CURRENT ADVICE ON THE PRESCRIBING OF FLASH GLUCOSE MONITORING SYSTEMS (FGMS) (FREESTYLE LIBRE®) IN BEDFORDSHIRE CCG (BCCG) and LUTON CCG (LCCG) – NOVEMBER 2020 UPDATE

In March 2019, NHS England issued guidance relating to national arrangements for funding of Flash Glucose Monitoring Systems for relevant diabetes patients. This guidance was updated in November 2020:-

CLICK HERE TO VIEW THE GUIDANCE

The national guidance includes patient criteria for funding and BCCG and LCCG agreed to adopt these national criteria with effect from **1st April 2019**. **See Appendix A** for the full criteria for funding which incorporates an additional category of patients eligible (see point 7)). National funding is provided for a 2 year period (from April 2019), after which, CCGs will make a decision on whether to continue funding. NB during the COVID 19 pandemic, the CCG Heads of Medicines Optimisation have agreed to fund FreeStyle Libre for all newly diagnosed type 1 diabetic patients.

Patients who fulfill the criteria for funding will be provided with the device and an initial supply of sensors to cover a minimum of 2 weeks (4 weeks during the COVID 19 pandemic), provided by the Specialist Diabetes Teams at Bedford Hospital, the Luton and Dunstable Hospital and the Integrated Care of Diabetes Services (Bedfordshire and Luton). The patient's GP will then take over prescribing the sensors for a 6 month period, after which the patient will be reviewed by the Specialist Diabetes Teams for eligibility for continued funding. The Specialist Diabetes Teams will advise the patient's GP of the outcome of the review and authorise the GP to continue or discontinue prescribing. Patients will then be subject to annual review by the Specialist Diabetes Teams for eligibility for continued funding with the same communication to GPs as outlined above. See the Patient Agreement (Appendix B) which contains more detailed information/ requirements for patients who are initiated on FGMS. The CCGs will undertake a periodic (approximately 6 monthly) audit of the use of FreeStyle use against agreed local and national guidance using the data contained in the Libreview database.

The current branded product of Flash Glucose Monitoring – FreeStyle Libre sensors will gradually be replaced by FreeStyle Libre 2 sensors which cost the same. The difference between the two products is that FreeStyle Libre 2 has an audible alarm which indicates hypoglycaemia and hyperglycaemia. Patients using the FreeStyle Libre reader will require a new reader, but patients using the app will be able to continue using this with the FreeStyle Libre 2 sensors.

The funding criteria for FreeStyle Libre 2 is the same as for FreeStyle Libre. Both sensors are included in the November 2020 Drug Tariff.

From 2021 FreeStyle Libre 2 will be gradually rolled out to patients as part of their normal review.

BCCG Patients only:

BCCG acknowledges that some patients have commenced Flash Glucose Monitoring under the previously approved CCG criteria for funding. BCCG will honour funding for these patients assuming that Flash Glucose Monitoring is demonstrably improving an individual's diabetes self-management at 6 month and annual review.

For patients under the care of other Trusts, GPs should contact the BCCG or LCCG Medicines

Bedfordshire Clinical Commissioning Group
Luton Clinical Commissioning Group

Optimisation Team for advice.

Frequently Asked Questions (FAQs)

1. **How many sensors will a GP prescribe for a patient?**

   2 sensors/ 28 days (26 per annum). If any of the sensors are defective, the patient will need to contact the manufacturer to obtain a replacement.

   The patient should contact the Abbott Customer Careline, on 0800 170 1177. The patient should call on the day that the FreeStyle Libre sensor falls off. The patient should keep the displaced FreeStyle Libre sensor and follow the instructions of the Abbott Customer Careline representative.

   Please note that a maximum of 3 replacement FreeStyle Libre sensors can be issued per individual.

2. **Will GPs prescribe FreeStyle Libre® glucose testing strips for patients who are assessed to fit the criteria for use of this device?**
   The blood glucose testing strips used in the FreeStyle Libre reader are premium price. There is a local need to make the best use of resources to benefit the wider population, and whilst it is anticipated that the use of strips will be reduced to a lower level (e.g. 2-3 boxes per month) by using the FreeStyle Libre flash glucose monitoring system, all patients using this system will be asked to use a suitable cost effective blood glucose testing meter and strip**.** A suitable meter for blood glucose and ketone testing will be provided by the specialist diabetes team free of charge**.**

3. **Can drivers use the Flash Glucose Sensors to monitor blood glucose levels prior to driving?**

   The DVLA has updated the guidance on glucose testing prior to driving which now permits the use of interstitial glucose readings e.g. using Flash Glucose Monitoring (FreeStyle Libre) and Continuous Glucose Monitoring systems **for group 1 drivers only. CLICK HERE FOR FULL INFORMATION** as finger prick tests are still required (even for group 1 drivers) under certain circumstances.

