GMMMG
Greater Manchester
Medicines Management Group
NHS

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FreeStyle Libre and FreeStyle Libre 2 Flash Glucose Monitoring System.

Medicines and Guidelines Subgroup discussed the above at its meeting on 12th February 2021. Following ratification by GMMMG and GM Directors of Commissioning, the recommendation of this subgroup is as follows:*

Drug/Indication	**FreeStyle Libre Flash (Abbott) Glucose Monitoring System* for use in adults, young people and children.** * - unless otherwise indicated, all statements herein referring to "FreeStyle Libre" also apply to FreeStyle Libre 2
Recommendation	**In line with updated NHS England guidance (November 2020), the group only recommends the use of FreeStyle Libre for:** 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 GMMMG also recommends use in type 1 patients actively trying to conceive and pregnant patients with type 2 diabetes on a basal bolus insulin regime. (Patients developing gestational diabetes are excluded from this recommendation unless they meet other criteria within this recommendation.) Pregnant patients will be expected to return to their previous method of blood glucose testing after 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. GMMMG recommends that "psychosocial circumstances" should be defined as patients who had warranted formal assessment for psychosocial support as a result of their diabetes. 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

GMMMG suggests that that the following may guide use here:

- Those who meet the current NICE criteria for insulin pump therapy (HbA1c 69.4mmol/mol (>8.5%) or disabling hypoglycaemia as described in NICE TA151) where a successful trial of Freestyle Libre may avoid the need for pump therapy
- 2 or more admissions with diabetic ketoacidosis *or* 2 or more episodes of hypoglycaemia requiring third party assistance (per year).
- Those who have recently developed impaired awareness of hypoglycaemia.[†] Note that for persistent hypoglycaemia unawareness, NICE recommends continuous glucose monitoring with alarms and Freestyle Libre does not have that function

The decision to start FreeStyle Libre system will only be made by the diabetes specialist. It will be provided either by the specialist team or by the patient's GP and initially on a 3-6 month trial basis only.

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)

GMMMG recommends that the following be considered as worthwhile improvements in patient outcomes whilst they are using the device, one or more of which should be met in order to continue use, **agreed with the patient before starting**:

- Reduction in blood glucose test strips (BGTS) use
- Reduction in HbA1C of 5.5mmol (0.5%) or more within 6 months
- Reductions in severe/non-severe hypoglycaemia
- Reductions in episodes of diabetic ketoacidosis
- Reductions in admissions to hospital

