

BSSE Area Prescribing Committee **Interim** Position statement

FreeStyle Libre® Glucose Monitoring System

(NOTE - Please read this position statement in line with the East of England Priorities Advisory Committee guidance statement)

Agent	FreeStyle Libre® flash glucose monitoring system
BSSE APC Position	<p>Flash glucose monitoring (fgm) is currently being reviewed by the Diabetes Medicines Management Advisory Group (DMMAG).</p> <p>To ensure equality of access, it is advised that the FreeStyle Libre® sensors are not recommended/prescribed until the DMMAG and BSSE APC have considered all the evidence and defined the patient cohort (both adult and paediatric patients) which is likely to gain most benefit from this new technology.</p> <p>The APC recognises that in the light of the CCGs' statutory duties to break even, the potential budgetary impact means that any future proposed arrangements for funding of the sensors on the NHS are likely to be subject to the Clinical Commissioning Groups prioritisation processes</p>
Formulary RAG status	FreeStyle Libre® Sensors = Non formulary (BLACK)

Key points
Taken from The East Of England Priorities Advisory Committee guidance statement¹

- FreeStyle Libre® is a flash glucose monitoring (fgm) system which monitors glucose levels using interstitial fluid levels rather than capillary blood glucose from finger prick testing.
- It consists of a handheld reader and a sensor, which is sited on the back of the arm. When the reader unit is passed over the sensor, the reader shows a reading based on interstitial fluid glucose levels. The sensor lasts for up to 14 days and then needs to be replaced.
- The reader can show a trace for the last eight hours and displays an arrow showing the direction the glucose reading is heading. Fgm is not the same as continuous glucose monitoring (CGM).
- The FreeStyle Libre® is calibrated as part of the production process and so does not require calibration using finger-prick testing, unlike CGM systems which do.
- A finger-prick test using a blood glucose meter is still required during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels (i.e. acute illness such as Influenza, diarrhoea and vomiting), if hypoglycaemia or impending hypoglycaemia is reported, or the symptoms do not match the system readings.
- FreeStyle Libre® users will still need to perform finger-prick blood tests prior to and during driving to meet current DVLA requirements, as FreeStyle Libre®, like CGM, measures interstitial fluid levels and not capillary blood glucose levels.
- There is currently limited evidence to support the use of FreeStyle Libre®.
- In an open label, randomised controlled trial involving 224 patients with type 2 diabetes, there was no difference in the change in HbA1c between intervention (FreeStyle Libre®) and control (self-monitoring of blood glucose) -3.1 ± 0.75 mmol/mol, $[-0.29 \pm 0.07\%$ (mean \pm SE)] and -3.4 ± 1.04 mmol/mol ($-0.31 \pm 0.09\%$) respectively; $p = 0.8222$. In participants younger than 65 years, the drop in HbA1c was more pronounced in the intervention group compared with controls $[-5.7 \pm 0.96$ mmol/mol, (adjusted mean \pm SE) $(-0.53 \pm 0.09\%)$ and -2.2 ± 1.31 mmol/mol ($-0.20 \pm 0.12\%$), respectively; $p = 0.0301$]. A significant association between treatment group and age was observed for change in HbA1c ($p = 0.0017$).
- In a second study involving 241 individuals with type 1 diabetes, mean time in hypoglycaemia changed from 3.38 h/day at baseline to 2.03 h/day at 6 months (baseline adjusted mean change -1.39) in the intervention group, and from 3.44 h/day to 3.27 h/day in the control group (-0.14); with the between-group difference of -1.24 (SE 0.239; $p < 0.0001$). Several secondary outcomes were also reported; HbA1c concentrations in the intervention group were essentially unchanged compared with the control group. There is limited data to confirm that use of FreeStyle Libre® will result in better controlled diabetes, an improvement in patient oriented outcomes such as a reduction in complications due to poorly controlled diabetes, hospitalisation rates or ambulance/GP call out rates, improvement in overall long-term diabetes control or quality of life. More data is also required to confirm effectiveness of this technology in less well controlled diabetes.
- In a multi-centre, non-masked, randomised controlled trial by Bolinder et al it was noted that the overall patient satisfaction improved in the intervention group, however there was no difference in diabetes distress, hypoglycaemia fear behaviour or worry scores. No device-related hypoglycaemia or safety issues were reported².
- There is limited data to support the routine use in children and young people. A small uncontrolled study has evaluated the accuracy of FreeStyle Libre® readings compared to capillary blood glucose testing strips and found the readings to be broadly comparable. However, there is insufficient data to confirm that use of FreeStyle Libre® in under 18s is associated with better disease control and associated outcomes.
- Standalone CGM currently costs around £5,000 per year and is recommended as an option in certain clinical scenarios in patients with type 1 diabetes. There is limited available data comparing fgm to standalone CGM.
- Current NICE clinical guidance in relation to type 1 diabetes, recommends that finger pricking and capillary blood should be used routinely for the monitoring of glucose. FreeStyle Libre® uses interstitial fluid to monitor blood glucose and consequently does not meet the standard expected by NICE. CGM, which also uses interstitial fluid, is recommended as an option, but only in certain circumstances and should not be used routinely.
- NICE clinical guidelines recommend that monitors should have an audible alarm to alert users to potential problems with blood glucose levels. FreeStyle Libre® does not have an audible alarm.
- A NICE Medtech Innovation Briefing (MIB110) on FreeStyle Libre® for glucose monitoring highlights the key uncertainty around the evidence for FreeStyle Libre® in that the randomised controlled trial of people with type 1 diabetes included only adults whose diabetes was already well controlled.
- The briefing also states that currently the resource impact is uncertain, and will depend upon the extent to which improved glucose control through the adoption of FreeStyle Libre® translates into fewer complications, reduced emergency admissions and less use of glucose test strips.

