York and Scarborough
Medicines Commissioning Committee

Commissioning Statement

Flash Glucose Monitoring system (FreeStyle Libre®)

March 2018

Technology	**FreeStyle Libre® (Abbott) Flash Glucose Monitoring System for use in adults, young people and children.**
Recommendation	The Medicines Commissioning Committee has considered the recommendation issued by the Regional Medicines Optimisation Committee on the 25th October 2017 along with additional committee discussions. **NHS Vale of York and NHS Scarborough and Ryedale CCGs do not routinely commission the use of Freestyle Libre®.** **FreeStyle Libre® is only commissioned for:** • patients with Type 1 diabetes mellitus (T1DM) and; • aged four and above and; • under specialist care and; • using multiple daily injections of insulin, or insulin pump therapy, and; • whom the specialist considers the use of the device will be cost-effective. The use of FreeStyle Libre® is expected to be cost neutral if a patient is currently finger prick testing 8 or more times daily. It will be regarded as cost effective when the introduction of FreeStyle Libre® reduces the testing frequency by at least seven times daily. In addition to all of the above the patient must meet one or more of the following criteria: • Meet current NICE criteria for insulin pump therapy (HbA1c ≥69.4 mmol/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 • Recently developed impaired awareness of hypoglycaemia such that there is an inability to detect the onset of hypoglycaemia because of absence of warning symptoms. The individual must also demonstrate a willingness to engage with further education where applicable and a high level of engagement with glucose testing and management. (Note that for persistent hypoglycaemia unawareness, NICE recommend continuous glucose monitoring with alarms and FreeStyle Libre® does not currently have this function).

- One severe hypoglycaemic episode, defined as an episode of hypoglycaemia requiring the assistance of another person, with no obvious precipitating cause and with clear evidence of impairment of hypoglycaemia unawareness on subsequent assessment by specialist diabetes team. The individual must also demonstrate a willingness to engage with further education where applicable and a high level of engagement with glucose testing and management.

- Two or more admissions to hospital per year with diabetic ketoacidosis or hypoglycaemia

- Patients who have considerable difficulties in finger prick testing due to a physical limitation

- Patients with functional impairment that impacts on their ability to interpret standard finger prick testing results

- Pregnant women with T1DM or T2DM on a basal bolus insulin regime and in women with T1DM who are trying to conceive. Use of FreeStyle Libre® in women with gestational diabetes is excluded unless the above criteria are met. After giving birth, women will be expected to return to their previous method of blood glucose monitoring

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®.

FreeStyle Libre® will be provided initially on a 6 month trial basis. The decision to continue will be made by the diabetes specialist team only if one or more of the following are demonstrated:

- Reduction in usage of blood glucose test strips [approximate target to be agreed] (Trial data showed a reduction in blood glucose testing to an average of 0.5 times per day in patients using FreeStyle Libre®; 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 severe/non- severe hypoglycaemia frequency
- Reversal of impaired awareness of hypoglycaemia
- Reduction in episodes of diabetic ketoacidosis
- HbA1c reduction of ≥0.5% (5 mmol/mol) within 6 months
- Reduction in hospital admissions
- Improved quality of life using validated rating scales

The provision of FreeStyle Libre® sensors will remain the responsibility of the diabetes specialist team in secondary care.

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. The diabetes specialist team in secondary care must gain consent from the patient (or patient representative) at the point of initiation of FreeStyle Libre®, commissioned by the NHS, to permit NHS staff to undertake an audit of data from both the specialist setting and the patient's GP Practice to enable the benefit of initiation and continuation of FreeStyle Libre® to be assessed. Secondary care specialists teams are responsible for collecting the audit data at the end of a six month trial from primary and secondary care in order for the commissioning of FreeStyle Libre® to continue. If data is not presented to the CCG within four weeks of the six month trial commissioning of FreeStyle Libre® will not continue for that individual patient. The diabetes specialist team in secondary care must complete a pro-forma for each patient demonstrating that the patient meets the above criteria and submit this pro-forma to the CCG. The CCG will audit the uptake on FreeStyle Libre® on a monthly basis. The commissioning statement will be formally reviewed at either 12 months or when the number of patients exceeds the anticipated uptake (in January 2018), whichever is soonest. **Treatment outcomes must be audited in all patients started on FreeStyle Libre® by specialist teams**. This audit data will be reviewed regularly by the CCGs and will inform the review of this recommendation twelve months following publication. 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. Use of Freestyle Libre® in patients with T2DM (other than in pregnancy) is **not** recommended. Patients already purchasing FreeStyle Libre® who do not meet the above criteria for initiation OR continuation will not be entitled to NHS prescriptions. 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/
Summary of Clinical Evidence	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.

	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 NICE Medtech innovation briefing 110. 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 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. 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. 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. 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: • 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.
Safety	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. 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.
Cost	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. 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. 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.
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Author	York and Scarborough Medicines Commissioning Committee
Responsible officer	Dr Shaun O'Connell