NHS
Bristol, North Somerset and South Gloucestershire
Clinical Commissioning Group

Commissioning Policy

Abbott FreeStyle Libre® Flash Glucose Monitoring System

Criteria Based Access

Date Adopted: 01 April 2019
Version: 1920.1.00

Shaping better health

Document Control

Title of document:	Abbott FreeStyle Libre® Flash Glucose Monitoring System Policy
Authors job title(s):	Commissioning Policy Development Manager, BNSSG CCG Principal Medicines Optimisation Pharmacist, BNSSG CCG
Document version:	V1920.1.00
Supersedes:	v1819.1.02
Clinical Approval – received from:	NHS England
Clinical Approval – date received:	NHS England
Discussion and Approval by Clinical Policy Review Group (CPRG):	This document will be shared for information at Meeting 1 CPRG 2019.
Discussion and Approval by CCG Commissioning Executive:	NHS England
Date of Adoption:	01 April 2019
Publication/issue date:	05 April 2019
Review due date:	Earliest of either NICE publication or three years from approval.
Equality Impact Assessment Screening (date completed):	In development

Version Control

Version	Date	Reviewer	Comment
v1819.1.00 DRAFT v1	16/05/2018	IFR Manager	Initial draft sent to Medicines Management following Commissioning Executive decision
v1819.1.00 DRAFT v2	19/06/2018	IFR Coordinator	Prepared for presentation at CPRG 20/06/2018
v1819.1.01	09/08/2018	IFR Manager	Finalised for website publication, specific " go live" date to be updated once notice given

v1819.1.02	27/11/2018	Commissioning Policy Development Support Officer	Updated for policy go live date
V1920.1.00	05/04/2019	Commissioning Policy Development Manager	BNSSG have are following NHS England criteria recommendations. This document has been updated to reflect this information.

THIS IS A CRITERIA BASED ACCESS POLICY
TREATMENT MAY BE PROVIDED WHERE PATIENTS MEET THE CRITERIA BELOW

THIS POLICY RELATES TO ALL PATIENTS

Abbott FreeStyle Libre® Flash Glucose Monitoring System Policy

General Principles

Funding approval will only be given in line with these general principles. Where patients are unable to meet these principles in addition to the specific treatment criteria set out in this policy, funding approval will not be given.

1. The routine use of FreeStyle Libre® for all patients with Type 1 and Type 2 Diabetes is not recommended but is available where patients meet this clinically approved criteria.
2. It is important to note that the FreeStyle Libre® is not the same as continuous glucose monitoring (CGM).

Background

The FreeStyle Libre® (FSL) is a flash glucose monitoring system which monitors glucose levels in interstitial fluid rather than capillary blood glucose levels from finger-prick testing.

The FSL system 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 for the last eight hours which can be accessed on demand. It can also indicate glucose level trends over time. The sensors last for 14 days.

The FSL system is indicated for measuring interstitial fluid glucose levels in people (aged 4 years and older) with Diabetes Mellitus. The product is classified as a device and received European CE Mark certification in August 2014. The sensors may also be read with an appropriate application on a smart phone which has near-field communication.

POLICY CRITERIA – CRITERIA BASED ACCESS
The provision of Abbott Freestyle Libre® Flash Glucose Monitoring System, i.e. sensor and reader device, is not routinely commissioned by the CCG and is subject to this restricted policy.
Funding will only be provided by the CCG for patients meeting criteria set out below: **1. a**) People with Type 1 diabetes **OR** **b)** 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** **c)** with diabetes associated with cystic fibrosis on insulin treatment **OR** **2**. Pregnant women with Type 1 Diabetes - 12 months in total inclusive of post-delivery period. **OR** **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. **OR** **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 Libre with appropriate adjunct support. **OR** **5**. 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.

OR

6. For those with Type 1 diabetes and recurrent severe hypoglycemia or impaired awareness of hypoglycemia, 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.

Other requirements which must be satisfied as per CCG agreement:

1. Education on Flash Glucose Monitoring has been provided (online or in person)

2. Agree to scan glucose levels no less than 8 times per 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)

Note:

Continuing prescription for long-term use of Flash Glucose Monitoring-post initial 6 months- would be contingent upon evidence of agreeing with the above conditions and that on-going use of the Flash Glucose Monitoring is demonstrably improving an individual's diabetes self-management- for example improvement of HbA1c or Time In Range; improvement in symptoms such as DKA or hypoglycaemia; or improvement in psycho-social wellbeing.

Patients may only be considered on an individual basis where their GP or consultant believes *exceptional* circumstances exist that warrant deviation from the rule of this policy.

A patient may be considered exceptional to the general standard Policy if both of the following apply:

- He/she is different to the general population of patients who would normally be refused the healthcare intervention, and
- There are good grounds to believe that the patient is likely to gain significantly more benefit from the intervention than might be expected for the average patient with that particular condition.

In assessing exceptionality, the EFR Panel will not consider social, demographic or employment circumstances.

Individual cases will be screened by the EFR Team and may then be reviewed at the CCG's Individual Funding Request Panel upon receipt of an appropriate and fully completed application from the patient's GP, consultant or clinician.

Applications cannot be considered from patients personally.

Connected Policies

- Continuous Glucose Monitoring System Policy

This policy has been developed with the aid of the following references:

1. NICE Medtech Innovation Briefing [MIB 110]: FreeStyle Libre® for glucose monitoring NICE July 2017. Available at https://www.nice.org.uk/advice/mib110
2. https://www.england.nhs.uk/wp-content/uploads/2019/03/flash-glucose-monitoring-national-arrangements-funding.pdf