4. **How Should the FreeStyle Libre sensor components be disposed of after use?**

   Used or unused sensor packaging can go in general waste.

   Once the FreeStyle Libre sensor has been placed on the arm, the used applicator (which contains a needle) and the lid can be screwed back together and can be placed in a yellow biohazard bag or sharps box.

   The used FreeStyle Libre sensor should be placed in a clinical waste sharps box.

5. **What about patients who are already self-funding FreeStyle Libre®?**

   Patients who have been buying the FreeStyle Libre® directly from the manufacturer (and wish to continue using the device) should still purchase their sensors via this route until they are reviewed, if appropriate, by the Specialist Diabetes Team at their next routine clinic appointment. BCCG and LCCG will only fund FreeStyle Libre® for patients who fulfill the eligibility criteria outlined below (Appendix A). It is important to ensure that patients are made aware that future decisions will not be based on what has already been purchased, but on what has been agreed for national NHS funding.

6. **What if the patient wishes to use (or continue using) FreeStyle Libre® but does not meet the national criteria for funding?**

   The patient can buy FreeStyle Libre® directly from the manufacturer - https://www.freestylelibre.co.uk/libre/ or Tel: 0800 1701177

7. **Will the recommendations for funding be reviewed?**

   Yes, these recommendations will be kept under review. In particular, a further review will be undertaken prior to the end of the national funding of the device and sensors (i.e. early 2021).

8. **If patients have any additional questions, who should they be directed to?**

   For BCCG Patients:
   BCCG Enquiry Telephone Line – 01525 624275 or Email – bedsccg.enquiries@nhs.net
   For LCCG Patients:
   LCCG Enquiry Telephone – 01582 532017 or Email – lccg.feedback@nhs.net

Appendix A

NHSE Criteria for Flash Glucose Monitoring Funding:-

1. People with Type 1 diabetes
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 (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.

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.

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.

7. 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:

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.

Appendix B

Flash Glucose Monitoring system (FGMS) agreement
For Patients aged 4 years and over

This form should be completed by the patient and/or their carer and an NHS diabetes specialist.

Agreement to use the flash glucose monitoring system (FGMS)

You have been given an FGMS system and the Diabetes Team expect you to take responsibility for using it correctly.

Patient's name	
Consultant name	
Unit/Hospital number	
Diabetes specialist nurse (DSN)	

I/We agree to:

- Attend all appointments as required by the Specialist Diabetes Team and GP.
- Attend the recommended FGMS training and take the advice of the diabetes team to understand what the device is showing and what action to take.
- Upload data from either the FreeStyle Libre®/FreeStyle Libre 2® handset or via LibreLink® app to Libreview at least once every 2 weeks unless the Diabetes Team are downloading this data for you at review.
- Share your data with your diabetes specialist team by adding the Practice ID code given to your LibreView® account settings unless the Diabetes Team are downloading this data for you at review.
- Agree to your data being shared for the purposes of audit.
- Attend (or have attended) a Type 1 diabetes structured education programme (DAFNE or equivalent if available locally) unless this is clinically inappropriate.
- Perform at least eight scans per day as well as using standard blood glucose testing strips as advised by the diabetes team.
- Agree to change to a more cost effective blood glucose testing meter and strip, if clinically appropriate.

I/We understand that the sensors will no longer be provided if (the above conditions are not met) and:

- The sensor is worn for less than 70% of the time
- Appropriate actions, as advised by the diabetes team are not carried out.
- The results below have not been achieved by the **six-month review** or improvement is not maintained at each **annual review** *[Delete as appropriate*]
    - A reduction in the number of hypoglycaemic events
    - Improvement in Time in Range
    - A reduction in the number of diabetic ketoacidosis events
    - An improvement in HbA1c
    - Improvement in psycho-social wellbeing
- For patients who are pregnant, the supply of sensors will be stopped:
    - After 12 months total treatment period (inclusive of post-delivery period) – unless the patient fulfils any of the other criteria for funding.
- I no longer fulfil the criteria for funding.

Funding for sensors is for a time-limited period. FGMS are a developing technology and therefore the current funding agreement will be reviewed regularly.

Flash Glucose Monitoring system (FGMS) agreement
For Patients aged 4 years and over

I/We understand that:

- A maximum of 26 sensors will be provided over a 12-month period. (**NB.** If a sensor proves to be defective, you must contact the manufacturer to arrange a replacement).
- Funding for treatment may be stopped in the future

	Patient	Carer	Consultant/DSN
Signed			
Print name			
Date			