

Commissioning Statement

Flash Glucose Monitoring system (FreeStyle Libre® 1 and Freestyle Libre® 2 from January 2021)

April 2019 (updated December 2020)

Technology	FreeStyle Libre® 1 and Freestyle Libre® 2 (from January 2021) Flash Glucose Monitoring System for use in adults, young people and children.
Recommendation	<p>The Medicines Commissioning Committee has considered the recommendation issued by NHS England on the 7th of March 2019, along with additional committee discussions.</p> <p>From January 2021, in addition to Freestyle Libre® 1, Freestyle Libre® 2 will be available for use on the NHS. The criteria below is for patients on both versions, however from January 2021 all new patients should be initiated on to Freestyle Libre® 2 and established patients on Freestyle Libre® 1 should be transferred to the newer device following a discussion with the specialist team who will provide counselling on the differences.</p> <p>FreeStyle Libre® 1 and 2 are only commissioned for:</p> <ol style="list-style-type: none"> 1. People with Type 1 Diabetes <ul style="list-style-type: none"> OR with any form of diabetes on haemodialysis and on insulin treatment who, in either of the above, are <u>clinically indicated as requiring intensive monitoring of over 8 times daily by their diabetes specialist</u>, 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, eligible for 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 requires 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 FreeStyle Libre® with appropriate adjunct support. 5. Previous self-funders of FreeStyle Libre® 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 FreeStyle Libre® 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 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,

	<p>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.</p> <ol style="list-style-type: none"> 7. People with Type 1 diabetes who have had 2 or more admissions due to diabetic ketoacidosis in the previous 12 months. 8. 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. <p>Other requirements:</p> <ol style="list-style-type: none"> 1. Education on Flash Glucose Monitoring has been provided (online or in person) 2. Agree to scan glucose levels at least 8 times per day and use the sensor over 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, such as BITES or DAFNE <p>Continued prescription for long-term use of FreeStyle Libre®, post initial 6 months, would be contingent upon evidence of agreeing with the above conditions and that on-going use of FreeStyle Libre® is demonstrably improving diabetes self-management. The decision to continue will be made by the diabetes specialist team in secondary care only if one or more of the following are demonstrated:</p> <ul style="list-style-type: none"> • Reduction in usage of blood glucose test strips (approximate target to be agreed, however it is acknowledged that more frequent testing may be required in certain circumstances e.g. during periods of illness or to fulfil DVLA requirements). • Reduction in hypoglycaemia frequency • Reversal of impaired awareness of hypoglycaemia • Reduction in episodes of diabetic ketoacidosis • Improvement of HbA1c • Reduction in hospital admissions • Improvement in psycho-social wellbeing <p>The additional benefits of Freestyle Libre® 2 are that the device contains 3 types of alarms which can notify users of high glucose levels, low glucose levels, or if there is a technical issue between the sensor and the reader. Furthermore, the glucose readings are more accurate in comparison to the previous generation.</p>
<p>Further information</p>	<p>The initiation of patients on to FreeStyle Libre® will be the responsibility of the diabetes specialist team in secondary care, continued supplies will be the responsibility of primary care prescribers.</p> <p>Secondary care specialist's teams are responsible for completing the audit data when FreeStyle Libre® is first started and after six months. If audit data is not collected within four weeks of the end of the six month trial, the patient will not be eligible for FreeStyle Libre®. Patients will need to be made aware of this and sign a contract agreeing to the terms of use of FreeStyle Libre®.</p> <p>Treatment outcomes must be audited in all patients started on FreeStyle Libre® by specialist teams. The specialist teams will be responsible for ensuring FreeStyle Libre® is being appropriately used by ensuring patients</p>

