle Libre® received European CE mark certification in August 2014. For more details on the device, please refer to NICE Medtech innovation briefing 110. The main points from the evidence are from 5 studies involving 700 people. These include 2 randomised controlled trials, 1 including people

	with type 1 diabetes (n=241; the IMPACT study) and the other including people with type 2 diabetes (n=224; the REPLACE study). 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. The evidence 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 average number of finger-prick blood glucose tests needed. In the IMPACT study, patients using FreeStyle Libre® experienced less time in hypoglycaemia than patients using self-monitored blood glucose (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%;$p<0.0001$). The mean number of SMBG tests per day reduced from 5.5 (SD 2.0) to 0.5 (SD 0.7) in the FreeStyle Libre® group. FreeStyle Libre® does not include an alarm that alerts users when glucose levels are too high or too low. The device measures interstitial glucose levels and finger-prick blood glucose testing would still be needed: • During times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels • If FreeStyle Libre® shows hypoglycaemia or impending hypoglycaemia • When symptoms do not match the system readings • To fulfil Driving and Vehicle Licensing Authority requirements to assess fitness to drive.
Safety:	There are currently limited safety data on the use of FreeStyle Libre® . The most commonly reported adverse effect related to sensor use in trials was skin reactions e.g. itching, rash, erythema, allergy, oedema and blisters. Some users may need to use a skin covering in order to be able to use the sensor. Accuracy of FreeStyle Libre® readings compared to capillary blood glucose testing has been found to be broadly comparable. However capillary blood glucose testing is still recommended 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, diarrhoea and vomiting), or if hypoglycaemia or impending hypoglycaemia is reported, or the symptoms do not match the system readings.
Cost:	The annual cost of sensors is currently £910 per patient (Dec 2020). The reader is not prescribable on the NHS but provided free of charge by the

	manufacturer. The use of FreeStyle Libre® is expected to be cost neutral if a patient is currently finger prick testing 8 or more times daily, and the introduction of FreeStyle Libre reduces the testing frequency to an average of 0.5 times daily. The resource impact depends upon the extent to which improved glucose control through the adoption of FreeStyle Libre® translates into fewer complications (hypoglycaemia and the longer term microvascular and macrovascular complications of hyperglycaemia), reduced admissions and reduced use of glucose test strips.
Effective from:	1 July 2021
Date:	December 2020
Review Date:	July 2023
Contact:	Chris Ranson, Senior Pharmacist, North Yorkshire CCG