Flash Glucose Monitoring System (FGS e.g. Freestyle Libre®)

Patient Agreement

Patient					
Name				**DOB**	
Email				**Tel. Number**	
Diabetes Specialist					
Name		**Trust**			
Email				**Tel. Number**	
GP					
Name		**Practice**			
Email				**Tel. Number**	

This form should be completed jointly by patient and NHS diabetes specialist. This document is required by the policy TVPC73 and its aim is to ensure FGS sensor prescribing is provided to patients with the correct training and support.

Flash Glucose Monitoring is a small sensor that you wear on your skin. It stores your glucose (also known as sugar) levels every few minutes and you can access them by scanning the sensor whenever you want to. It is instead of the finger prick testing of your glucose needed at the moment. However, at present it isn't clear from the trials that have been done whether it will be better for patient health. Patients using FGS will still need to perform finger prick tests at certain times as directed by their consultant e.g. before driving or when the FGS indicates certain glucose levels (higher or lower than normal range). It is also noted that there is no relevant standard of accuracy for this system.

Patient Criteria In line policy TVPC73 – tick which bracket the patient falls in to	
Type 1 diabetes OR with any form of diabetes on hemodialysis and on insulin treatment who, are clinically indicated as requiring intensive monitoring >8 times daily, as demonstrated on a meter download/review over the past 3 months	☐
Diabetes associated with cystic fibrosis on insulin treatment	☐
Pregnant women with Type 1 Diabetes - 12 months in total inclusive of post-delivery period	☐
Type 1 diabetes unable to routinely self-monitor blood glucose due to disability who require carers to support glucose monitoring and insulin management.	☐
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 Libre with appropriate adjunct support.	☐
Previous self-funders of Flash Glucose Monitors 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 these criteria prior to them commencing use of Flash Glucose Monitoring had these criteria been in place prior to April 2019 AND has shown improvement in HbA1c since self-funding.	☐
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 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.	☐
Those who meet the current NICE criteria for insulin pump therapy (HbA1c ≥69mmol/mol (8.5%)) or disabling hypoglycaemia(as described in NICE TA151) where a successful trial of FGS may avoid the need for pump therapy.	☐
Patient has frequent admissions (more than 2 per year) with DKA or hypoglycaemia	☐

Personal target outcomes Agree specific patient outcomes for 6 month trial (one or more of outcomes below). Add any other/alternative patient specific criteria.	
Admission reduction	
Reduction in finger prick/SMBG strip use while maintaining outcomes (especially if testing 12 times per day or more)	
Reduction in severe/non- severe hypoglycaemia frequency	
Reduction in episodes of DKA	
Reversal of impaired awareness of hypoglycaemia	

HbA1c reduction of 6mmol/mol (0.5%) within 6 months	
Continued delay of pump therapy initiation due to sustained HbA1c < 69mmol/mol (8.5%) or reduction in disabling hypoglycaemia	
Improvement in Time In Range	
Improvement in psycho-social wellbeing.	

Patient Requirements Patient must engage with recommended best clinical care	
Latest 3 months blood glucose testing data on meter as evidence of engagement with monitoring	☐
Have locally approved training on use of FGS and how to interpret and act on readings.	☐
Have agreed care plan in place	☐
Attended structured education	☐
Must commit to using Freestyle Libre® Sensor at least 70% of the time and scan no less than 8 times per day .	☐
Commit to on-going regular follow-up and monitoring.	☐
Keeps up to date with influenza vaccination	☐
No deterioration in HbA1c (for those who do not have a target outcome in table below) while using FGS .	☐

9 Care processes The aim of FGS is to improve your diabetes management, care and future health. To support this aim, it is understood that eligible patients will wish to engage with the 9 key care processes recommended by NICE.
Blood glucose level measurement (HbA1c)
Blood pressure measurement
Cholesterol level measurement
Retinal screening
Foot check
Kidney function testing (urine)
Kidney function testing (blood)
Weight check
Smoking status check

Patient responsibilities

Patients must agree

- To undertake locally approved training on use of FGS and how to interpret and act on readings
- To attend local structured diabetes education
- To miss no more than 1 specialist clinic appointment in a row
- To give permission for data to be entered in national audit
- To return any faulty sensors to Abbott directly for replacements.
- To use locally agreed best value blood glucose test strips for any ongoing monitoring requirements, as agreed with specialist.*

Specialist responsibilities

- To ensure patient meets eligibility criteria and requirements
- To ensure patient diabetes health care plan in place
- To agree personal targets with patient
- To encourage patient to attend all education and engage with 9 processes of care
- To provide a copy of this Patient/Carer agreement to the GP, along with outpatient clinic letter
- To enter patient data into audit (ABCD national audit)
- To review benefit after 6 months and inform GP of outcome and if continuation is indicated.
- To recommend locally agreed best value blood glucose test strips for any ongoing monitoring requirements*

GP responsibilities

- Only prescribe 2 sensors per month (28 days)

- Do not issue additional prescriptions for faulty sensors – patient must secure replacements via Abbott
- Prescribe locally agreed best value blood glucose test strips for any ongoing monitoring requirements, in appropriate quantities*
- Only prescribe for 6 months initially. Specialist will review benefit and communicate if continuation is indicated
- Encourage patient to attend all education and engage with 9 processes of care

Continuation criteria

- Achieve specific target outcome(s)
- Fulfil patient requirements and responsibilities

Patient agreement: The information above has been explained to me. I will see whether FGS helps me manage my diabetes in the ways I have agreed - my “personal target outcomes”. I agree to do everything described above under "patient requirements” and “patient responsibilities”. I understand that I will receive NHS Freestyle Libre sensors for 6 months. After that they will only be continued if I have achieved the personal target outcomes and complied with the patient requirements and responsibilities.
Patient signature …… **Date**……..

* Specialist opinion estimates ongoing strip requirements of up to three per day. See Guideline For Blood Glucose Monitoring and Ketone Testing and Sick day Rules Guidance