

## FreeStyle Libre® Flash Glucose Monitoring System Position Statement for GPs

### Summary of recommendations

- GPs should **not** prescribe FreeStyle Libre® sensors to patients with type 2 diabetes.
- FreeStyle Libre® flash glucose monitoring system is recommended within City & Hackney CCG for people with type 1 diabetes, under specialist care, who are using multiple daily injections (MDI - 4 or more doses of insulin a day) or insulin pump therapy.
- The NHS London Procurement Partnership recommends NHS funding of FreeStyle Libre® sensors for the following patient cohorts:
  1. Patients with type 1 diabetes on MDI or insulin pump therapy who test frequently.
  2. Patients with type 1 diabetes with HbA1c >8.5% (69.4mmol/mol) or disabling hypoglycaemia who would be eligible for insulin pump therapy as per NICE TA151.
  3. Patients with type 1 diabetes on MDI or insulin pump therapy where conventional monitoring is not possible with self-monitoring blood glucose (SMBG) testing.
- Current self-funders of FreeStyle Libre® sensors will need to provide sufficient record of prescribing data for blood glucose test strips or clinical data to demonstrate that they meet the criteria for funding by the NHS.
- Training for primary care practitioners will be provided by the local specialist diabetes team.
- Initiation of FreeStyle Libre® should only be carried out by the local specialist diabetes team. The first 2 months of treatment (i.e. 4 sensors) will be provided by secondary care, GPs are expected to take over prescribing after this period where an agreed transfer of care document has been received from secondary care.
- Transfer of prescribing must be accompanied by clear monitoring responsibilities and information on ongoing review using the transfer of care documents.

## Background

- The FreeStyle Libre® flash glucose monitoring system is a device for the self-monitoring of glucose levels. Unlike traditional finger-prick devices (that measure the glucose level in the blood), this device measures the glucose level in the interstitial fluid, via a sensor that sits just under the skin.
- It can provide a near-continuous record, which is produced by the patient scanning the sensor with their reader-device, as and when required. It will not provide warnings or alarms about low or high glucose levels and finger-prick blood glucose measurements are required in certain circumstances (e.g. before and during driving as required by DVLA, if impending hypoglycaemia or when interstitial fluid glucose levels may not accurately reflect blood glucose levels).
- The FreeStyle Libre® device has the option to use the handset as a SMBG and ketone meter, in conjunction with FreeStyle Optium blood glucose and ketone strips. It is not essential to use this functionality (and these strips) and patients can continue to use their current self-monitoring blood glucose meter alongside the Libre® device.
- Assessment of available evidence in the NICE Medtech Innovation Briefing 110 (July 2017) deemed the FreeStyle Libre® device to be clinically acceptable in terms of accuracy when compared to self-monitoring blood glucose measurement devices.
- 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.
- The London Diabetes Clinical Network, working in collaboration with the NHS London Procurement Partnership (LPP) produced a prescribing guidance across the NHS in London for the implementation of FreeStyle Libre®. This guidance recommends the prescribing of FreeStyle Libre® sensors only for certain patient cohorts with type 1 diabetes on MDI or insulin pump therapy who test frequently.
- FreeStyle Libre® has been included in the Drug Tariff since 1<sup>st</sup> November 2017. The current commercial list price of FreeStyle Libre® is £57.95 plus VAT for the reader. The Drug Tariff price for the sensor is £35.00; this is a disposable sensor that must be replaced every 2 weeks.

## References

- National Institute for Health and Care Excellence (NICE). MIB110: FreeStyle Libre for glucose monitoring (2017). Available at: <https://www.nice.org.uk/advice/mib110/chapter/Summary> [accessed: 27/10/2017]
- London diabetes clinical networks and NHS London Procurement Partnership Medicines Optimisation Workstream. Implementation of Freestyle Libre® prescribing guidance across the NHS in London (Feb 2017).

## Appendix 1 FreeStyle Libre® Frequently Asked Questions

### **What has changed from 1<sup>st</sup> November 2017?**

FreeStyle Libre® sensor was added to the Drug Tariff since 1<sup>st</sup> November 2017 under section 9A (Detection Sensor, interstitial fluid for glucose), which allows it to be prescribed on NHS prescriptions in the community. Current prescribing guidance across the NHS in London recommends the prescribing of FreeStyle Libre® sensors on the NHS only for certain cohorts of patients with type 1 diabetes.

### **Is FreeStyle Libre® a type of Continuous Glucose Monitoring (CGM)?**

Flash glucose monitoring should not be confused with Continuous Glucose Monitoring (CGM) and is not a suitable alternative for patients who are eligible for CGM in accordance with NICE guidance.

### **What about people who are already self-funding FreeStyle Libre®?**

Patients who have been buying the FreeStyle Libre® directly from the manufacturer (and wish to continue using the device) will need to provide sufficient record of primary prescribing data for blood glucose test strips or clinical data to demonstrate that they meet the criteria for funding by the NHS. Patients who do not meet the criteria for NHS funding should continue to purchase their sensors. **It is important to ensure that patients are made aware that prescribing decisions will not be based on what has already been purchased, but on what has been agreed for local NHS funding.**

### **What about people who have previously received their device and sensors from hospital?**

It is not guaranteed that FreeStyle Libre® sensors will automatically be prescribed in primary care if it was previously received from a hospital. Only patients who meet the criteria for NHS funding can be will be transferred to primary care prescribing once primary care practitioners in City and Hackney have received training on the FreeStyle Libre® monitoring system and the transfer of care documents have been received from the specialist team in secondary care.

### **What about people with type 2 diabetes?**

The clinical networks have acknowledged the potential benefit of the FreeStyle Libre® device in those with type 2 diabetes on multiple daily injections. It is anticipated that the guidance will be reviewed later in 2018. The CCG's position statement will be updated when this guidance becomes available.