



November 2017

FreeStyle Libre Flash Glucose Monitoring System.

The Formulary and Managed Entry Subgroup discussed the above at its meeting on 27th September 2017. 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.
Recommendation	<p>The group only recommends the use of Freestyle Libre for:</p> <p>Patients with Type 1 diabetes mellitus (DM), aged 4 years and above, or total pancreatic failure who despite intensive specialist input continue to have poor control (target HbA1c not achieved or frequent episodes of hypoglycaemia particularly at night) of their blood glucose levels and meet one or more of the following:</p> <ul style="list-style-type: none"> • finger prick test at least 8 times per day and this testing frequency is deemed clinically appropriate • 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 • Those who require third parties to carry out monitoring i.e. carers of people in their own homes, because conventional blood testing is not possible i.e. patients with poor peripheral circulation making the use of finger prick testing very difficult, patients with functional impairment that impacts on their ability to read and act on standard finger prick testing • In pregnant patients with type 1 and type 2 DM on a basal bolus insulin regime and in type 1 patients actively trying to conceive. (Patients developing gestational diabetes are excluded from this recommendation unless they meet other criteria above.) Pregnant patients will be expected to return to their previous method of blood glucose testing once they have given birth. <p>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.</p> <p>Patients must be able to accurately interpret and act appropriately on bio feedback information from the Libre. Use will only be continued at the discretion of the diabetes specialist team if there is a sustained improvement in patient outcomes whilst they are using the device i.e. one or more of the following</p>

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

† 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, DVLA driving requirements.

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.

Specialist teams must audit and monitor outcomes in any patients started on the new system; information gathered will inform a review of this recommendation in 12 months' time. 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 aged 4 to 12 years, a caregiver at least 18 years old must supervise, manage and help the child in using the system and interpreting its readings.

Note that the **system does not include an alarm** to indicate when hyperglycaemia, hypoglycaemia or impending hypoglycaemia is reported or the symptoms do not match the system readings. In addition, as the 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, where the symptoms do match the reading and prior to and during driving to meet current DVLA requirements. 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 in pregnancy) 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.

<p>Clinical Trial Data – Efficacy</p>	<p>The FreeStyle Libre system consists of a sensor worn on the upper arm that measures <i>interstitial glucose</i> 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.</p> <p>The main points from the evidence are from 5 studies involving 700 people. This includes 2 randomised controlled trials; one that includes 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.</p> <p>Patients using FreeStyle Libre experienced less time in hypoglycaemia than patients using 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 ($p=0.0006$).</p> <p>The number of hypoglycaemic events per day reduced by mean of 0.45 (by over 25%; $p<0.0001$).</p> <p>The limited data available 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.</p>
<p>Clinical Trial Data – Safety</p>	<p>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.</p>
<p>Cost Effectiveness/ Affordability</p>	<p>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.</p> <p>However it is expected that if limited to those finger prick testing at <u>least 8</u> times a day then overall expenditure would be cost neutral. This will be evaluated further after 12 months.</p> <p>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.</p>
<p>Patient Perspective</p>	<p>All of the included studies report a high level of user preference for FreeStyle Libre over finger prick blood glucose monitoring, although some people had problems with inserting or wearing the sensor (despite allergies to medical adhesive being included in the exclusion criteria for several of these studies).</p> <p>The device may therefore offer some advantages in terms of patient</p>

	acceptability and quality of life and patients will be pleased at the option to use Freestyle Libre if it has been found to be suitable for them. Some patients may currently be self-funding Freestyle Libre however patients will only be offered a trial of this if specialists agree that it would be of benefit and a continuing benefit is seen at each review.
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***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

▼ Newly marketed drugs and vaccines are intensively monitored for a minimum of two years, in order to confirm the risk / benefit profile of the product. Healthcare professionals are encouraged to report all suspected adverse drug reactions regardless of the severity of the reaction.

Amendment 12.17: 5.5mmol added for clarity to HBA1c 0.5% reduction on page 2.