	<p>satisfy the above criteria. The specialist team will provide audit data to the CCG if requested who will periodically review the data.</p> <p>All patients (or carers) must be willing to undertake training in the use of FreeStyle Libre®. They must commit to regular scans of the device demonstrating evidence of FreeStyle Libre® use in self-management, and commit to ongoing regular follow-up and monitoring. They must also agree the expected outcomes with usage and that NHS provision of FreeStyle Libre® will be withdrawn if one or more of the above criteria are not met.</p> <p>Prescribing instructions:</p> <ul style="list-style-type: none"> • The specialist team will provide the patient with a 2 week sensor supply and the FreeStyle Libre® device. • The specialist team will notify the GP their patient has been initiated on FreeStyle Libre® • GPs will need to then issue a prescription for 2 FreeStyle Libre® sensors per month. • After 6 months, the specialist team will advise if the patient is eligible for continued supplies of FreeStyle Libre® sensors on prescription. <p>Adjunct blood testing strips should be prescribed according to locally agreed best value guidelines with an expectation that demand/frequency of supply will be reduced.</p> <p>Patients with Type 2 Diabetes who do not meet the above criteria are NOT eligible for FreeStyle Libre® on the NHS. Reluctance to carry out finger prick testing (e.g. due to distress or inconvenience) alone is not considered to be criteria qualifying the use of FreeStyle Libre®. Patients already purchasing FreeStyle Libre® who do not meet the above criteria will not be entitled to NHS prescriptions.</p> <p>A clinician can make an Individual Funding Request (IFR) for treatment when a patient does not meet the stated criteria for funding. Funding can only be approved if a case of “exceptional clinical need” has been demonstrated. http://www.valeofyorkccg.nhs.uk/your-health/individual-funding-requests/</p>
<p>Summary of Clinical Evidence</p>	<p>FreeStyle Libre® measures interstitial glucose levels from a sensor applied to the skin as an alternative to routine finger-prick blood glucose testing, and can produce a near-continuous record of measurements which can be accessed on demand. It can also indicate glucose level trends over time. Glucose readings can be seen anytime by scanning the sensor with a FreeStyle Libre® reader or an android mobile device with ‘Near-field Communication’ (NFC) capabilities via the LibreLink companion app.</p> <p>FreeStyle Libre® is indicated in people aged 4 or over with diabetes mellitus, who have multiple daily injections of insulin or who use insulin pumps and are self-managing their diabetes. FreeStyle Libre® received European CE mark certification in August 2014. For more details on the device, please refer to <u>NICE Medtech innovation briefing 110</u>.</p> <p>The main points from the evidence are from 5 studies involving 700 people. These include 2 randomised controlled trials, 1 including 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</p>

	<p>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>The evidence 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>In the IMPACT study, patients using FreeStyle Libre® experienced less time in hypoglycaemia than patients using self-monitored blood glucose (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 ($p = 0.0006$). The number of hypoglycaemic events per day reduced by mean of 0.45 (by over 25%; $p < 0.0001$). The mean number of SMBG tests per day reduced from 5.5 (SD 2.0) to 0.5 (SD 0.7) in the FreeStyle Libre® group.</p> <p>FreeStyle Libre® does not include an alarm that alerts users when glucose levels are too high or too low. The device measures interstitial glucose levels and finger-prick blood glucose testing would still be needed:</p> <ul style="list-style-type: none"> • During times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels • If FreeStyle Libre® shows hypoglycaemia or impending hypoglycaemia • When symptoms do not match the system readings • To fulfil Driving and Vehicle Licensing Authority requirements to assess fitness to drive.
<p>Safety</p>	<p>There are currently limited safety data on the use of FreeStyle Libre®. The most commonly reported adverse effect related to sensor use in trials was skin reactions e.g. itching, rash, erythema, allergy, oedema and blisters. Some users may need to use a skin covering in order to be able to use the sensor.</p> <p>Accuracy of FreeStyle Libre® readings compared to capillary blood glucose testing has been found to be broadly comparable. However capillary blood glucose testing is still recommended during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels (e.g. acute illness such as Influenza, diarrhoea and vomiting), or if hypoglycaemia or impending hypoglycaemia is reported, or the symptoms do not match the system readings.</p>
<p>Cost</p>	<p>The annual cost of sensors is £910 per patient. The reader is not prescribable on the NHS but provided free of charge by the manufacturer.</p> <p>The use of FreeStyle Libre® is expected to be cost neutral if a patient is currently finger prick testing 8 or more times daily, and the introduction of FreeStyle Libre reduces the testing frequency to an average of 0.5 times daily.</p> <p>Note there is no additional cost to Freestyle Libre® 2, the sensors are priced the same as Freestyle Libre® 1.</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>Date effective</p>	<p>01 January 2021</p>

from	
Date published	
Review date	01 January 2024
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