	• Improvement of time in range • Improvement in psychosocial well being † - Note: Libre will be withdrawn should complete hypoglycaemic awareness be regained and maintained. Patients should be made aware of this at the commencement of the trial. Patients will be expected to actively engage with the service which is providing their diabetic care e.g. by attending all appointments. They must commit to training in the use of FreeStyle Libre, agree the expected outcomes with usage e.g. reduction in the use of BGTS [approximate target to be agreed*] or meeting one or more of the above criteria for continuation and agreeing that NHS provision of Libre will be withdrawn if these criteria are not met. * in trials of FreeStyle Libre, BGTS usage averaged 0.5 strips per day but it is acknowledged that use will be greater in some circumstances e.g. illness. The DVLA now permits car and motor cycle users to monitor their blood glucose using flash glucose monitoring. Please consult the DVLA website for further details and the most up to date requirements which, at the time of writing, are here. Full details of the expected outcomes of treatment must be documented, communicated to the GP and the results also communicated to the GP not more than 6 months after the GP commenced prescribing Libre so that the GP is clear as to whether the criteria for continuation have been met. Primary care is advised to record a review date on the patient record to avoid inappropriate continuation of prescribing. Users must be supported and trained by the diabetes specialist team on how to use FreeStyle Libre and how to interpret and act on the readings. When used by a child under 12 years, a caregiver at least 18 years old must supervise, manage and help the child in using the system and interpreting its readings. While the FreeStyle Libre system does not include an alarm**,** Freestyle Libre 2 has optional glucose alarms to indicate hyperglycaemia and hypoglycaemia, providing the reading device is within contact distance of the sensor. As the original FSL device measures interstitial glucose levels and not capillary blood glucose, measurements will be slightly delayed and users will still need to perform finger-prick blood tests during periods of illness, rapidly changing interstitial glucose levels and where the symptoms don't match the reading. The FSL 2 device is more accurate meaning this additional finger-prick testing is not required, except where the user's symptoms do not match the blood glucose reading, and also if driving, in line with the DVLA guidance. It is expected that the most cost effective choice (<£10 per pack of 50) of test strip is prescribed in line with the GMMMG guidance. **Use of FreeStyle Libre in type 2 diabetics (other than within criteria 1, 2 and 7 in this document) is not recommended.** **Prescribing of FreeStyle Libre as a management tool by healthcare professionals to obtain a more detailed picture of the glucose profile for an individual is limited to specialist diabetes teams only. GPs should not be requested to prescribe in these circumstances but may be requested to provide ongoing prescribing if one or more of the above criteria for continuation are met after such a trial.** **Patients already purchasing FreeStyle Libre who do not meet the criteria here for initiation OR continuation will not be entitled to NHS prescriptions.**
Efficacy Data	The FreeStyle Libre 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 which can be accessed on demand. It can also indicate glucose level trends over time. The FreeStyle Libre system is indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with diabetes mellitus. The group noted that 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. While these are results from an audit, rather than from controlled clinical studies, recent data from the Association of British Clinical Diabetologists (ABCD) Nationwide Audit (10,370 FreeStyle Libre users [97% with type 1 diabetes], real world experience within the United Kingdom) showed reductions in: • HbA1c (by -5.2 mmol/mol reducing from 67.5 (±20.9) mmol/mol (8.3%) at baseline to 62.3 (±18.5) mmol/mol (7.8%) after 7.5 months P<0.0001) (Number of persons [*n*] for whom follow-up was available = 3,182). HbA1c reductions were greater in those with higher initial HbA1c. • Hypoglycemic unawareness (baseline Gold score was 2.7 (±1.8) and reduced to 2.4 (±1.7)) (P<0.0001) • Diabetes distress: component 1 (feeling overwhelmed with demands of living with diabetes) significantly improved from 2.9 at baseline to 2.2 at follow-up)(P<0.0001), component 2 (feeling that I am often failing with my diabetes routine) improved significantly from 3.0 to 2.2 at follow-up) (P<0.0001) • Hospital admissions due to hyperglycemia / diabetic ketoacidosis (from 269 to 86, *n* = 1,978) • Hospital admissions due to hypoglycaemia (from 120 to 45, *n* = 1,952) • Paramedic callouts (from 275 to 38, *n* = 1,940) • Number of episodes of severe hypoglycemia defined as those requiring third-party assistance (from 1,032 to 237, *n* = 1,944)
Clinical Trial Data – Safety	There is limited safety data available on the use of the FreeStyle Libre device. The only published study carried out by Bailey et al study 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. No safety data was presented in the ABCD Clinical audit.
Cost Effectiveness/ Affordability	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. However it is expected that if limited to those finger prick testing at least 8 times a day then overall expenditure would be cost neutral. **A year's cost of sensors is £910 per patient.** The Freestyle Libre reader is not available on prescription and will be provided free of charge by the company. In 2020/21 CCGs will be reimbursed for each set of sensors prescribed for

	up to 20% of their type 1 diabetes population using sensors at an annual cost of £742.56 per each patient's sensor sets which takes into account reduced BGTS use.
Patient Perspective	Patients may be switched from the original Freestyle Libre sensors to Freestyle Libre 2 at their next review or when convenient. Used sensors should be disposed of in a sharps bin.

***This recommendation is valid unless it is has been superseded by a NICE TA or national guidance. The recommendation will only be reviewed when there is substantial new data that may change the initial recommendation. For recommendations that are >24 months old please note that there may be new data available and this should be checked prior to prescribing.*

References available on request.