



Interim Local Commissioning Positioning Statement

Drug: FreeStyle Libre® Glucose Monitoring System

Date of Statement: 31 July 2018

Verdict:

The Coventry & Warwickshire Area prescribing Committee recommends that the CCGs within the Coventry & Warwickshire area follow the Regional Medicines Optimisation Committee's (RMOC) recommendations regarding commissioning of the above system, and that only eligible patients stipulated in the RMOC recommendations are funded by the NHS.

As per the RMOC recommendations initial and ongoing supplies of the above system should only be through diabetes specialist centres, and is not suitable for primary care prescribing.

Status: Specialist Only (SO)

Indication: The FreeStyle Libre® is a flash glucose monitoring (FGM) system which allows people age 4 or older, with diabetes mellitus, to monitor glucose levels and trends without performing capillary testing. A sensor, approximately the size of a £2 coin, is applied to the skin, usually the back of the arm. When the reader unit passes over the sensor, the reader display shows a reading based on interstitial fluid glucose levels; the fibre draws interstitial fluid from the muscle into the sensor, where glucose levels are automatically measured every minute and stored at 15-minute intervals for 8 hours. Glucose levels can be seen at any time by scanning the reader over the sensor. Results can be obtained through clothing. The reader can show a trace for the last eight hours and displays an arrow showing the direction the glucose reading is heading¹.

Evidence: NICE has produced a MedTech Innovation briefing (updated September 2017) [1]. There is no current technology appraisal¹.

There is limited evidence of effectiveness. The evidence summarised comes 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. A key uncertainty around the evidence is that the RCT of people with type 1 diabetes included only adults whose diabetes was well controlled¹.

FreeStyle Libre does not provide real-time continuous glucose monitoring or a hypoglycaemia alarm. A finger-prick test is still required during acute illness, if hypoglycaemia or impending hypoglycaemia is reported, or the symptoms do not match the system readings^{1,2}.

Drug costs: FreeStyle Libre® sensor: contains 1 sensor, 1 sensor applicator and 1 wipe £35³

FreeStyle Libre® is available to buy online at the following cost: <https://www.freestylelibre.co.uk/libre/products.html> :

Starter pack (Reader and two sensors) £159.95 Reader £57.95 Sensors (14 days) £57.95 replace every 2 weeks

Summary: [The Regional Medicines Optimisation Committee](#) has advised that until further trial data is available, audit data on the use of FreeStyle Libre® is collected through its use in limited and controlled settings. Criteria for use are stated in the position statement⁴.

- The NICE Medtech Innovation Briefing (MIB110) FreeStyle Libre® for glucose monitoring states that the resource impact is currently 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 blood glucose test strips¹.
- PrescQIPP guidance states that in the absence of a positive decision from NICE, FreeStyle Libre® is not considered to be cost-effective and is not recommended for funding².
- This recommendation will be reviewed in the light of new evidence to support the cost-effective use of FreeStyle Libre®².
- Diabetes UK⁵ (in its comment to NICE¹) has suggested that FreeStyle Libre® might be particularly useful for certain groups of people (e.g. pregnant women, people with poor peripheral circulation, older people, and hospital in-patients who need regular monitoring) or that it may benefit people in certain jobs where finger-prick testing is not always practical¹.

References:

1. National Institute for Health and Care Excellence. FreeStyle Libre for glucose monitoring Medtech innovation briefing [MIB110] Published date: July 2017 Last updated: September 2017. Available at <https://www.nice.org.uk/advice/mib110/chapter/The-technology> accessed 5.10.17
2. PrescQIPP. The East of England Priorities Advisory Committee. Guidance Statement. FreeStyle Libre® Glucose Monitoring System. September 2017. Available at <https://www.prescqipp.info/resources/category/407-freestyle-libre-glucose-monitoring-system> accessed 16.10.17 [log in required]
3. Drug Tariff. November 2017. Available at www.nhsbsa.nhs.uk accessed 31.10.17
4. Regional Medicines Optimisation Committee (RMOC). Flash Glucose Monitoring Systems. Position Statement. October 2017. Available at <https://www.sps.nhs.uk/wp-content/uploads/2017/11/Flash-Glucose-monitoring-System-RMOC-Statement-final-2.pdf> accessed 19/12/17
5. Diabetes UK Consensus Guideline for Flash Glucose Monitoring Date published September 2017. Available at https://www.diabetes.org.uk/resources-s3/2017-09/1190_Flash%20glucose%20monitoring%20guideline_SB_V9%5B4%5D.pdf?_ga=2.128629836.1339632840.1505301182-2056973880.1505301182 accessed 24.10.17

FreeStyle Libre – Frequently Asked Questions (FAQ) for patients

1. What is FreeStyle Libre?

FreeStyle Libre 'flash glucose monitoring system' measures glucose levels in people with diabetes using a sensor applied to the skin. FreeStyle Libre is an alternative to finger-prick blood glucose testing, and can produce a near-continuous record of measurements which can be accessed on demand. Readings are taken by scanning the sensor with a FreeStyle Libre reader or some mobile phones.

People using FreeStyle Libre still need to use finger-prick blood glucose testing:

- when they feel unwell; for example when they have the flu, diarrhoea or are vomiting
- when the FreeStyle Libre reader shows low glucose readings (hypoglycaemia) or warns that hypoglycaemia is likely
- when symptoms do not match meter readings
- before they drive and during driving (to meet DVLA requirements).

2. Is the FreeStyle Libre device available to be prescribed?

On the 1st November 2017, Freestyle Libre sensors were added to the NHS 'Drug Tariff' therefore it would be possible for GPs to prescribe FreeStyle Libre sensors on the NHS. However, this does not mean they are suitable for all patients.

There are lots of drugs and devices that can be prescribed but not all offer good value for money to the NHS (this is known as being cost-effective). The NHS has processes in place to identify cost-effective drugs or devices; recommendations are then made nationally (e.g. National Institute for Health and Care Excellence [NICE] guidance) or locally.

3. What does NICE say about FreeStyle Libre?

NICE have not provided national guidance on the use of this device. They issued a 'Medtech innovation briefing' which summarised the costs, evidence base and perceived benefits, however, it did not include a recommendation.¹

4. Should patients ask GPs to prescribe FreeStyle Libre?

At this time, prescribers will refrain from prescribing the sensors until arrangements are in place so that those patients who receive them are those who are most likely to benefit given the available evidence.

Patients who choose to self-fund Freestyle Libre may continue to do so.