Prescribing Commissioning Policy

FreeStyle Libre® Flash Glucose Monitoring System

NHS Eastern Cheshire CCG, NHS South Cheshire CCG and NHS Vale Royal CCG have agreed a policy to support prescribing of the FreeStyle Libre® flash glucose monitoring system for patients with Type 1 Diabetes. The CCGs do not commission the use of FreeStyle Libre® for patients with type 2 diabetes.

All patients considered for FreeStyle Libre® flash glucose monitoring should be:

(1) Using either (i) a basal-bolus insulin regimen in line with NICE guidance[1,2] or (ii) a continuous subcutaneous insulin infusion i.e. an insulin pump (in line with the local commissioning policy[5]); and

(2) Intensively monitoring their blood glucose i.e. finger prick testing at least 8 times per day and this testing frequency is deemed clinically appropriate; and

(3) Able to use the system in conjunction with diet and lifestyle changes to actively manage their insulin requirements, so they can achieve agreed targets for glycaemic control and reduce the adverse effects of hypoglycaemia or hyperglycaemia.

It is expected that diabetes specialists initiating the FreeStyle Libre® system will support patients with techniques to enable them to manage their diet/lifestyle and insulin requirements appropriately in response to their glucose levels (e.g. encouraging patients to develop knowledge and skills by attending an individual structured education programme that may include carbohydrate counting).

Patients should only continue with the FreeStyle Libre® system beyond a 6-month trial if they meet all of the following criteria:

- **Maintain HbA1c < 48mmol/mol (<6.5%), or achieve/maintain a 6mmol/mol (0.5%) reduction in HbA1c compared with baseline (including historical HbA1c control as a result of self-purchased glucose monitoring systems); and**
- **Achieve glycaemic control target without problematic hypoglycaemia; and**
- **Use of blood glucose testing strips (BGTS) does not average more than twice daily (i.e. no more than 50 strips per calendar month*); and**
- **The FreeStyle Libre® sensor is scanned regularly at intervals of no more than 8 hours (the sensor can only store 8 hours of data so if it is not scanned the information will be lost); and**
- **Use of the FreeStyle Libre® sensors is not excessive i.e. no more than 2 sensors every 28 days (this would indicate that the sensor is not suitable for the individual patient).**

***In trials of FreeStyle Libre®, BGTS usage averaged 0.5 strips per day in adults but it is acknowledged that use will be greater in some circumstances e.g. illness, DVLA driving requirements.**

Background

NICE NG17[1] recommends that patients using basal-bolus insulin regimens should test their blood glucose levels at least 4 times per day (before each meal and before bed). Furthermore, testing may need to be more frequent (up to 10 times per day) if any of the following apply:

- Target HbA1c is not achieved
- The frequency of hypoglycaemic episodes increases
- There is a legal requirement to do so (e.g. DVLA requirement)
- During periods of illness

- Before, during, or after sport
- When planning pregnancy, during pregnancy and during breastfeeding
- If there is a need to know blood glucose levels more than 4 times per day for other reasons (e.g. impaired awareness of hypoglycaemia, high-risk activities, patient-led diabetes education activities such as DAFNE)

There will be some patients testing their blood glucose more than 10 times per day due to their lifestyle (e.g. driving for a long period of time, undertaking high-risk activity occupation, travel) or if the person has an impaired awareness of hypoglycaemia.

NICE NG18[2] recommends that children with Type 1 Diabetes should have their blood glucose levels tested at least 5 times per day.

The FreeStyle Libre® system is indicated for measuring interstitial fluid glucose levels in people with diabetes aged 4 and older. The 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 obtain a reading. The sensor may also be read with an appropriate smart phone application that has near-field communication. Each sensor can store up to 8 hours of near continuous interstitial glucose measurements which can be accessed on demand by scanning. It can also indicate glucose level trends over time. FreeStyle Libre® is classified as a medical device rather than a licensed medicine and received European CE mark certification in August 2014. It has been available for self-funding since then, and entered the Drug Tariff to become NHS reimbursable from 1st November 2017.

The FreeStyle Libre® system is approved within the local health economy formulary for patients with Type 1 Diabetes subject to the criteria set out in this document. The formulary status is 'Pink (Specialist Recommendation)'. This includes recommendation by a Consultant Diabetologist or Diabetes Specialist Nurse (DSN) who has undergone training in FreeStyle Libre® and the associated management of diet, lifestyle and insulin dose adjustment. FreeStyle Libre® sensors will initially be prescribed on a 6-month trial basis only and full details of the expected outcomes of treatment must be documented on the patient records. The results of the trial in each individual patient should be documented in the patient records 6 months after FreeStyle Libre® is commenced. It is expected that the Consultant or DSN will explicitly communicate to the GP as to whether the trial period has been successful and whether the Freestyle Libre® device should be continued. Primary care clinicians are advised to record a review date on the patient's medication record to avoid inappropriate continuation of prescribing.

Patients should only continue with the FreeStyle Libre® system beyond a 6-month trial if they meet the agreed criteria and targets for glycaemic control (summary on page 1).

Patients must be able to accurately interpret and act appropriately on the information from the FreeStyle Libre®, therefore users must be supported and trained by the recommending specialist on how to obtain maximum benefit from using the device. When used by a child aged 4 to 17 years, a caregiver aged at least 18 years old must supervise the child and help them use the system, interpret and act upon the readings.

