NHS
Harrogate and Rural District
Clinical Commissioning Group

Interim General Commissioning Statement

Technology	Freestyle Libre® Sensors for the monitoring of glucose levels in people with diabetes
Background	The Freestyle Libre® flash glucose monitoring system measures interstitial fluid glucose levels. The system comprises a sensor and a reader.
Commissioning Statement	NHS Harrogate and rural district CCG does not routinely commission or recommend the use of Freestyle Libre sensors for patients with Type 1 or Type 2 diabetes except in the following circumstances: • Patients with Type 1 diabetes mellitus (T1DM) **and**; • Aged four years 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 effective if a patient is currently finger prick testing 8 or more times a day. It is expected that the introduction of Freestyle Libre reduces the testing frequency by at least seven times daily. In addition to the above the patient must meet one or more of the following criteria: • 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. Reluctance to carry out finger prick testing (due to distress or inconvenience) alone is not considered to be criteria qualifying the use of FSL. The decision to start Freestyle Libre will only be made by the diabetes specialist and will be provided initially on a 6 month trial. The provision of the Freestyle Libre sensors will remain the responsibility of the diabetes specialist team in secondary care. 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: • Agreed reduction in BGTS use (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 FSL; however it is acknowledged that more frequent testing may be required in certain circumstances eg during periods of illness or to fulfil DVLA requirements). • Reduction in HbA1C of 0.5% or more within 6 months • Reductions in severe/non-severe hypoglycaemia • Reductions in episodes of diabetic ketoacidosis • Reductions in admissions to hospital 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. If no improvement is demonstrated in one or more of these areas over a 6 month trial then the use of Freestyle Libre® should be discontinued and an alternative method of monitoring used 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, this audit data should be provided to the CCG. The audit data will be shared with the West Yorkshire and Harrogate Healthcare partnership to allow a final decision for one aligned commissioning policy across the whole of the HCP. 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. Use of Freestyle Libre in type 2 diabetics (other than in pregnancy) is not routinely commissioned. Patients already purchasing Freestyle Libre who do not meet the criteria here for initiation OR continuation will not be entitled to NHS prescriptions.
Referral guidance	Exceptional cases can be referred to the CCG Individual Funding Request Panel for prior approval
Summary of evidence / rationale	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. 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. 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 ($p=0.0006$). The number of hypoglycaemic events per day reduced by mean of 0.45 (by over 25%; $p<0.0001$). 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. 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.
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