	<ul style="list-style-type: none"> The products are available to buy online and some patients have chosen to self-fund. The current cost of the reader and two sensors (i.e. first 28 days) is £159.95 (including VAT). A single sensor (14 days) is £57.95 (i.e. 28 days cost for sensor replacement is £115.90). The year one cost of the FreeStyle Libre® per person is approximately £1,255 (excluding VAT), based on the prices listed on the manufacturer's website. According to NICE clinical guideline NG17, the annual cost of self-monitoring blood glucose (SMBG) with single-use lancets and blood glucose strips once per day is £106; SMBG four times daily is £423 and ten times daily is £1,059. FreeStyle Libre® sensors will be included in the Drug Tariff and available to prescribe on NHS prescription from 1st November 2017 and the proposed <u>Drug Tariff Price will be £35 per sensor.</u> No studies on the cost-effectiveness of FreeStyle Libre® in the UK were identified. Current prevalence data suggests that 432 patients per 100,000 population have type 1 diabetes. If all eligible patients were switched to FreeStyle Libre® from current standard practice, the additional investment required is likely to be between £126k and £376k per 100,000 population (based on current retail price), excluding first year set up costs. Until more evidence/data becomes available in relation to improvements in real patient orientated outcomes such as complication rates and hospital admissions, or a positive recommendation from a full NICE technology appraisal (TA), FreeStyle Libre® is not recommended for routine funding in either primary or secondary care. 			
Costs (FreeStyle Libre® costs from Abbott website and following verbal communication)	FreeStyle Libre® Starter pack (Reader plus two sensors)	£159.95 (Not on the NHS)		
	Sensor x 1 (14 days)	£57.95	Assuming 2 sensors per month £115.90 per month £1506.70 per year	
	Sensor x 1 (14 days) [proposed NHS cost from Nov 2017]-meter and first sensor provided FOC by Abbott	£35	Assuming 2 sensors per month £70 per month £910 per year	
(FreeStyle Optium® cost taken from BNF)	FreeStyle Optium® meter	Free		
	FreeStyle Optium® strips	£15.87 (50)	4 times a day testing	£462.13 per year
		0.32 per strip	Up to 10 times a day testing	£1155.34 per year
	Total (strips + lancets) per year @ 4 times a day testing			£502.17 per year
	Total (strips + lancets) per year @ 10 times a day testing			£1255.44 per year
(GlucRx Nexus® cost taken from the BNF)	GlucRx Nexus® meter	Free		
	GlucRx Nexus® Strips	£9.95 (50)	4 times a day testing	£289.74 per year
		0.20 per strips	Up to 10 times a day testing	£724.36 per year
	GlucRx Nexus® Lancets	£5.50 (200)	4 times a day testing	£40.04 per year
		0.03 per lancet	Up to 10 times a day testing	£100.10 per year
Total (strips + lancets) per year @ 4 times a day testing			£329.78	
Total (strips + lancets) per year @ 10 times a day testing			£824.46	

References:

- 1) East Of England Priorities Advisory Committee guidance statement - FreeStyle Libre® Glucose Monitoring System
- 2) Bolinder J, Antuna R, Geelhoed-Duijvestijn P, Kroger J, Weitgasser R. Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial [published online September 12, 2016]. Lancet. 2016
- 3) Data on file. Dunn T, Xu Y, Hayter G; Evidence of a Strong Association Between Frequency of Flash Glucose Monitoring and Glucose Control Measures During Real-World Usage

NICE NG17 Type 1 diabetes in adults: diagnosis and management, published August 2015
 NICE NG18 Diabetes (type 1 and type 2) in children and young people, published August 2015
 NICE Medtech innovation briefing [MIB110] FreeStyle Libre® for glucose monitoring, published July 2017