Note that the FreeStyle Libre® system **does not include an alarm** to indicate hyperglycaemia, hypoglycaemia or impending hypoglycaemia. In addition, as the device measures interstitial rather than capillary glucose levels, readings are slightly delayed. Therefore users will still need to perform finger-prick tests during periods of illness, rapidly changing interstitial glucose levels, or prior to and during driving to meet current DVLA requirements. The most cost effective choice of test strip should be prescribed in line with the local health economy formulary[3].

Clinical Evidence
The main points from the evidence are from 5 studies involving 700 people. It 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). Patients in these 2 studies 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).

Three of the studies reported that device accuracy, compared with self-monitored blood glucose, ranged from 84% to 88% accuracy and from 99% to 100% clinical acceptability. 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.

Safety
There is limited safety data available on the use of the FreeStyle Libre® device. The only published study carried out[4] reported no unexpected adverse device effects reported during the trial period. Finger-prick testing 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 the 14 day lifespan of the FreeStyle Libre® sensor.

Cost-effectiveness/Affordability
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. However it is expected that if limited to those finger-prick testing at least 8 times a day then overall expenditure would be cost neutral provided that there is a reduction in the number of times a day finger-prick testing is performed whilst using FreeStyle Libre®.

The NHS list price for the sensors is £35 each (£910 per patient per year) plus the additional cost of blood glucose monitoring test strips and lancets. The FreeStyle Libre® reader is not available on prescription and will be provided free of charge by the manufacturer along with the first sensor. The recommending clinician will have supplies of the FreeStyle Libre® starter pack.

Patient Perspective
All of the included studies report a high level of user preference for FreeStyle Libre® over conventional finger-prick blood glucose monitoring, although some people had problems with inserting or wearing the sensor (despite allergies to medical adhesive being included in the exclusion criteria for several of these studies). If patients request the option of a dressing to cover the sensor this should be purchased by the patient.

Implementation
This prescribing commissioning policy applies to all services contracted by or delivered on behalf of NHS Eastern Cheshire CCG, NHS South Cheshire CCG and NHS Vale Royal CCG. This would apply to: GPs, Hospital and Community NHS Trusts and independent providers.

The Regional Medicines Optimisation Committee (RMOC) issued a position statement[6] regarding FreeStyle Libre® recommending criteria for its use. It is felt that this prescribing commissioning policy offers a practical method to implement the RMOC recommendations in the local health economy. It is expected that FreeStyle Libre® is only initiated by clinicians who are competent to educate patients to use the results for management of insulin regimens, diet and lifestyle. Initially, it is expected that this will be consultants and diabetes specialist nurses employed by acute trusts or community providers. On commencing FreeStyle Libre® flash glucose monitoring the initiating clinician will complete a contract with the patient/carer to ensure that all parties are clear regarding aims of treatment and targets to be achieved/maintained.

At the end of the 6 month trial, the initiating clinician will review progress and monitor attainment/maintenance of treatment targets, including managed withdrawal of Freesyle Libre® and re-establishment of BGTS in patients who are unable to achieve and maintain the targets for glycaemic control as agreed with the patient at the time of initiation. Practice team members will provide ongoing review of continued progress and monitor continued/sustained attainment of treatment targets at the patient's annual diabetes review.

Patients with Type 1 Diabetes who have previously purchased FreeStyle Libre® or other continuous glucose monitoring devices will only be eligible for funding of FreeStyle Libre® sensors on NHS prescription if they have achieved the stated targets for glycaemic control and BGTS frequency through use of these devices as stated on the first page.

It should be noted that ALL patients provided with a FreeStyle Libre® system will also continue to need a supply of BGTS for monitoring blood glucose in specific circumstances (to assess hypoglycaemia when symptoms do not correlate with interstitial glucose readings). In addition, patients need to have appropriate arrangements for ketone monitoring (blood or urine) to detect diabetic ketoacidosis as outlined in NICE NG17. The FreeStyle Libre® reader has the facility to monitor both blood glucose levels and blood ketone levels using compatible test strips.

The Policy will be circulated to GP Prescribing Leads and Practices Managers, and made available via the MMT website www.centralandeasterncheshireMMT.nhs.uk.

References

1. NICE NG17. Type 1 diabetes in adults: diagnosis and management. Last updated July 2016. Available at: https://www.nice.org.uk/guidance/ng17.
2. NICE NG18. Diabetes (type 1 and type 2) in children and young people: diagnosis and management. Last updated November 2016. Available at: https://www.nice.org.uk/guidance/ng18.
3. Central and Eastern Cheshire Medicines Management Team Formulary. Available at: www.centralandeasterncheshireMMT.nhs.uk.
4. Bailey et al. The Performance and Usability of a Factory-Calibrated Flash Glucose Monitoring System. Diabetes Technol Ther. 2015 Nov 1; 17(11): 787–794
5. NHS Eastern Cheshire, NHS South Cheshire, NHS West Cheshire and NHS Vale Royal CCGs. Cheshire Commissioning Policy 2017/18. Last updated 14th August 2017. http://www.easterncheshireccg.nhs.uk/downloads/publications/policies/commissioning/Commissioning%20Policy-%20Final%20with%20Revisions%20140817%203.pdf.
6. Regional Medicines Optimisation Committee. FreeStyle Libre Position Statement. November 2017. Available at: https://www.sps.nhs.uk/wp-content/uploads/2017/11/Flash-Glucose-monitoring-System-RMOC-Statement-final-2.pdf.